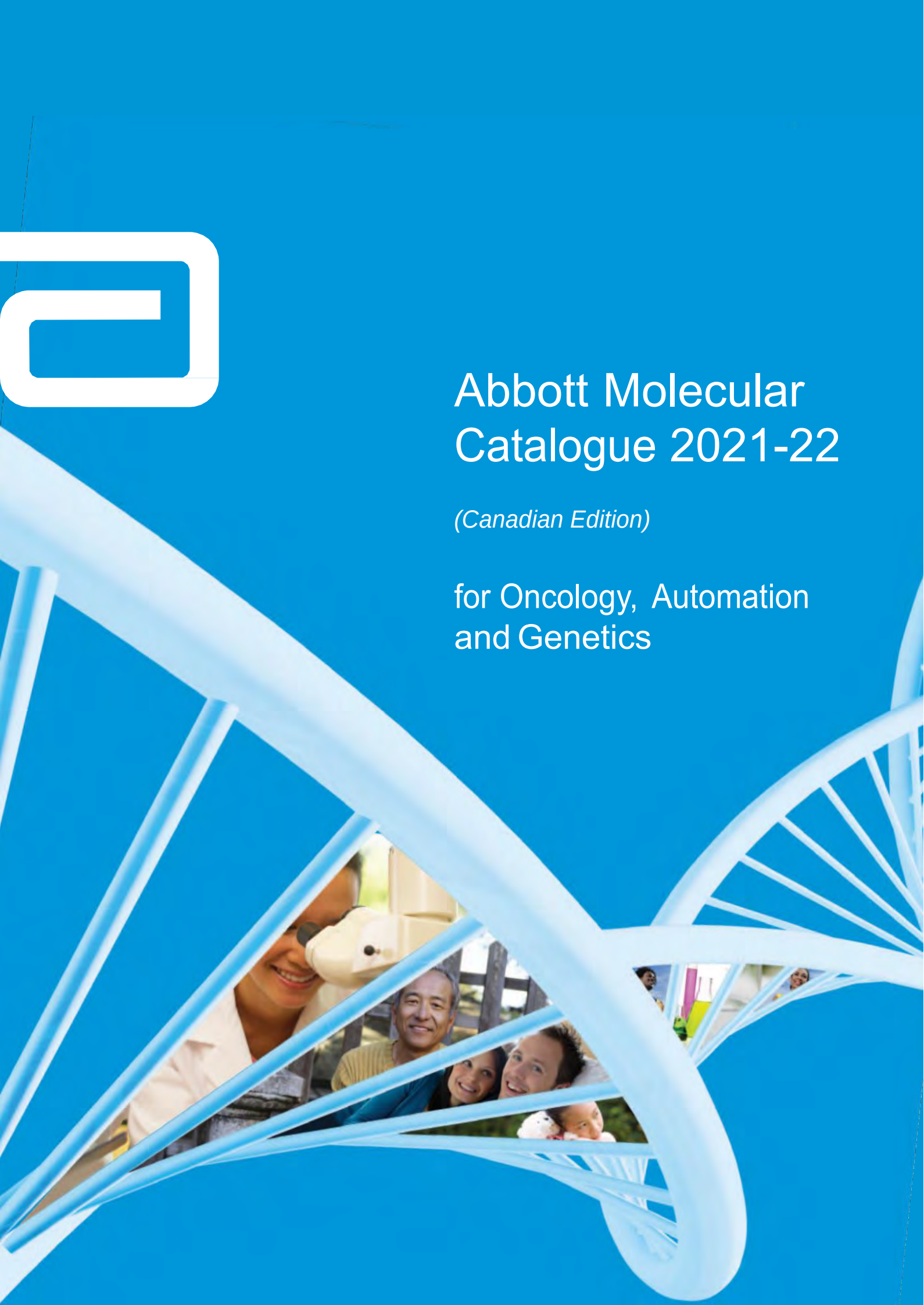
Abbott Molecular Catalogue 2021-22

(Canadian Edition)

for Oncology, Automation and Genetics



Welcome

As a leader in molecular diagnostics, Abbott is committed to exploring new clinical frontiers through the development and delivery of innovative systems and assay solutions that provide earlier disease diagnosis, selection of appropriate therapies and monitoring of disease progression at the molecular level. Our expanding portfolio brings your molecular laboratory multiple technology and platform options that enable the fast, accurate results you require. Our state-of-the-art research and development and manufacturing facilities are dedicated to producing the highest quality, most reliable systems and reagents available in the field of molecular diagnostics today providing you confidence through the delivery of consistent results.

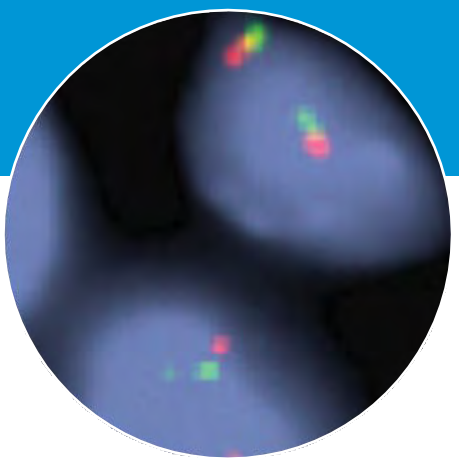
Abbott Molecular is pleased to demonstrate our continued investment to advancing science, by introducing a cadre of new products in this catalog edition including; new FISH products, and a completely new styled web presence with updated chromosome search function. Further details of some of these significant releases are highlighted in a special **"What's New"** Section of this catalog on the following pages.

Building on a proven track record of service to the worldwide community of researchers and clinicians, Abbott continues to deliver patented Vysis FISH Technology that incorporates a proprietary direct fluorescence labeling technique providing the following benefits:

- Specific high intensity signals without the requirement of separate amplification and/or detection steps
- Superior reproducibility
- Clearer results
- Easy interpretation

Abbott Molecular FISH Automation solutions unlock the potential to extend laboratory capabilities by increasing throughput, improving reproducibility and expanding assay menues. Various platform options provide the flexibility to select the desired level of automation for your specific laboratory needs.

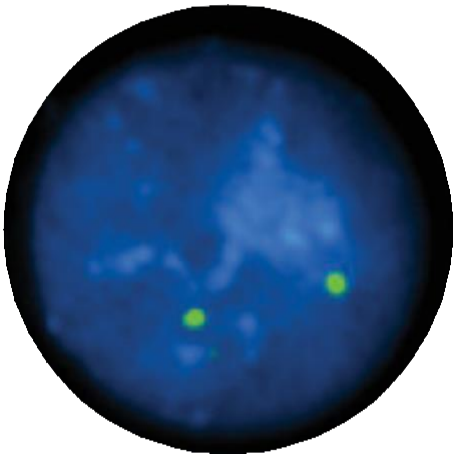
Please contact our scientific experts or your local representative today if you have further questions on any of our products or visit our web site at: www.abbottmolecular.com.



HUGO Gene Names

In order to remain consistent with current scientific nomenclature, Abbott Molecular is incorporating the latest Human Genome Organization (HUGO) naming convention into new products as well as re-packaged existing products. HUGO strives to foster interaction and coordination of information and technology among investigators and the global society in genomics, proteomics, bioinformatics, systems biology and the clinical services in order to provide consistency and simplicity for everyday use of genetic information.

The HUGO Gene Nomenclature Committee (HGNC) at the European Bioinformatics Institute assigns a unique name and symbol to every human gene.



The HGNC is a non-profit body which is jointly funded by the US National Human Genome Research Institute (NHGRI) and the Wellcome Trust (UK) and is part of the Human Genome Organization (HUGO).

Abbott Molecular is proud of its efforts to promote global standardization, consistency and stability in the naming and identification of genomic segments. Cross referencing previous Vysis probe names and new HUGO gene names can be performed by visiting the HUGO gene nomenclature committee website at www.genenames.org.

Example:

Old Abbott Molecular Product:
Vysis LSI CHOP (12q13) Dual Color, Break Apart Rearrangement Probe

New Abbott Molecular Product name according to HUGO gene nomenclature:
Vysis LSI DDIT3 Break Apart FISH Probe Kit

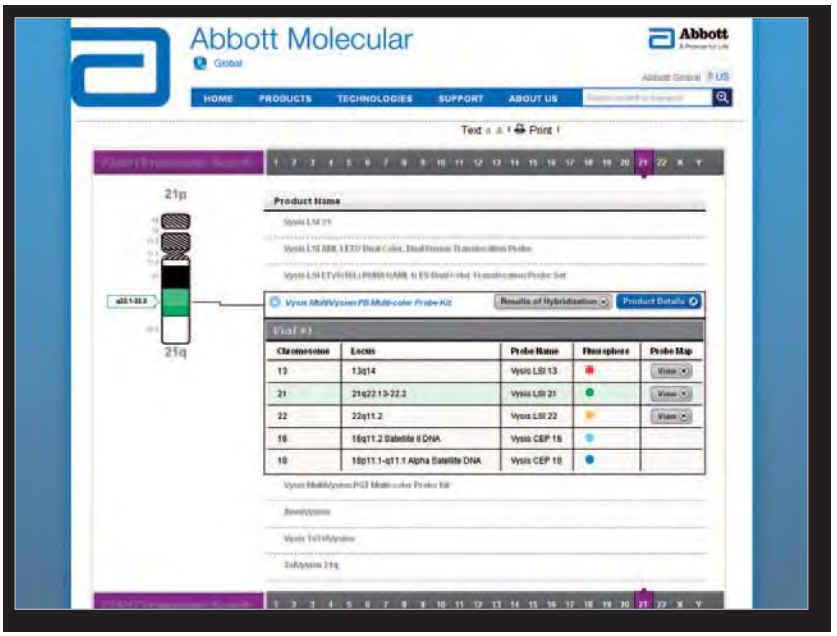
A new way to manage your molecular world, online.

Announcing the launch of our new website **abbottmolecular.com,** a web portal devoted to advancing molecular science. The transformation of our on-line presence enables improved navigation and enhanced search functionality.

Search. Simplified.

Clear Guidance for Laboratory Professionals.

At your request, we've re-engineered the Chromosome Search Tool to provide faster access to the most up-to-date Vysis FISH Probe information – experience a faster, more comprehensive chromosome search.



You're just a click away:
www.abbottmolecular.com

Packaging and Label Changes

Abbott Molecular is pleased to announce the release of new and improved packaging for all Vysis FISH products. The new and improved packaging highlights light-resistant, recyclable paperboard that is environmentally friendly and provides more efficient utilization of storage space for your lab.

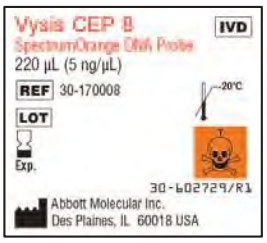
Package labeling has been updated to improve visibility of storage requirements and hazard information. Rest assured that the identity and purity of product components have not been altered. Components in the new packaging are identical to those in the previous packaging. For added convenience, product ordering numbers will remain the same for all products.

Primary Kit Label

1. *New* Abbott Branding
2. Updated Translation
3. 2D bar code
4. Concentration Values
5. Universal Symbols for storage condition, intended use, hazards, lot number, expiration date, EC REP, and reference number
6. New Product Specific Color
7. HIBCC bar code
8. Abbott Molecular contact information and website address

ProbeChek Slide Label

Tube Label



Abbott Molecular Catalog

Automation

FISH

Automation is essential for laboratories interested in reducing the amount of hands-on-time required to run FISH assays, while increasing laboratory throughput, flexibility, reproducibility and productivity. Abbott Molecular is pleased to offer FISH automation options to suit the needs of your laboratory.

- The ThermoBrite Slide Processing System is a temperature programmable, humidity controlled instrument designed to automate denaturation and hybridization steps for FISH. Rapid temperature ramping and accuracy within +/– 1 °C ensure superior temperature uniformity across all 12 slide positions. Up to 40 user defined protocols and 3 operating modes ensure ease of use and flexibility.

Product description	Quantity	Order No.	Number
ThermoBrite 110/120 VAC		07J91-010	1-3
ThermoBrite Humidity Strips	10 pk	07J68-001	1-3
VIP 2000		02J11-062	1-4

ThermoBrite

Programmable Temperature Controlled Slide Processing System
The ThermoBrite System provides an easy, safe, system for in-situ hybridization procedures. This programmable, open system automates the denaturation and hybridization steps in slide-based FISH procedures and provides walk-away convenience for laboratory personnel.

The low cost unit accepts a wide range of sample types, is easy to use and reduces hands-on time by more than 50 % while ensuring overall precision and accuracy in all slide-based assays.

User Programmable Settings
- 40 user defined protocols and 3 operating modes
- Easy to read backlit display
- Numeric keypad allows for easy programming
- Can be used as a fixed temperature slide warmer

Easy to use
- Eliminates manual steps and reduces hands-on time during FISH procedures
- Slides do not need to be fully loaded to maintain temperature accuracy
- Slide guide keeps slides in place and allows for one hand removal
- Humidity Control Cards inside the lid maintain a humid environment

More stringent temperature control
- Rapid temperature ramp-up and accuracy of ± 1° C
- Superior temperature uniformity across all slide positions
- Optimal humidity control
- Heats slide to temperatures ideal for FISH procedures

ThermoBrite Slide Processing System
The ThermoBrite System holds up to 12 slides. The lid seals when closed providing optimal chamber humidity. The system maintains uniform temperature across all slide positions. Slides can be easily added or removed with one hand. The numeric keypad allows for easy programming with 40 user programmable settings and 3 modes of operation: Denaturation/Hybridization, Hybridization, and Fixed Temperature.

Technical Specifications

Dimensions	Height 146 mm (5 5/16 inches) Width 228 mm (8 5/16 inches) Depth 451 mm (17 3/4 inches) Weight 8.5 kg (18.7 lbs)
Capacity	12 Slides
Processing Time	Programmable 0 to 100 hours; Continuous mode
Power 120 VAC at 3A **240 VAC at 1.6A**	
Temperature Control	Programmable 30-99° C
Ambient Operating Temperature	5-40° C(41-104° F)
Ambient Operating Humidity	20-80% relative

Ordering Information	Quantity	Order No.
ThermoBrite 110/120 VAC		07J91-010
ThermoBrite Humidity Strips	10 pk	07J68-001

VIP2000

Completely redesigned with flexibility and usability in mind, the VIP2000 provides your lab with a low-cost solution for FISH automation.

- Enhanced cover design for improved access
- New multiple size slide basins and racks for greater efficiency and flexibility
- Updated software and user interface for a better experience

Evolve your fish workflow with vip2000 upgrades

IMPROVED COVER DESIGN

- Ergonomic lids with tension-controlled hinges allow the door to stay open for easier basin access
- New covers and lids fit seamlessly onto existing chassis
- All design elements driven by real-world laboratory environment assessments and extensive customer feedback

NEW SLIDE BASINS AND RACKS

- Three sizes ensure efficient reagent usage and reduced waste: 150ml, 250ml, 500ml
- Batch multiple tissue types together in combination with Universal Pre-treatment Reagents to reduce overall processing time
- Color-coded basin labels for easier identification

UPDATED SOFTWARE AND USER INTERFACE

- New touchscreen computer for easier management of each run
- Keyboard and mouse functionality still available
- Updated operating system (Windows 8) to improve data integration
- User-friendly program offers the same robust functionality of the VP2000

Technical Specifications

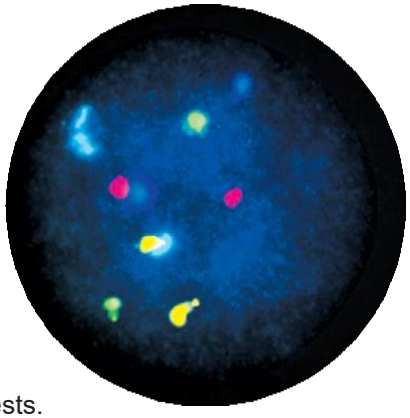
Software Proprietary	VIP2000
Slide Capacity per Run	10, 20 or 50
Ambient Reagent Basins/Volume 12:	150mL, 250mL or 500mL
Heated Reagent Basins 3:	150mL, 250mL or 500mL
Program Capacity	>1000
Events per Program	>100
Water Bath Flow Rate	1L/min
Dimensions	Length 79cm (31 inches)
Width 61cm (24 inches)	
Height 56cm (22 inches)	
Weight - 127 lb. (58 kg)	
Computer Configuration	Pentium Class PC 600 MB or greater
Heated Reagent Basin Temperature	Ambient to 80 ºC
Operating Temperature	15-30 ºC
Drying Station Temperature	Ambient to 80 ºC
Systems	117 VAC, 50/60 Hz

Ordering Information	Order No.
VIP2000	02J11-062

Genetics

Prenatal, Postnatal and Preimplantation Genetics

Identification and characterization of chromosome anomalies in preimplantation, prenatal, and postnatal genetics is critical for managing quality of life. FISH is a powerful tool for determining many types of chromosome anomalies. In addition to AneuVysion, the only FDA-cleared product for rapid detection of aneusomy in amniotic fluid samples, Abbott Molecular offers an expansive line of DNA FISH probes for preimplantation, prenatal and postnatal genetic testing and research.



Abbott Molecular products, powered by Vysis FISH technology, provide the following advantages:

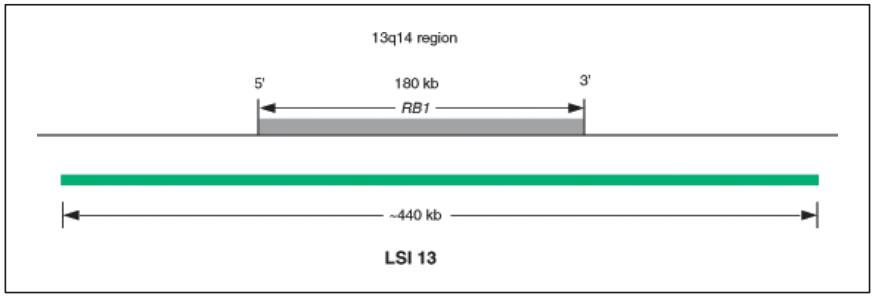
- Rapid, sensitive, and specific detection and characterization of chromosome abnormalities
- Ability to test metaphase chromosomes from cultured samples and interphase cells from specimens that cannot be cultured
- Direct-labeled probes, as compared to indirect labeling methods, provide:
  - Less background signal, thereby simplifying interpretation
  - Reduced costs associated with labeling reagents and technician time
- Dual and Tri Colored probe mixes for many microdeletion detection tests.
  - Each mix includes a probe specific for the critical chromosome region implicated in the disease of interest and a control probe to another region on the same chromosome labeled with a different fluorophore.
  - Inclusion of a control probe in most products ensures proper hybridization and facilitates identification of the chromosome of interest.

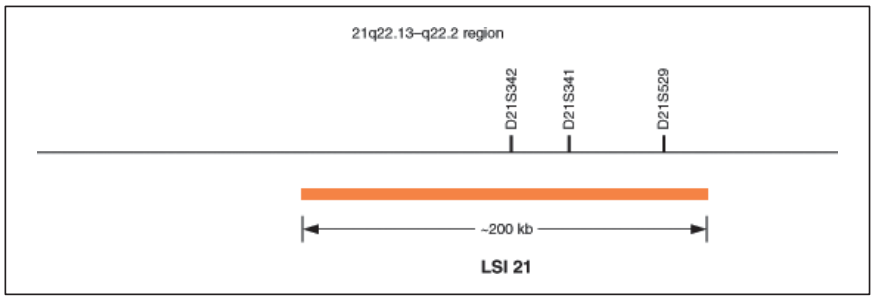
Product description	Quantity	Order No.	Page Number
Aneuploidy Probes			
AneuVysion Multicolor DNA Probe Kit FDA Cleared	10 Assays	05J38-010	2-3
AneuVysion Multicolor DNA Probe Kit FDA Cleared	30 Assays	05J38-030	2-3
AneuVysion Multicolor DNA Probe Kit FDA Cleared	50 Assays	05J38-050	2-3
Microdeletion Probes			
Cri-du-Chat Region Probes			
Vysis Cri-du-Chat Region Probe – LSI D5S23, D5S721 SpectrumGreen	20 µl	05J20-025	2-5
Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Previously: Vysis Cri-du-Chat Region Probe – LSI EGR1 SO/D5S23, D5S721 SpectrumGreen	20 µl	08L68-020	2-6
DiGeorge Region Probes			
Vysis LSI D22S75 (N25 region) SO/LSI ARSA SpectrucGreen Probe	10 µl	05N24-010	2-7
Vysis DiGeorge Region Probe – LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen	20 µl	08L59-020	2-7
Vysis DiGeorge Region Probe – LSI TUPLE1 SpectrumOrange/TelVysion 22q SpectrumGreen	10 µl	01N14-010	2-8
Prader-Willi/Angelman Region Probes			
Prader-Willi/Angelman Region Probe – LSI D15S10 SpectrumOrange/ CEP 15 (D15Z1) SpectrumAqua/PML SpectrumGreen	10 µl	05N58-010	2-9
Vysis Prader-Willi/Angelman Region Probe – LSI D15S11 SpectrumOrange/ CEP 15 (D15Z1) SpectrumGreen Probe	20 µl	05J19-014	2-9
Vysis Prader-Willi/Angelman Region Probe – LSI GABRB3 SpectrumOrange/ CEP 15 (D15Z1) SpectrumGreen	20 µl	05J22-015	2-10
LSI SNRPN SpectrumOrange/CEP 15 (D15Z1) SpectrumAqua/LSI PML SpectrumGreen TriColor Probe	10 µl	06N27-010	2-10
Others			
Vysis 1p36 Microdeletion Region Probe – LSI p58 (1p36) SpectrumOrange/TelVysion 1p SpectrumGreen/LSI 1q25 (SpectrumAqua)	20 µl	05J21-020	2-11
Vysis Kallman Region Probe – LSI KAL SpectrumOrange/CEP X SpectrumGreen	20 µl	05J23-070	2-11
Vysis LSI MAPT SpectrumGreen Probe	10 µl	02N19-010	2-12
Vysis Miller-Dieker Region/Isolated Lissencephaly Probe LSI LIS1 SpectrumOrange/LSI RARA SpectrumGreen	20 µl	05J88-001	2-12
Vysis Smith-Magenis Region Probe – LSI SMS Region SpectrumOrange/LSI RARA SpectrumGreen	20 µl	05J25-003	2-13
Vysis Sotos Region Probe – LSI NSD1 (5q35) SpectrumOrange/ LSI D5S23, D5S721 SpectrumGreen Probe	20 µl	05J48-007	2-13
Vysis SRY Probe – LSI SRY SpectrumOrange	20 µl	05J27-089	2-14
Vysis SRY Probe LSI SRY SpectrumOrange/CEP X SpectrumGreen	20 µl	06N29-020	2-15
Vysis Steroid Sulfatase Defi ciency Probe – LSI STS SpectrumOrange/ LSI CEP X SpectrumGreen	20 µl	05J28-040	2-16
Vysis Williams Region Probe – LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen	20 µl	06N28-020	2-16
Vysis Wolf-Hirschhorn Region Probe – LSI WHS SpectrumOrange/ CEP 4 SpectrumGreen	20 µl	05J29-074	2-17
Vysis LSI Xq 13.2 (XIST) SpectrumOrange Probe	10 µl	01N61-001	2-17
Preimplantation			
Vysis MultiVysion PB Multi-color Probe	60 µl	08L62-020	2-18
Vysis MultiVysion PGT Multi-color Probe	30 µl	08L69-010	2-20
Telomere Probes			
Vysis ToTelVysion	30 µl	05J05-001	2-21
Vysis TelVysion Probes	5 µl	see listing	2-22

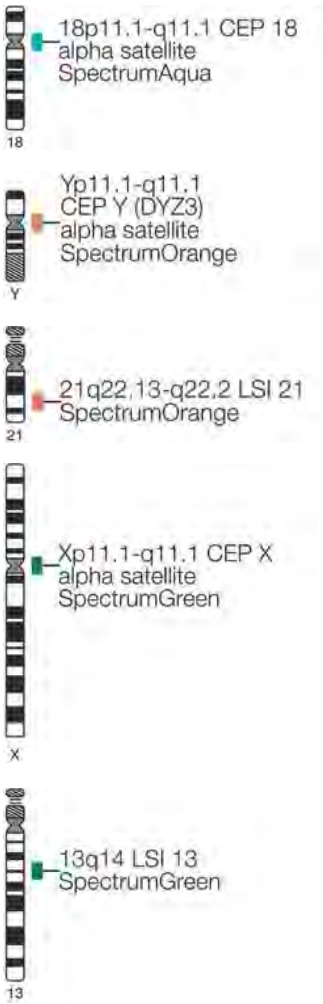
Aneuploidy Probes

AneuVysion Multicolor DNA Probe Kit

FDA CLEARED



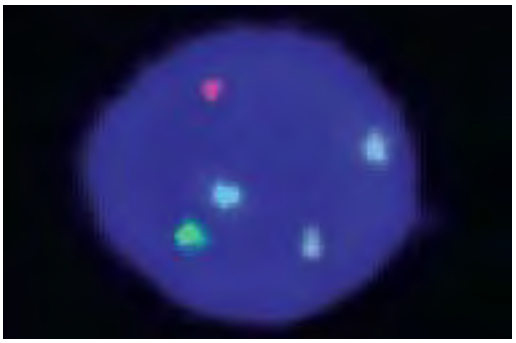




The AneuVysion Prenatal Test is an FDA cleared test, which utilizes patented fluorescence in situ hybridization (FISH) technology applied to uncultured amniocytes, and provides detection of trisomies 13, 18, and 21 (Down syndrome) and sex chromosome aneusomies in as little as 24 hours. Together these conditions account for nearly two-thirds of all abnormalities identified at the time of amniocentesis, and 85–90 % of clinically significant chromosomal abnormalities detected in live-born infants. Review of AneuVysion testing of over 29,000 amniotic fluid samples has found that the test is 99.9 % accurate for the detection of trisomies 13, 18, 21, and aneusomies of X and Y.

There are several benefits of the AneuVysion Test. Because the results are rapidly available, within 24 hours after the amniocentesis sample is received in the laboratory (rather than 7–22 days for routine chromosome analysis), patients can benefit psychologically from a shorter time period of uncertainty. A normal AneuVysion result may allow patients a sense of relief in knowing that the majority of chromosome abnormalities for which their fetus was at risk have been ruled out with a very high degree of accuracy. Importantly, in accordance with professional standards, the availability of AneuVysion results along with consistent clinical information (i. e., fetal anomalies detected by ultrasonography) allows for pregnancy management options that otherwise might not be available due to late gestational age. Finally, in the rare case of a culture failure when standard cytogenetic results cannot be obtained, information on chromosome number for the most likely aneusomies is available.

Ordering Information	Quantity	Order No.
AneuVysion FDA Cleared	10 Assays	05J38-010
AneuVysion FDA Cleared	30 Assays	05J38-030
AneuVysion FDA Cleared	50 Assays	05J38-050



Analysis of an uncultured amniocyte (sometimes referred to as direct analysis) hybridized with the AneuVysion 18/X/Y probe set. Abnormal result: three aqua signals indicate three copies of chromosome 18, one green signal indicates one copy of the X chromosome and one orange signal indicates one copy of the Y chromosome.

References

1. Am, J., Hum, Genet, 1992; 51: 55-65.
2. Am, J., Obstet, Gynecol, 1991; 1055-1057.
3. Prenat Diagn 2000; 20: 1-6.
4. Prenat Diagn 2000; 20: 1-6.
5. Prenat Diag 2001; 21: 293-301.
6. Genetics in Medicine 2000; 26: 356 – 361.

Aneuploidy Probes

AneuVysion

The AneuVysion Test Kit
Each AneuVysion kit includes five FISH probes packaged in two probe mixtures, wash reagents, DAPI II counterstain, and a package insert with detailed protocol information.

Probe Mixture #1

CEP 18: D18Z1 alpha satellite DNA probe corresponding to 18p11.1-q11.1 labeled with SpectrumAqua

CEP X: DXZ1 alpha satellite DNA probe corresponding to Xp11.1-q11.1 labeled with SpectrumGreen

CEP Y: DYZ3 alpha satellite DNA probe corresponding to Yp11.1-q11.1 labeled with SpectrumOrange

Mixture #1 is complete with labeled probes and non-labeled blocking DNA in hybridization buffer.

Probe Mixture #2

LSI 13: DNA probe corresponding to the RB1 gene (13q14) labeled with SpectrumGreen.

LSI 21: DNA probe corresponding to loci D21S259, D21S341, and D21S342 (21q22.13-q22.2) labeled with SpectrumOrange.

Mixture # 2 is complete with labeled probes and non-labeled blocking DNA in hybridization buffer.

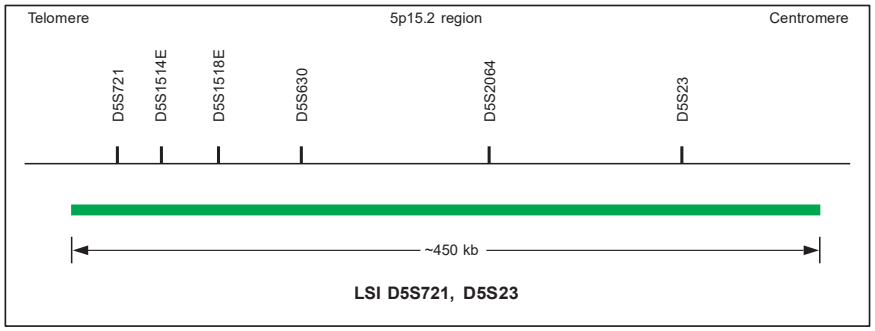
Products for use with AneuVysion

ProbeChek Prenatal Control Slides for Amniocyte; Normal Male Amniocyte Control
05J39-005 — 5 Slides
Fixed biological specimen derived from normal human male amniocytes applied to glass microscope slides.

ProbeChek Prenatal Control Slides for Positive Control
05J36-005 — 5 Slides
Fixed biological specimen derived from human triploid fibroblast cells applied to glass microscope slides. Control slides are excellent training and validation tools for the AneuVysion Test.

Microdeletion Probes – Cri-du-Chat Region Probes

Vysis Cri-du-Chat Region Probe – LSI D5S23, D5S721 SpectrumGreen



LSI D5S23, D5S721 probe detects deletions of 5p15.2. The LSI D5S23, D5S721 probe is available alone, or in combination with LSI EGR1 (5q31) as a control.

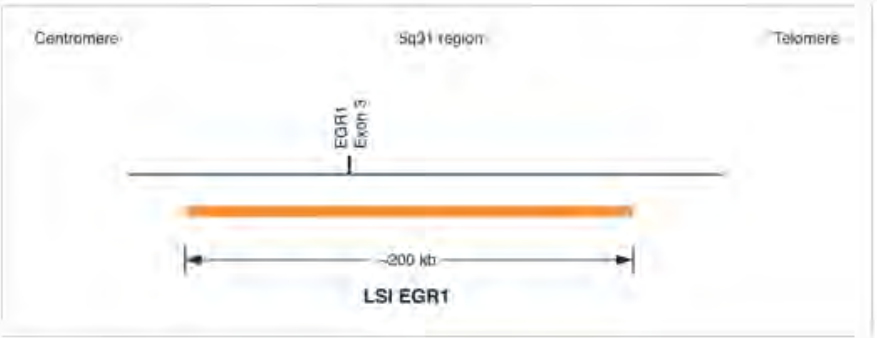
Ordering Information	Quantity	Order No.
Vysis Cri-du-Chat Region Probe – LSI D5S23, D5S721 SpectrumGreen	20 µl	05J20-025

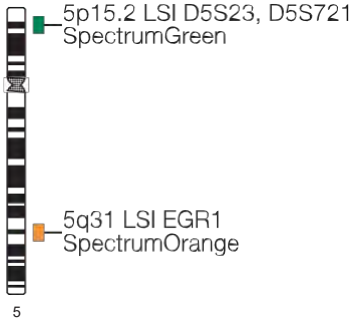
References

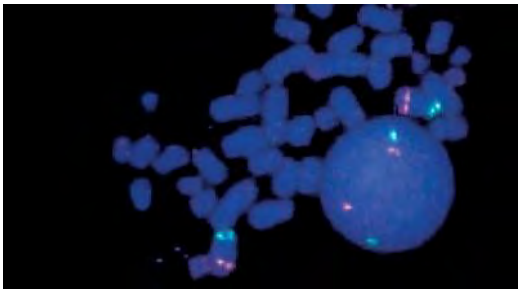
1. Church DM, Yang J, et al.; Genomic Res 7, 8:787.801, 1997 chromosome abnormality. Clin Genet 64:310-316, 2003.
2. Heilstedt HA et al., Physical map of 1p36, placement of monosomy 1p36, and clinical characterization of the syndrome. Am J Hum Genet 72:1200-1212, 2003.

Microdeletion Probes – Cri-du-Chat Region Probes

Vysis LSI EGR1/D5S23,D5S721 Dual Color Probe







LSI EGR1/D5S23, D5S721 Dual Color Probe hybridized to normal cells showing the two orange, two green (2O2G) signal pattern

LSI EGR1/D5S23, D5S721 Dual Color Probe may be used to detect deletions of 5q31 containing the EGR1 locus. The LSI D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.

The LSI EGR1/D5S23, D5S721 Probe is a mixure of the approximately 200 kb SpectrumOrange labeled LSI EGFR1 probe and the approximately 450 kb SpectrumGreen labeled LSI D5S34, D5S721 probe.

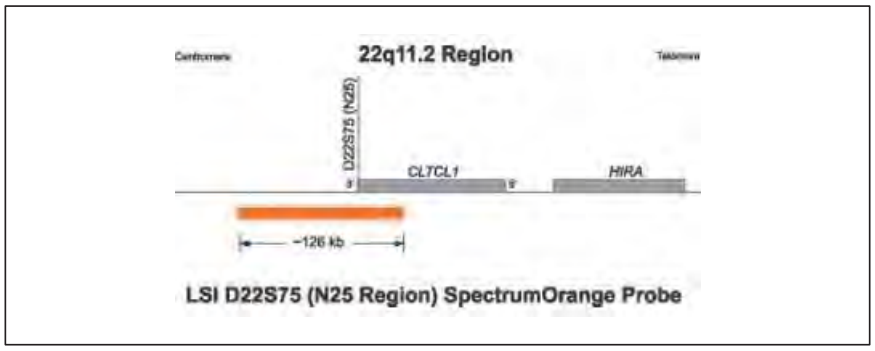
Ordering Information	Quantity	Order No.
LSI EGR1/D5S23, D5S721 Dual Color Probe	20 µl	08L68-020

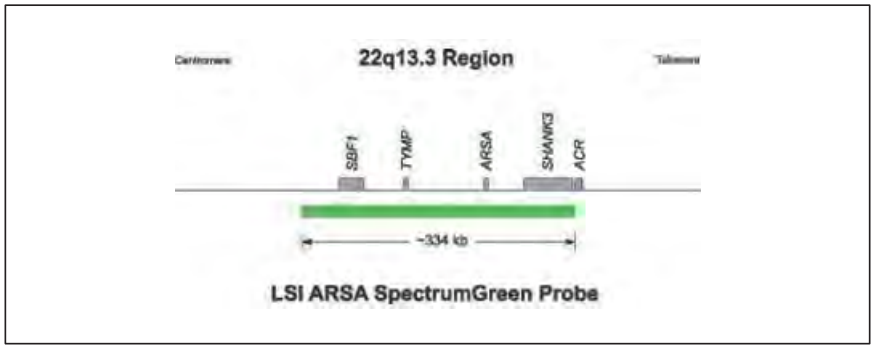
References

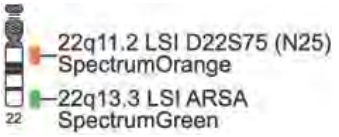
1. Lai F, Godley LA, Joslin J, et al. Transcript Map and Comparative Analysis of the 1.5 Mb Commonly Deleted Segment of Human 5q31 in Malignant Myeloid Diseases with a del(5q). Genomics 2001;71:235-45.
2. Joslin JM, Fernald AA, Tennant TR, et al. Haploinsufficiency of EGR1, A Candidate Gene in the del(5q), leads to the Development of Myeloid Disorders. Blood 2007;110(2):719-726.
3. Zou YS, Fink SR, Stockero KJ, et al. Efficacy of Conventional Cytogenetics and FISH for EGR1 to Detect Deletion 5q in Hematological Disorders and to Assess Response to Treatment with Lenalidomide. Leuk Res 2007;31:1185-89.
4. Vance GH, Kim H, Hicks GA, et al. Utility of Interphase FISH to Stratify Patients into Cytogenetic Risk Categories at Diagnosis of AML in an Eastern Cooperative Oncology Group (ECOG) Clinical Trial (E1900). Leuk Res 2007;31:605-09.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med 2006;8:16-23.

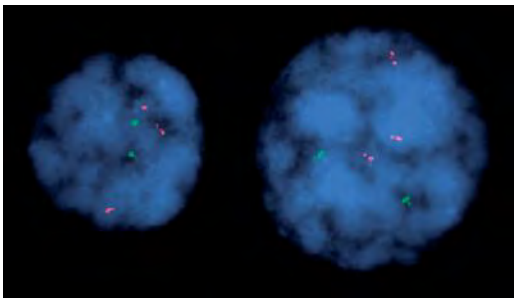
Microdeletion Probes – DiGeorge Region Probes

Vysis LSI D22S75 (N25 region) SpectrumOrange/ LSI ARSA SpectrumGreen Probe







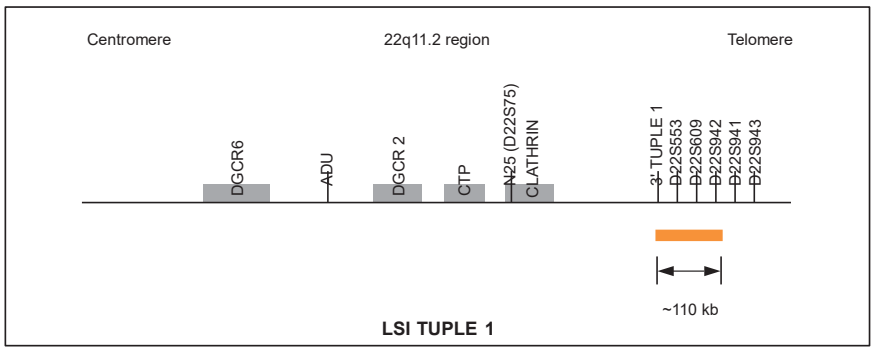


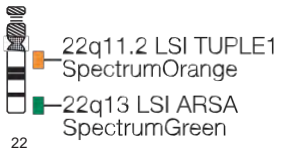
Metaphase and interphase cells hybridized with Vysis LSI D22S75 (N25) region probe (orange) and LSI ARSA probe (green).

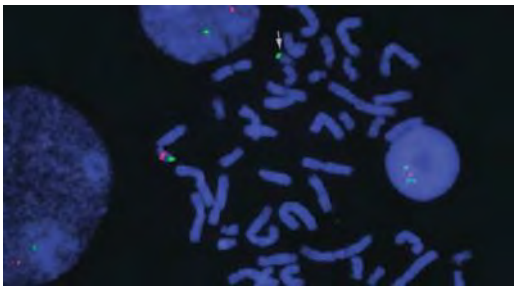
The Vysis LSI D22S75 (N25 region) SpectrumOrange FISH probe covers a region including and flanking N25. The probe is coupled with a LSI ARSA control probe that maps to the telomeric end of 22q (22q13).

Ordering Information	Quantity	Order No.
Vysis LSI D22S75 (N25 region) SO/LSI ARSA Sgn Probe	10 µl	05N24-010

Vysis DiGeorge Region Probe – LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen







LSI TUPLE1 probe hybridized to metaphase and interphase cells. Absence of the orange signal on one chromosome 22 (arrow) indicates deletion of the TUPLE1 locus at 22q11.2.

This probe mixture contains the SpectrumOrange LSI TUPLE (HIRA) probe (3´nocoding region of TUPLE1, D22S553, D22S609 and D22S942) and the SpectrumGreen LSI ARSA (Arylsulfatase A gene) control probe that maps to 22q13.2.

Continuation on the following page >

Microdeletion Probes – DiGeorge Region Probes

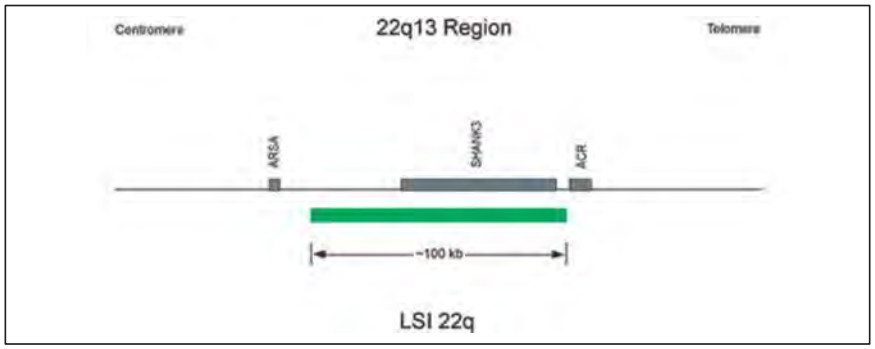
Continuation:
Vysis DiGeorge Region Probe – LSI TUPLE1 SpectrumOrange/LSI ARSA SpectrumGreen

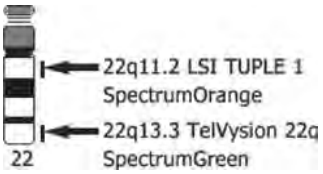
The 110 kb TUPLE1 probe does not contain the more telomeric loci D22S941 and D22S943. It is not known if the TUPLE1 probe contains the gene DVL22.

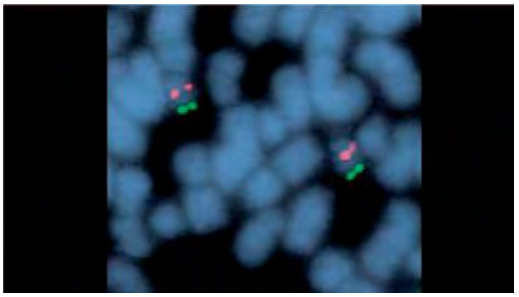
Ordering Information	Quantity	Order No.
Vysis DiGeorge Region Probe – LSI TUPLE1 SpectrumOrange/LSI ARSA SpectrumGreen	20 µl	08L59-020

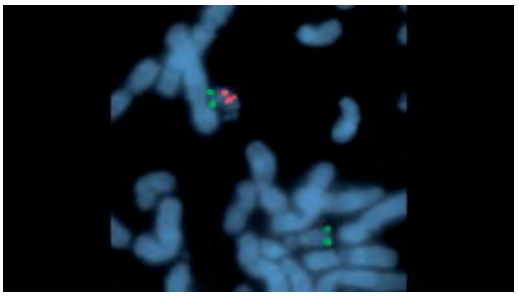
References
1. Shaikh TH, Kurahashi H, Saitta SC, et al.Human Molecular Genetics 2000;9(4):489-501.
2. Park IS, Ko JK, Kim YH, et al. International Journal of Cardiology 2007; 114:230–235.
3. Yakut t, Sebnem Kilic S, Cil E, et al. Pediatr Surg Int 2006;22:380–383.
4. Manji S, Roberson JR, Wiktor A, et al. Genetics IN Medicine 2001;3(1):65-66.
5. Ensenauer RE, Adeyinka A, Flynn HC , et al. Am J Hum Genet 2003;73:1027–1040.
6. Portnoi ME, Lebas F, Gruchy N, et al. Am J Med Genet A 2005;137(1):47-51.
7. National Center for Biotechnology Information (NCBI Build) 36.1, March 2006.
8. Wiktor AE, Van Dyke DL, Stupca PJ, et al.Genet Med 2006;8(1):16-23.

Vysis DiGeorge Region Probe – LSI TUPLE1 (HIRA) SpectrumOrange/TelVysion 22q SpectrumGreen









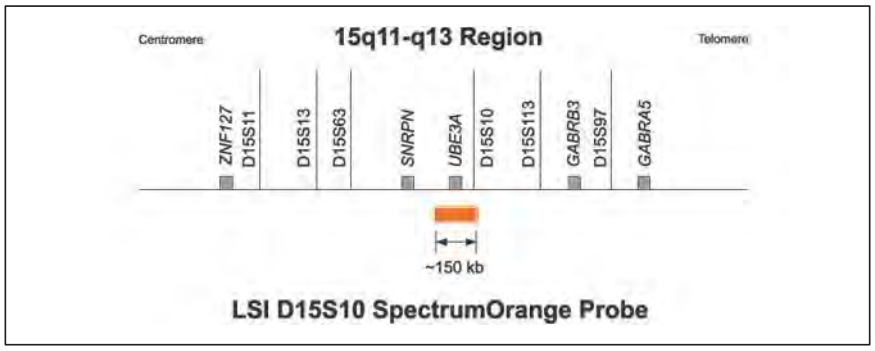
Vysis LSI TUPLE1 (HIRA) is a 117 kb SpectrumOrange probe that hybridizes to the 22q11 region of chromosome 22. The hybridization target spans from 87 kb centromeric to the HIRA gene to a point within the gene, 13 kb from from its telomeric end. TelVysion 22q is 96 kb in size, labeled in SpectrumGreen and hybridizes to the 22q13 subtelomeric region of chromosome 22

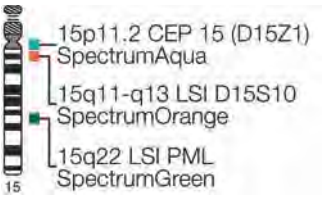
Ordering Information	Quantity	Order No.
Vysis DiGeorge Region Probe – LSI TUPLE1 (HIRA) SpectrumOrange/TelVysion 22q SpectrumGreen	10 µl	01N14-010

References
See above: Vysis DiGeorge Region Probe – LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen

Microdeletion Probes – Prader-Willi/Angelman Region Probes

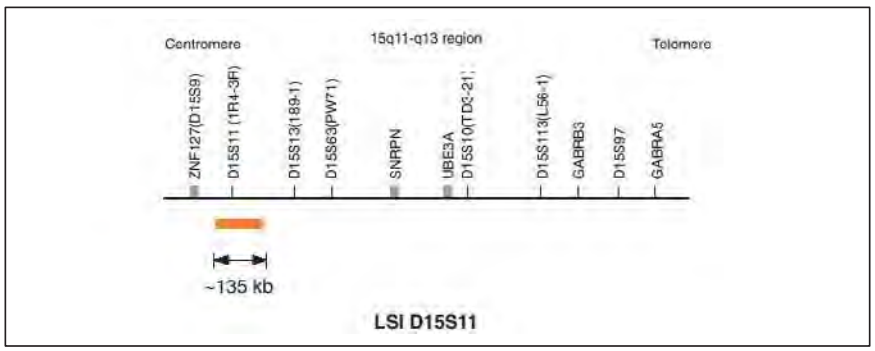
Vysis Prader-Willi/Angelman Region Probe – LSI D15S10 SpectrumOrange/ CEP 15 (D15Z1) SpectrumAqua/PML SpectrumGreen Probe

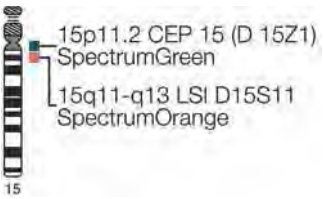




Ordering Information	Quantity	Order No.
Vysis Prader-Willi/Angelman Region Probe – LSI D15S10 (SO)/CEP 15 (D15Z1) (SA)/PML (SG)	10 µl	05N58-010

Vysis Prader-Willi/Angelman Region Probe – LSI D15S11 SpectrumOrange/ CEP 15 (D15Z1) SpectrumGreen





Four products are offered for the detection or characterization of abnormalities involving 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), a control probe useful for detecting rare translocations in AS and PWS.

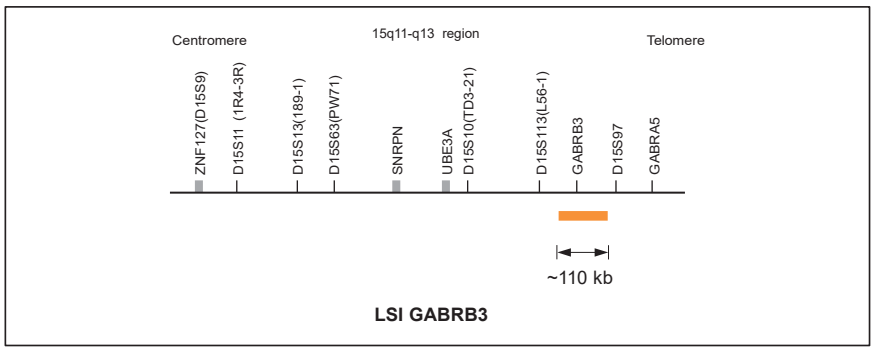
Ordering Information	Quantity	Order No.
Vysis Prader-Willi/Angelman Region Probe – LSI D15S11 SpectrumOrange/CEP 15 (D15Z1) SpectrumGreen	20 µl	05J19-014

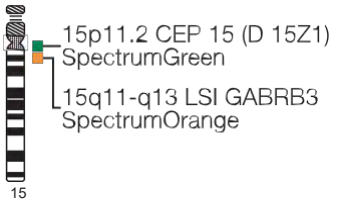
References

1. Cotter, P. 1999. Prenat. Diagn. 19:721-726.

Microdeletion Probes – Prader-Willi/Angelman Region Probes

Vysis Prader-Willi/Angelman Region Probe – LSI GABRB3 SpectrumOrange/ CEP 15 (D15Z1) SpectrumGreen



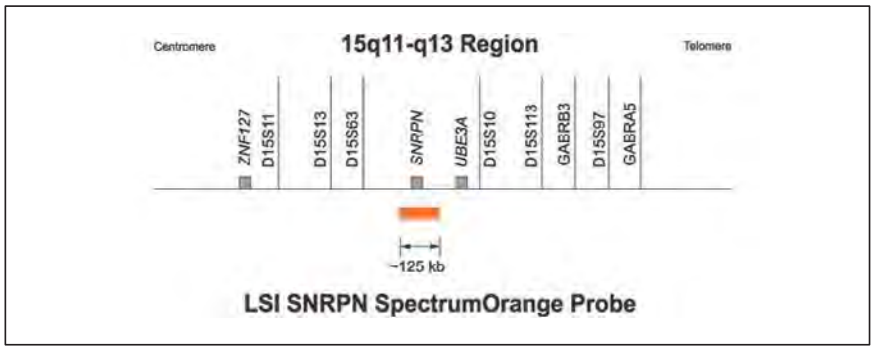


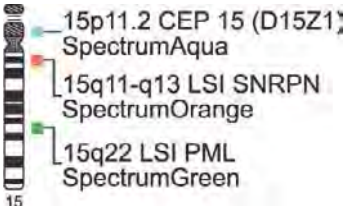
Multiple products are offered for the detection or characterization of abnormalities involving Multiple products are offered for the detection or characterization of abnormalities involving 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), Multiple products are offered for the detection or characterization of abnormalities involving 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), a control probe useful for detecting rare translocations in AS and PWS. a control probe useful for detecting rare translocations in AS and PWS. 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), a control probe useful for detecting rare translocations in AS and PWS.

Ordering Information	Quantity	Order No.
Vysis Prader-Willi/Angelman Region Probe – LSI GABRB3 SpectrumOrange/CEP 15 (D15Z1) SpectrumGreen	20 µl	05J22-015

References
1. Cotter, P. 1999. Prenat. Diagn. 19:721-726.

LSI SNRPN SpectrumOrange/CEP 15 (D15Z1) SpectrumAqua/ LSI PML SpectrumGreen TriColor Probe

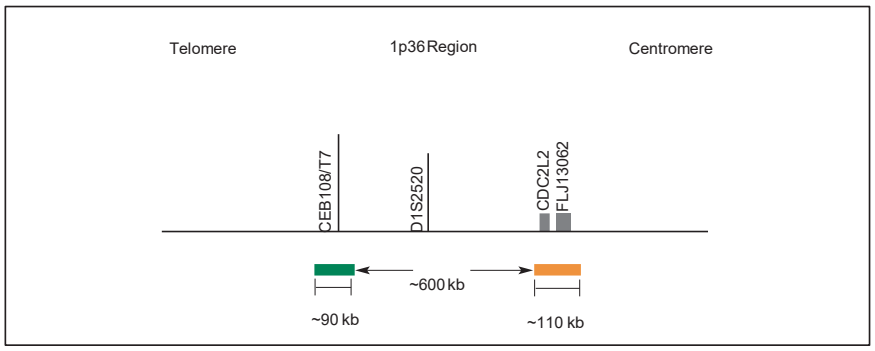


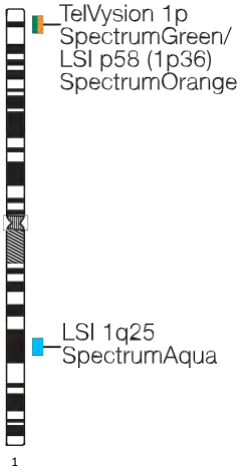


Ordering Information	Quantity	Order No.
Vysis LSI SNRPN SpectrumOrange/CEP 15 (D15Z1) SpectrumAqua/ LSI PML SpectrumGreen TriColor Probe	10 µl	06N27-010

Microdeletion Probes – Others

Vysis 1p36 Microdeletion Region Probe – LSI p58 (1p36) (SO)/TelVysion 1p (SG)/LSI 1q25 (SA)

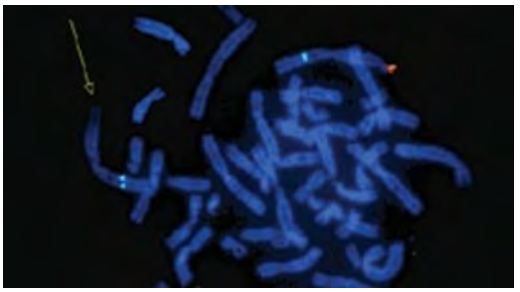




Terminal deletions involving the 1p subtelomere region and interstitial deletions of 1p36, as well as derivative chromosomes and complex rearrangements resulting in monosomy 1p36, are targeted with this probe set.

The 1p36 Microdeletion Probe Set includes FISH probes to the 1p subtelomere region labeled in SpectrumGreen, p58 (CDC2L1) within 1p36 labeled in SpectrumOrange, and a control probe on 1q25 labeled in SpectrumAqua.

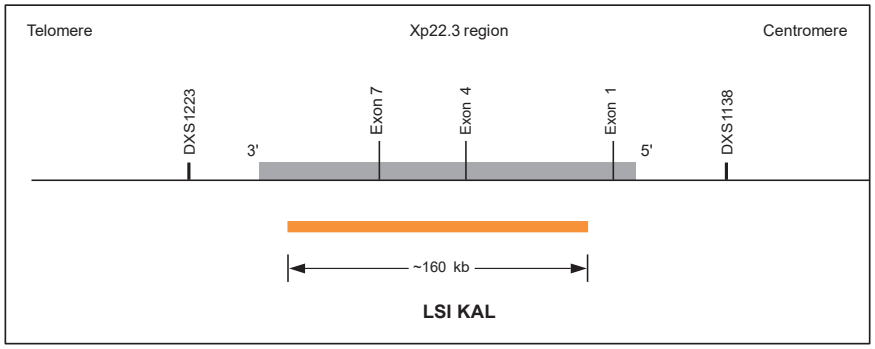
Ordering Information	Quantity	Order No.
Vysis 1p36 Microdeletion Region Probe – LSI p58 (1p36) (SO)/TelVysion 1p (SG)/LSI 1q25 (SA)	20 µl	05J21-020

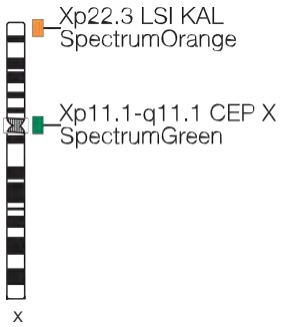


1p36 Microdeletion Probe hybridized to a metaphase cell. Absence of the SpectrumOrange and SpectrumGreen signals on distal 1p36 (arrow) indicates a deletion of both TelVysion 1p and LSI p58.

References
1. Heilstedt HA et al., Clin Genet 64:310-316, 2003
2. Heilstedt HA et al., Am J hum Genet 72: 1200-1212, 2003

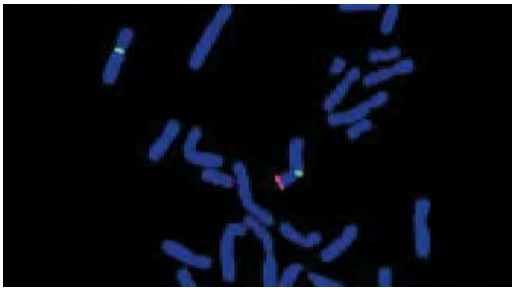
Vysis Kallman Region Probe – LSI KAL SpectrumOrange/CEP X SpectrumGreen





LSI KAL may be used to identify deletions of the KAL gene. This mixture contains the SpectrumOrange LSI KAL probe and the SpectrumGreen CEP X control probe. LSI KAL is known to contain KAL exons 4-7. The KAL probe does not extend past exon 1 or into the 3' region of the gene.

Ordering Information	Quantity	Order No.
Vysis Kallman Region Probe – LSI KAL SpectrumOrange/CEP X SpectrumGreen	20 µl	05J23-070

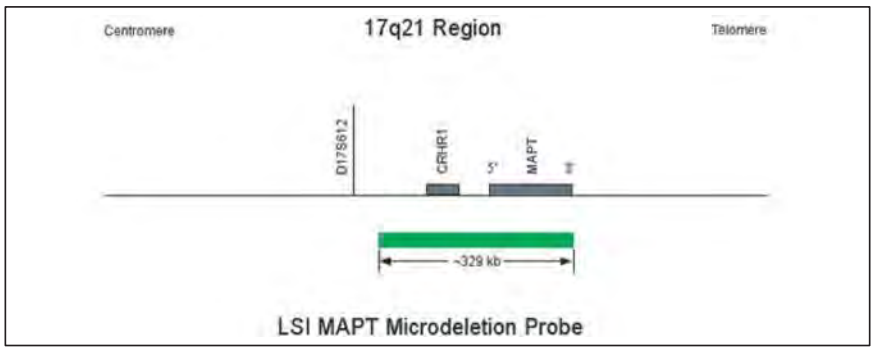


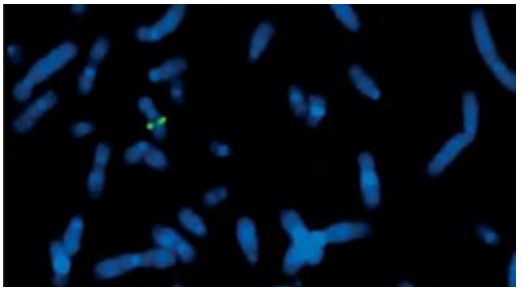
LSI KAL hybridized to a metaphase cell. Absence of the orange-pink signal on one chromosome X indicates deletion of the KAL locus.

References
1. Herrel, S. et. al. 1995. Genomics 25:526-37.

Microdeletion Probes – Others

Vysis LSI MAPT SpectrumGreen Probe



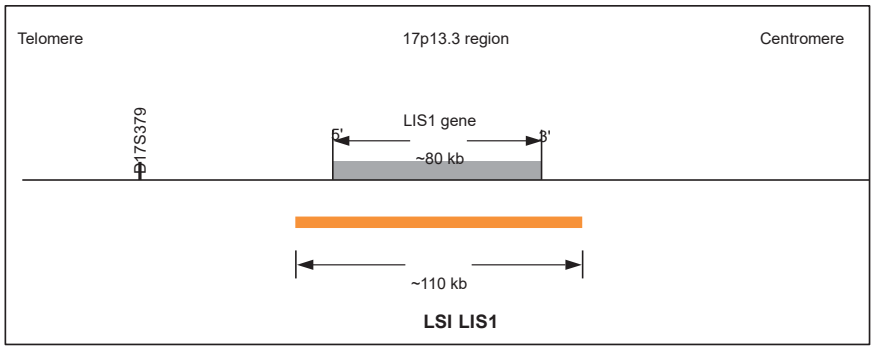


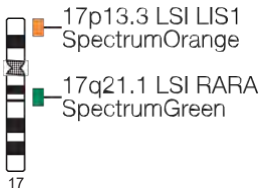
MAPT SpectrumGreen probe hybridized to a metaphase cell. Absence of the green signal on one chromosome 17 indicates deletion of the MAPT locus.

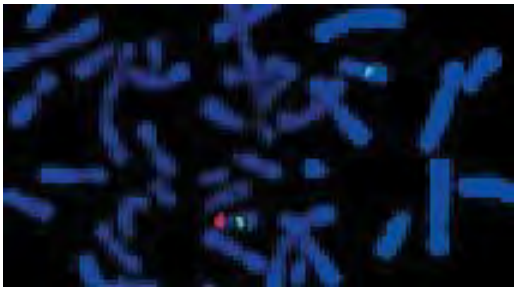
Vysis LSI MAPT is a 329 kb SpectrumGreen probe that can be used for assessment of the presence or absence of the MAPT locus on chromosome 17. It spans the entire MAPT gene.

Ordering Information	Quantity	Order No.
Vysis LSI MAPT SpectrumGreen Probe	10 µl	02N19-010

Vysis Miller-Dieker Region/Isolated Lissencephaly Probe LSI LIS1 SpectrumOrange/LSI RARA SpectrumGreen







Metaphase spread containing one chromosome 17 with SpectrumGreen LSI RARA and absence of the SpectrumOrange LSI LIS1 signal (arrow). The normal chromosome 17 shows the presence of SpectrumOrange LSI LIS1 and SpectrumGreen LSI RARA.

The Vysis LSI LIS1 FISH probe is approximately 110 kb in size and homologous to the LIS1 gene located at 17p13.3. The LSI LIS1 probe is directly labeled with SpectrumOrange and is mixed with a control probe, LSI RARA. LSI RARA is specific to the 17q21.1 region and is directly labeled with SpectrumGreen fluorophore.

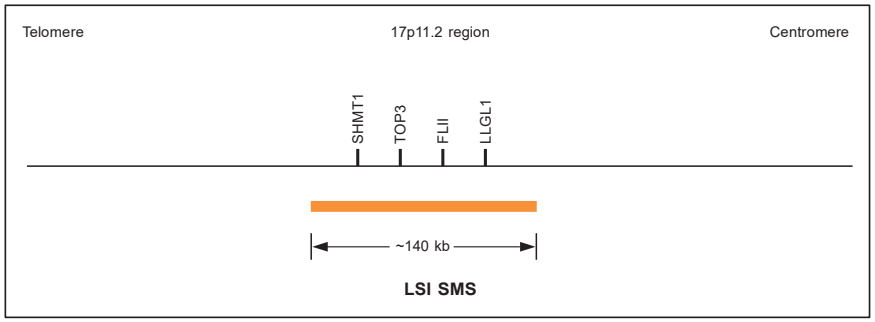
Ordering Information	Quantity	Order No.
Vysis Miller-Dieker Region/Isolated Lissencephaly Probe LSI LIS1 SpectrumOrange/LSI RARA SpectrumGreen	20 µl	05J88-001

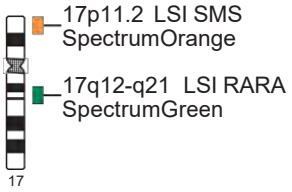
References

1. Ledbetter, S. A. et. al. Microdeletions of Chromosome 17p13 as a Cause of Isolated Lissencephaly, Am. J. Hum. Genet.50:182-189, 1992.
2. Dobyns, W. B. et. al. Clinical and Molecular Diagnosis of Miller-Dieker Syndrome, Am. J. Hum. Genet. 48:584-594, 1991.
3. Van Zelderen-Bhola, S.L et. al. Prenatal and Postnatal Investigation of a Case with Miller-Dieker Syndrome Due to a Familial Cryptic Translocation t(17;20) (p13.3;q13.3) Detected by Fluorescence *In Situ* Hybridization, Prenatal Diagnosis 17:2:173-179, 1997.
4. Kuwano, A. et. al. Detection of Deletions and Cryptic Translocations in Miller-Dieker Syndrome by In Situ Hybridization, Am. J. Hum.Genet. 49:707-714,1991.

Microdeletion Probes – Others

Vysis Smith-Magenis Region Probe – LSI SMS Region SpectrumOrange/ LSI RARA SpectrumGreen





LSI SMS is approximately 140 kb in size and homologous to the Smith-Magenis region. The LSI SMS probe is directly labeled with SpectrumOrange and is mixed with the LSI RARA control probe. LSI RARA is specific to 17q21.1 and is directly labeled with SpectrumGreen.

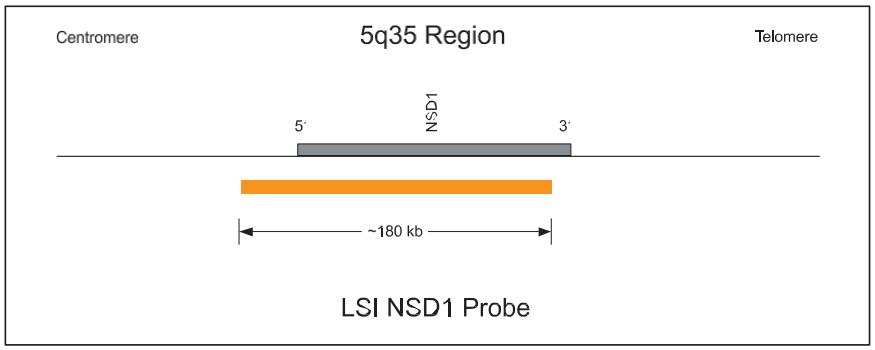
Metaphase spread containing one chromosome 17 with the SpectrumGreen LSI RARA Control Probe and absence of the SpectrumOrange LSI SMS Probe signal. The normal chromosome 17 shows the presence of the SpectrumOrange LSI SMS Probe and the SpectrumGreen LSI RARA Control Probe.

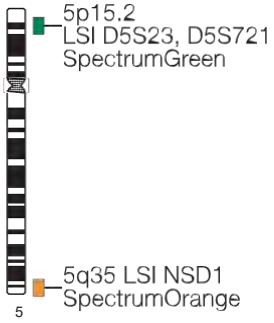
Ordering Information	Quantity	Order No.
Vysis Smith-Magenis Region Probe – LSI SMS Region SpectrumOrange/LSI RARA SpectrumGreen	20 µl	05J25-003

References

1. Juyal, R.C., et. al. Molecular Analyses of 17p11.2 Deletions in 62 Smith-Magenis Syndrome Patients, Am. J. Hum. Genet. 58:998-1007, 1996.
2. Zori, R.T. et. al. Clinical, Cytogenetic, and Molecular Evidence for an Infant With Smith-Magenis Syndrome Born From a Mother Having Mosaic 17p11.2p12 Deletion, Am. J. Med. Genet. 47:504-511, 1993.
3. Schmickel, R.D. Contiguous gene syndromes: a component of recognizable syndromes. J. Pediat 109:231-241 1986.
4. Elsea, S..H., et. al. Haploinsuffi ciency of Cystolic Serine Hydroxymethyltransferase in the Smith-Magenis Syndrome. Am. J. Med. Genet. 57:1342-1350, 1995.
5. Cambell, H.D., et. al. Genomic Structure, Evolution, and Expression of Human FLII, a Gelsolin and Leucine-Rich-Repeat Family Member: Overlap with LLGL. Genomics 42:46-54, 1997.
6. Elsea, S.H., et. al. Gene for Topoisomerase III Maps within the Smith-Magenis Syndrome Critical Region: Analysis of Cell-Cycle Distribution and Radiation Sensitivity. Am. J. Med. Genet. 75:104-108, 1998.

Vysis Sotos Region Probe – LSI NSD1 (5q35) SpectrumOrange/ LSI D5S23, D5S721 SpectrumGreen Probe

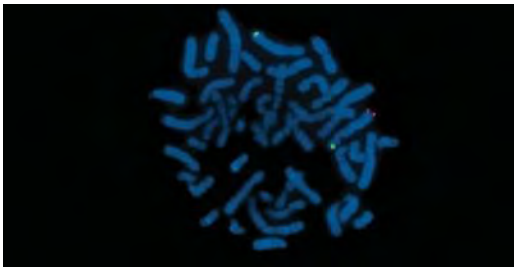




Ordering Information	Quantity	Order No.
Vysis Sotos Region Probe – LSI NDS1 (5q35 SpectrumOrange)/ LSI D5S23, D5S721 SpectrumGreen Probe	20 µl	05J48-007

References

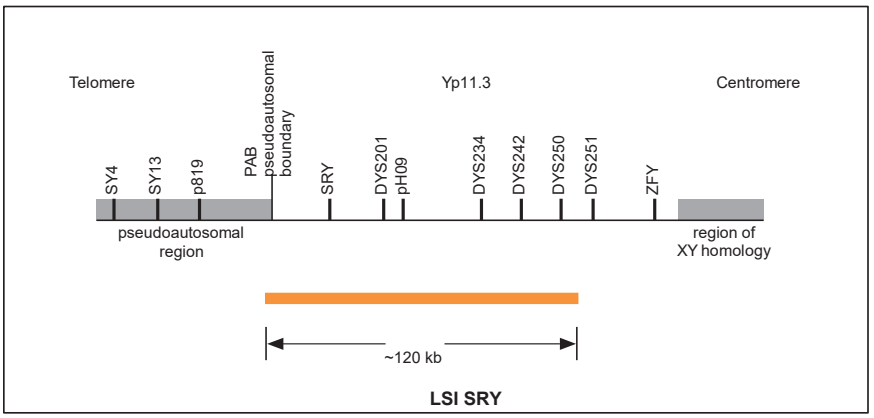
1. Haqq C. and Donahoe P., 1998. Physiological Reviews 78:1, 1-33.
2. Whitfield L. et. al., 1995. Genomics 27:306-311.
3. Tuck-Muller, C.M., 1995. Hum. Genet. 96:1;119-129.
4. Yenamandra A, et. al., 1997. Amer. J. Med. Genetics 72:125-128.
5. Patsalis P., 1997. Clin Genet Mar;51(3):184-190.
6. Reddy P., 1997. J of Urology 158:1305-1307.
7. Sinclair, 1990. A.H. Nature 346: 240-244.

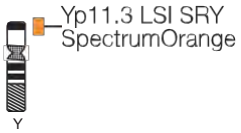


LSI NSD1 (5q35) SpectrumOrange Probe Set hybridized to a metaphase cell. Absence of the SpectrumOrange signals on distal 5q35 indicates a deletion.

Microdeletion Probes – Others

Vysis SRY Probe – LSI SRY SpectrumOrange





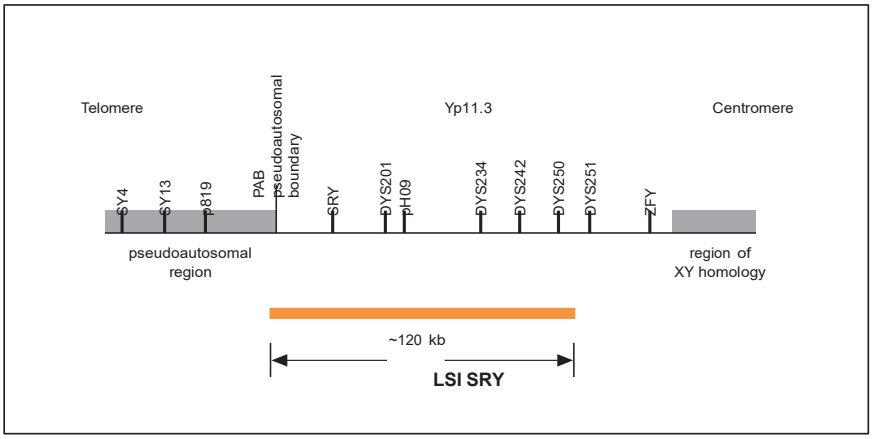
The SRY gene is located within 10kb of the pseudoautosomal region of Yp. The LSI SRY probe is useful in detecting deletions of SRY or presence of the gene in rearrangements involving the X chromosome, autosomes and marker chromosomes.

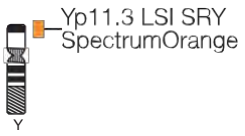
The LSI SRY DNA FISH probe is an approximately 120 kb probe specific to the SRY gene and flanking sequences. This probe is directly labeled with SpectrumOrange and is available as a single probe or mixed with the CEP X SpectrumGreen probe.

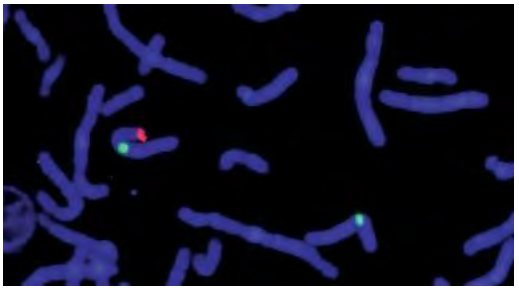
Ordering Information	Quantity	Order No.
Vysis SRY Probe – LSI SRY SpectrumOrange	20 µl	05J27-089

Microdeletion Probes – Others

Vysis SRY Probe LSI SRY SpectrumOrange/CEP X SpectrumGreen







LSI SRY SpectrumOrange/CEP X SpectrumGreen hybridized to a specimen obtained from an XX male. Note the presence of an orange LSI SRY probe signal on one X chromosome.

The SRY gene is located within 10 kb of the pseudoautosomal region of Yp. The LSI SRY probe is useful in detecting deletions of SRY or presence of the gene in rearrangements involving the X chromosome, autosomes and marker chromosomes.

The LSI SRY DNA FISH probe is an approximately 120 kb probe specific to the SRY gene and flanking sequences. This probe is directly labeled with SpectrumOrange and is available as a single probe or mixed with the CEP X SpectrumGreen probe.

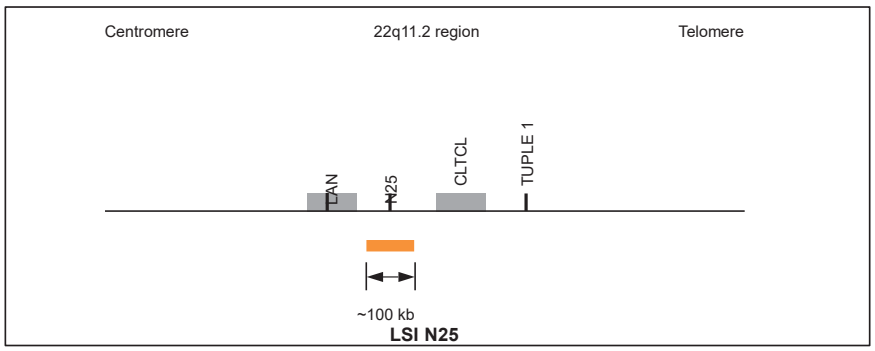
Ordering Information	Quantity	Order No.
Vysis SRY Probe LSI SRY SpectrumOrange/ CEP X SpectrumGreen	20 µl	06N29-020

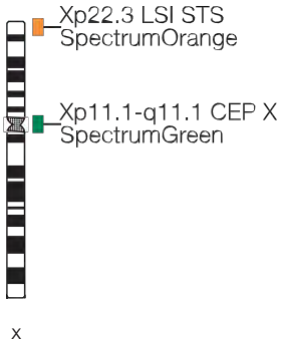
References

1. Haqq C. and Donahoe P., 1998. Physiological Reviews 78:1, 1-33.
2. Whitfield L. et. al., 1995. Genomics 27:306-311.
3. Tuck-Muller, C.M., 1995. Hum. Genet. 96:1;119-129.
4. Yenamandra A, et. al., 1997. Amer. J. Med. Genetics 72:125-128.
5. Patsalis P., 1997. Clin Genet Mar;51(3):184-190.
6. Reddy P., 1997. J of Urology 158:1305-1307.
7. Sinclair, 1990. A.H. Nature 346: 240-244

Microdeletion Probes – Others

Vysis Steroid Sulfatase Deficiency Probe – LSI STS SpectrumOrange/LSI CEP X SpectrumGreen



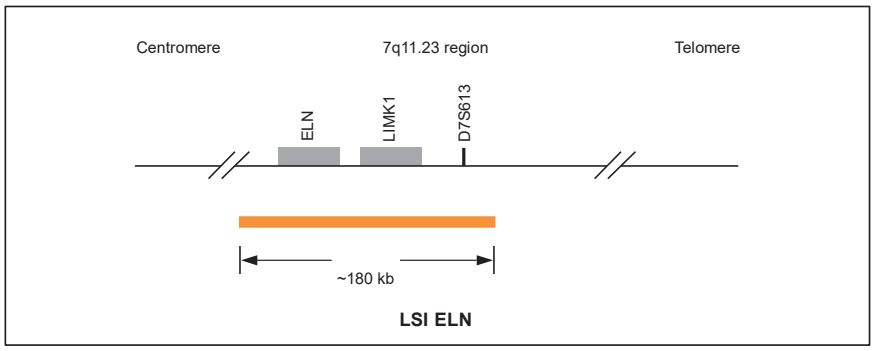


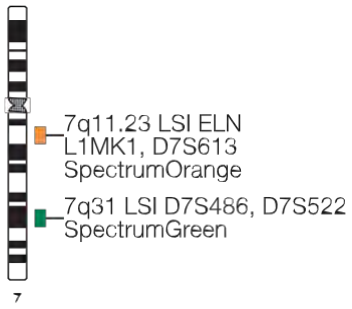
LSI STS may be used to identify deletions of the STS gene located in band Xp22.3. This mixture contains the SpectrumOrange LSI STS probe and the SpectrumGreen CEP X control probe. The LSI STS, approximately 220 kb in size, includes the entire STS gene. The STS probe does not contain the more telomeric locus GMGXY3 or the more centromeric locus DXS237.

Ordering Information	Quantity	Order No.
Vysis Steroid Sulfatase Deficiency Probe – LSI STS SpectrumOrange/LSI CEP X SpectrumGreen	20 µl	05J28-004

LSI STS probe hybridized to a metaphase cell. Absence of the orange signal on one chromosome X indicates a deletion of the STS gene.

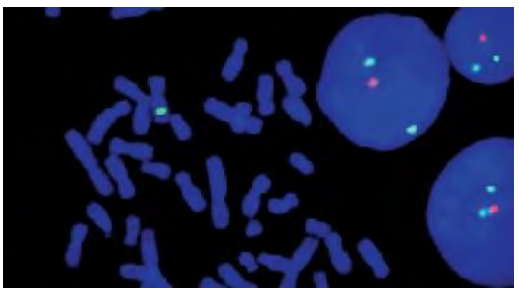
Vysis Williams Region Probe – LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen





Targeting 7q11.23, the Elastin gene (ELN) gene region, the Williams (ELN) Region Probe consists of a probe (approximately 180 kb in size) for ELN, LIMK1, and the D7S613 locus, and a control probe for the region containing loci D7S486 and D7S522 (7q31).

Ordering Information	Quantity	Order No.
Vysis Williams Syndrome Region Probe – LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen	20 µl	06N28-020

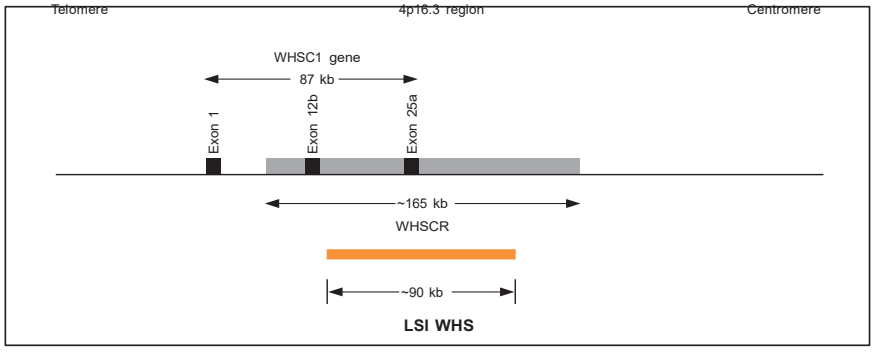


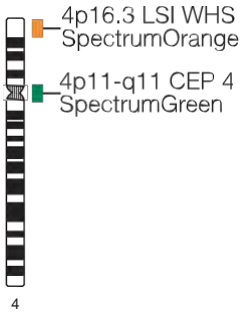
Metaphase and interphase cells hybridized with LSI ELN. Absence of the orange signal on one chromosome 7 indicates a deletion of the Williams Region.

References
1. Osborne, L. et. al. 1996. Genomics 36; 328-336.

Microdeletion Probes – Others

Vysis Wolf-Hirschhorn Region Probe – LSI WHS SpectrumOrange/CEP 4 SpectrumGreen

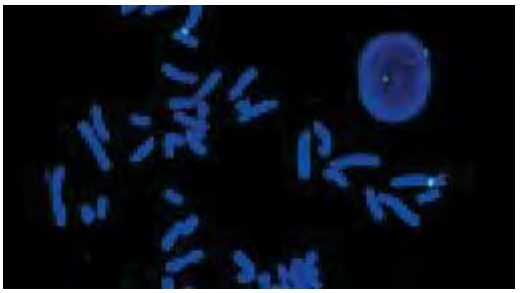




The Wolf-Hirschhorn (WHS) probe set targets p arm of chromosome 4.

The LSI WHS probe is directly labeled with SpectrumOrange and is mixed with a control probe, CEP 4 labeled with SpectrumGreen fluorophore.

Ordering Information	Quantity	Order No.
Vysis Wolf-Hirschhorn Region Probe – LSI WHS SpectrumOrange/CEP 4 SpectrumGreen	20 µl	05J29-074

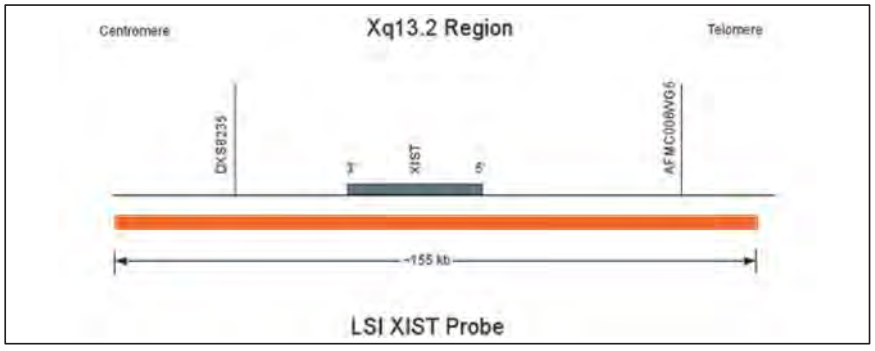


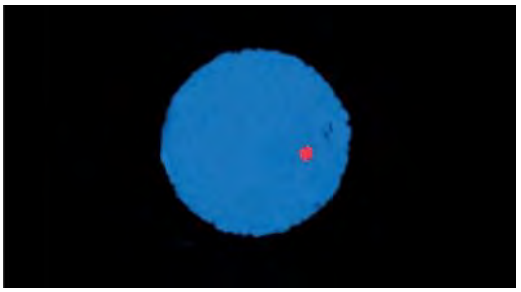
Metaphase spread containing one chromosome 4 with the CEP 4 SpectrumGreen but without the LSI WHS SpectrumOrange signal.The normal chromosome 4 shows the presence of the LSI WHS SpectrumOrange and the CEP 4 SpectrumGreen.

References

1. Hirshhorn, K., et. al., Deletion of Short Arms of Chromosome 4-5 in a child with defects of midline fusion. Humangenetik, 1: 479-482, 1965.
2. Estabrooks, L.L. et. al., Preliminary Phenotypic Map of Chromosome 4p16 Based on 4p Deletions. Am J. Med. Genet., 57; 581-586, 1995.
3. Altherr, M. R. et. al Molecular Confirmation of Wolf-Hirschhorn Syndrome with a Subtle Translocation of Chromosome 4. Am. J. Hum. Genet., 49: 1235-1242, 1991.
4. Ingrid, S., et. al., WHSC1, a 90 kb SET domain-containing gene, expressed in early development and homologous to a Drosophila dysmorphy gene maps in the Wolf-Hirschhorn syndrome critical region and is fused to IGH in t (4;14) multiple myeloma. Human Molecular Genetics, 7:1, 1071-1082, 1998.

Vysis LSI Xq13.2 (XIST) SpectrumOrange Probe





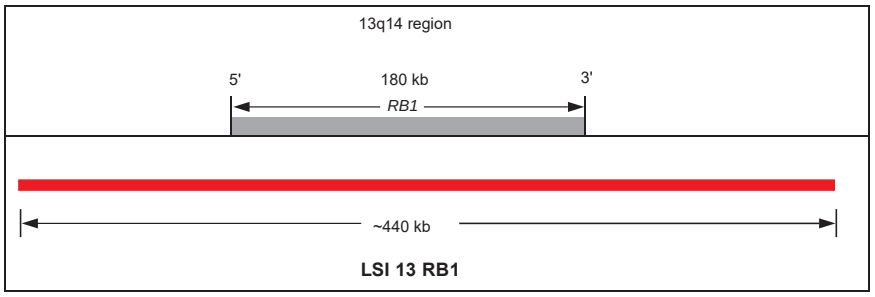
In a normal male cell hybridized with LSI Xq13.2 (XIST) SpectrumOrange probe, the expected signal pattern is one orange signal.

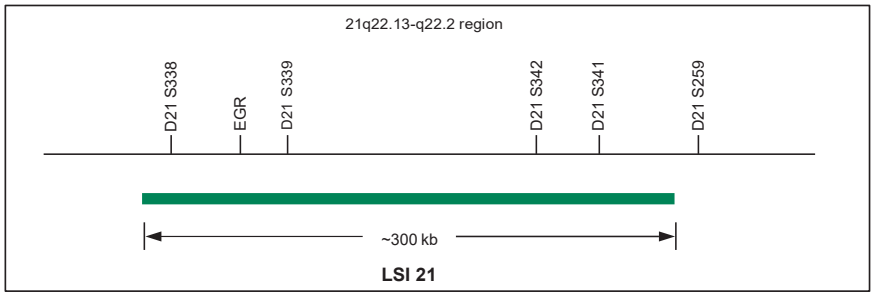
Vysis LSI Xq13.2 (XIST) is a 155 kb SpectrumOrange probe that can be used for assessment of the presence or absence of the XIST locus on chromosome X. The probe spans the entire XIST gene

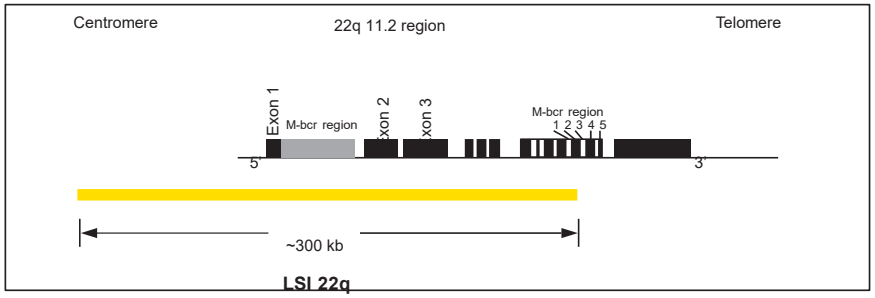
Ordering Information	Quantity	Order No.
Vysis LSI Xq13.2 (XIST) SpectrumOrange Probe	10 µl	01N61-001

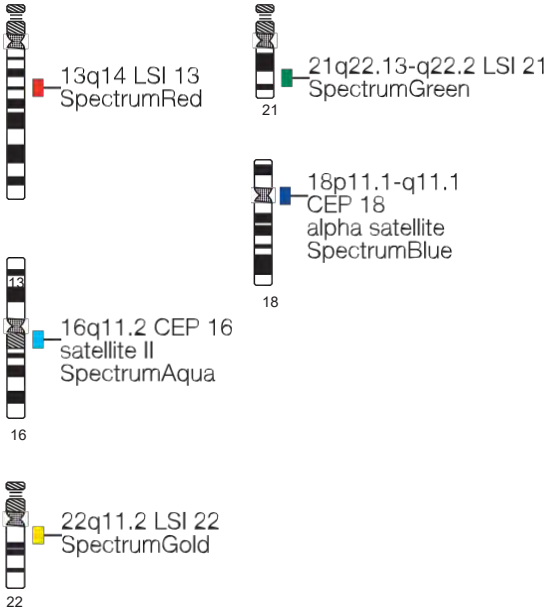
Preimplantation

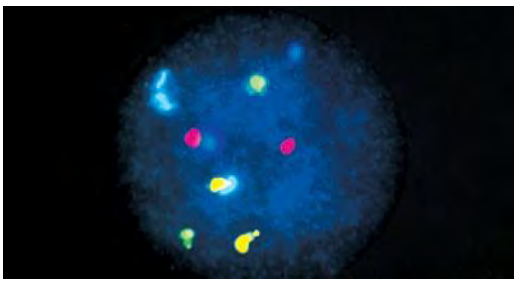
Vysis MultiVysion PB Multi-color Probe











Analysis of MultiVysion PB hybridized to an embryonic cell showing normal results with 2 signals for each color of probe.

MultiVysion PGT and MultiVysion PB fluorescence *in situ* hybridization (FISH) probe sets are designed for determination of chromosome copy number in single cells.

Unlabeled DNA is included with both probe sets to block sequences contained within the target loci that are common to other chromosomes. This probe set is premixed in Hybridization Buffer.

LSI 13: DNA probe spanning the RB1 (13q14) labeled with SpectrumRed.

CEP 16: D16Z3 satellite II DNA probe corresponding to 16q11.2 labeled with SpectrumAqua.

CEP 18: D18Z1 alpha-satellite DNA probe corresponding to 18p11.1-q11.1 labeled with SpectrumBlue.

LSI 21: DNA probe corresponding to loci D21S341, D21S342, D21S339, EGR, and D21S338 (21q22.13-q22.2) labeled with SpectrumGreen.

LSI 22: DNA probe corresponding to the BCR locus (22q11.2) labeled with SpectrumGold.

Human placental DNA labeled with (SpectrumAqua, SpectrumBlue, and SpectrumOrange) is included in the mixture to provide a nuclear stain.

Continuation on the following page >

Preimplantation

Continuation:
Vysis MultiVysion PB Multi-color Probe

Ordering Information	Quantity	Order No.
Vysis MultiVysion PB Mulit-color FISH Probe Kit	60 µl *	08L62-020

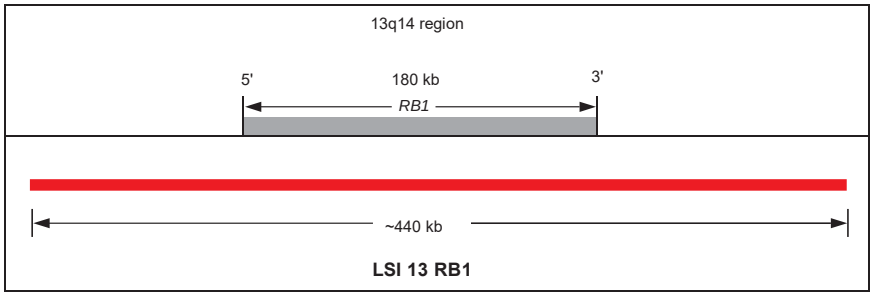
* 60 µl calculated for 20 assays

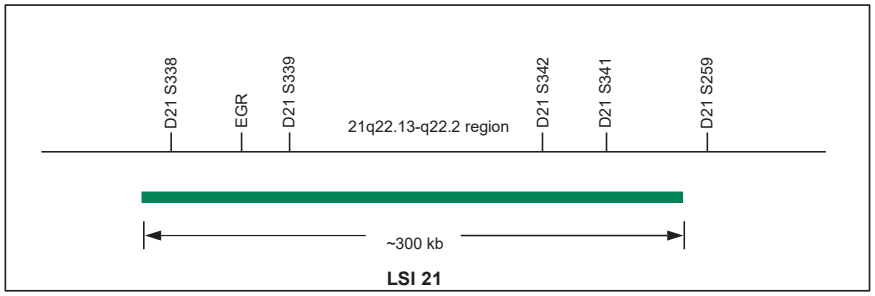
References

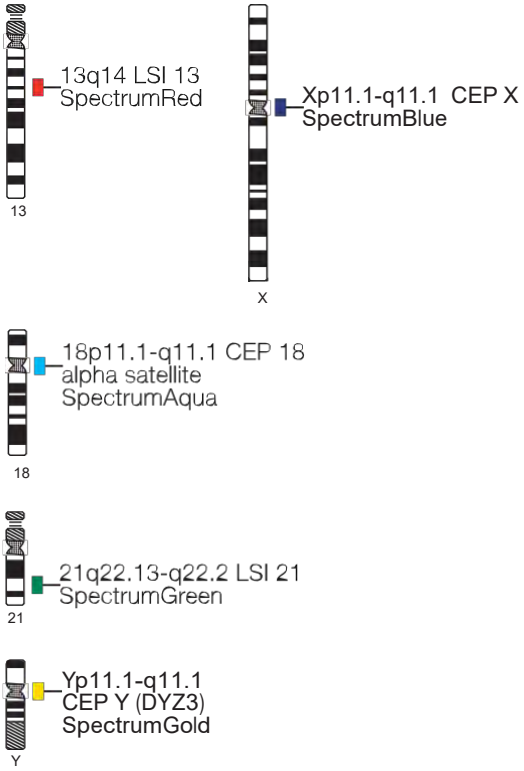
1. Munné S, Sandalinas M, Escudero T, et al. Improved implantation after preimplantation genetic diagnosis of aneuploidy. Reprod Biomed Online. 2003;7(1):91-7
2. Munné S, Chen S, Fischer J, et al. Preimplantation genetic diagnosis reduces pregnancy loss in women aged 35 years and older with a history of recurrent miscarriages. Fertil Steril. 2005;84(2):331-5.
3. Bloechle M, Marr S, Guillot P, et al. P-698: Polar body analysis of 314 unfertilized oocytes: what can we learn? Fertil Steril. 2006;86(3) Suppl. 2:S392-3.
4. Kahraman S, Benkhalifa M, Donmez E, et al. The results of aneuploidy screening in 276 couples undergoing assisted reproductive techniques. Prenat Diagn. 2004;24(4):307-11.
5. Baart EB, Martini E, and D. Van Opstal. Screening for aneuploidies of ten different chromosomes in two rounds of FISH: a short and reliable protocol. Prenat Diagn. 2004;24(12):955-61.
6. Verlinsky Y, Cieslak J, Freidine M, et al. Pregnancies following pre-conception diagnosis of common aneuploidies by fluorescent in-situ hybridization. Hum Reprod. 1995;10(7):1923-1927
7. Verlinsky Y and Kuliev A, eds. Preimplantation Diagnosis of Genetic Diseases: A New Technique for Assisted Reproduction. New York: Wiley Liss. 1994
8. Staessen C, Platteau P, Van Assche, et al. Comparison of blastocyst transfer with or without preimplantation genetic diagnosis for aneuploidy screening in couples with advanced maternal age: a prospective randomized controlled trial. Hum Reprod 2004;19(12):2849-58

Preimplantation

Vysis MultiVysion PGT Multi-color Probe







MultiVysion PGT and MultiVysion PB fluorescence *in situ* hybridization (FISH) probe sets are designed for determination of chromosome copy number in single cells.

Unlabeled DNA is included with both probe sets to block sequences contained within the target loci that are common to other chromosomes. This probe set is premixed in Hybridization Buffer.

LSI 13: DNA probe spanning the RB1 gene (13q14) labeled with SpectrumRed.

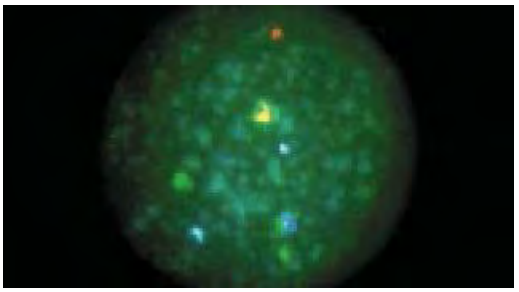
CEP 18: D18Z1 alpha-satellite DNA probe corresponding to 18p11.1-18q11.1 labeled with SpectrumAqua.

LSI 21: DNA probe corresponding to loci D21S341, D21S342, D21S339, EGR, and D21S338 (21q22.13-q22.2) labeled with SpectrumGreen.

CEP X: DXZ1 alpha-satellite DNA probe corresponding to Xp11.1-q11.1 labeled with SpectrumBlue.

CEP Y: DYZ3 alpha-satellite DNA probe corresponding to Yp11.1-q11.1 labeled with SpectrumGold.

Human placental DNA labeled with (SpectrumAqua, SpectrumBlue, and SpectrumOrange) is included in the mixture to provide a nuclear stain.



Analysis of MultiVysion PB hybridized to an embryonic cell showing normal results with 2 signals for each color of probe.

Ordering Information	Quantity	Order No.
Vysis MultiVysion PGT Multi-color FISH Probe Kit	30 µl	08L69-010

* 30 µl calculated for 10 assays

References

See Vysis MultiVysion PB Multi-color Probe (p. 2-19)

Telomere Probes

Vysis ToTelVysion

ToTelVysion consists of 41 TelVysion probes, including various LSI and CEP probes (62 probes in total).

The 41 TelVysion probes are specific to:

- p and q subtelomeres of chromosomes 1-12 and 16-20
- q subtelomeres of the acrocentric chromosomes (13, 14, 15, 21, and 22)
- Xp/Yp and Xq/Yq pseudo-autosomal region subtelomeres
- A unique region within 300 kb of each chromosome telomere

The probes in ToTelVysion are provided in 15 mixtures. All probes are directly labeled, providing bright signals with minimal background noise. By utilizing SpectrumOrange, SpectrumGreen, SpectrumAqua, and a combination of SpectrumOrange and SpectrumGreen (to yield a yellow signal), each probe within a mixture is labeled with a unique color.

Ordering Information	Quantity	Order No.
Vysis ToTelVysion	30 µl*	05J05-001

* 30 µl calculated for 10 assays

Telomere Probes

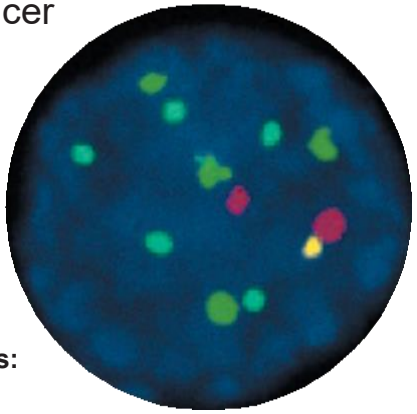
ToTelVysion and TelVysion Probes

Product description	Locus	Telomere	Probe Size	Quantity	Order No.
ToTelVysion				30 µl	05J05-001
TelVysion 1p SpectrumGreen	CEB108/T7	1p	90 kb	5 µl	05J03-091
TelVysion 2p SpectrumGreen	VIJyRM2052 (GenBank U32389)	2p	175 kb	5 µl	05J03-092
TelVysion 3p SpectrumGreen	3PTEL25 (D3S4559)	3p	184 kb	5 µl	05J03-013
TelVysion 4p SpectrumGreen	GS10K2/T7, 4p022 (D4S3359, GDB: 6244599)	4p	145 kb	5 µl	05J03-014
TelVysion 5p SpectrumGreen	c84c11/T3	5p	191 kb	5 µl	05J03-015
TelVysion 6p SpectrumGreen	6PTEL48	6p	80 kb	5 µl	05J03-096
TelVysion 7p SpectrumGreen	VIJ2yRM2185 (GenBank G31341)	7p	60 kb	5 µl	05J03-097
TelVysion 8p SpectrumGreen	AFM 197XG5 (D8S504, GDB: 199153)	8p	135 kb	5 µl	05J03-098
TelVysion 9p SpectrumGreen	305J7-T7	9p	115 kb	5 µl	05J03-099
TelVysion 10p SpectrumGreen	10PTEL006 (GenBank Z96139)	10p	80 kb	5 µl	05J03-090
TelVysion 11p SpectrumGreen	D11S2071, (GenBank U12896)	11p	107 kb	5 µl	05J03-021
TelVysion 12p SpectrumGreen	8M16/SP6	12p	100 kb	5 µl	05J03-022
TelVysion 16p SpectrumGreen	16TEL05,STSG608831; STSG608938	16p	142 kb	5 µl	05J03-026
TelVysion 17p SpectrumGreen	282M16/SP6	17p	70 kb	5 µl	05J03-027
TelVysion 18p SpectrumGreen	VIJyRM2102 (D18S552)	18p	160 kb	5 µl	05J03-028
TelVysion 19p SpectrumGreen	129F16/SP6	19p	80 kb	5 µl	05J03-029
TelVysion 20p SpectrumGreen	20PTEL18 (D20S1157)	20p	160 kb	5 µl	05J03-030
TelVysion Xp/Yp SpectrumGreen	DXYS129,DXYS153	Xp/Yp	175 kb	5 µl	05J03-033
TelVysion 1q SpectrumOrange	VIJyRM2123, 1QTEL10 (D1S3738, GDB: 9043912)	1q	100 kb	5 µl	05J04-091
TelVysion 2q SpectrumOrange	VIJyRM2112 (D2S447), 2QTEL47	2q	60 kb	5 µl	05J04-092
TelVysion 3q SpectrumOrange	3QTEL05 (D3S4560)	3q	95 kb	5 µl	05J04-093
TelVysion 4q SpectrumOrange	AFM A224XH1 (D4S2930)	4q	130 kb	5 µl	05J04-094
TelVysion 5q SpectrumOrange	GS35o8/T7, 5QTEL70 (D5S2907)	5q	105 kb	5 µl	05J04-095
TelVysion 6q SpectrumOrange	VIJyRM2158	6q	100 kb	5 µl	05J04-096
TelVysion 7q SpectrumOrange	VIJyRM2000 (GenBank G31340)	7q	93 kb	5 µl	05J04-097
TelVysion 8q SpectrumOrange	VIJyRM2053	8q	100 kb	5 µl	05J04-098
TelVysion 9q SpectrumOrange	VIJyRM2241 (D9S325)	9q	95 kb	5 µl	05J04-099
TelVysion 10q SpectrumOrange	D10S2490	10q	116 kb	5 µl	05J04-090
TelVysion 11q SpectrumOrange	D11S1037	11q	153 kb	5 µl	05J04-081
TelVysion 12q SpectrumOrange	VIJyRM2196	12q	165 kb	5 µl	05J04-082
TelVysion 13q SpectrumOrange	VIJyRM2002 (D13S327)	13q	75 kb	5 µl	05J04-083
TelVysion 14q SpectrumOrange	D14S1420	14q	110 kb	5 µl	05J04-024
TelVysion 15q SpectrumOrange	WI-5214 (D15S936 (GenBank G04801)	15q	100 kb	5 µl	05J04-025
TelVysion 16q SpectrumOrange	16QTEL013 (GenBank Z96319)	16q	110 kb	5 µl	05J04-026
TelVysion 17q SpectrumOrange	D17S928, (GenBank Z23646)	17q	160 kb	5 µl	05J04-027
TelVysion 18q SpectrumOrange	VIJyRM2050, 18QTEL11, STSG193, AFM254VD5, CU18-010L/CU18-010R, STS-F04195, TIGR-A008P37, STSG52963	18q	170 kb	5 µl	05J04-028
TelVysion 19q SpectrumOrange	D19S238E	19q	150 kb	5 µl	05J04-029
TelVysion 20q SpectrumOrange	20QTEL14	20q	140 kb	5 µl	05J04-030
TelVysion 21q SpectrumOrange	VIJyRM2029	21q	170 kb	5 µl	05J04-031
TelVysion 22q SpectrumOrange	MS607 (GenBank X58044), ACR	22q	80 kb	5 µl	05J04-032
TelVysion Xq/Yq SpectrumOrange	EST Cdy 16c07 for SYBL1 – maps within cosmid C8.2 (GenBank Z43206)	Xq/Yq	170 kb	5 µl	05J04-033

Oncology

Bladder Cancer

Early disease detection and diagnosis is paramount to improving health outcomes for bladder cancer patients. The detection of bladder cancer with DNA Fluorescence in situ Hybridization (FISH) probe technology equips pathologists with an insightful tool that detects molecular changes that may occur prior to morphological changes visible through traditional diagnostic procedures.
The UroVysion Bladder Cancer Kit is the first and only urine-based molecular diagnostic assay that aids in the initial diagnosis of bladder cancer while also detecting disease recurrence through subsequent monitoring. The UroVysion Bladder Cancer Kit is supported by years of scientific data allowing urologists to make evidence based decisions regarding therapeutic options for bladder cancer patients.



Understanding the need of laboratories and pathologists to produce and report consistent quality results with UroVysion, Abbott Molecular also provides the following accessory products:

- UroVysion Proficiency Panel (see page 3-5)
- ProbeChek Control Slide for UroVysion Bladder Cancer Kit (see page 3-4)

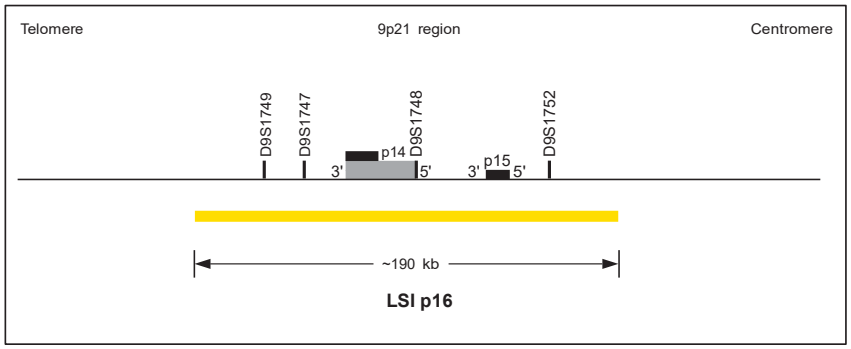
All Abbott Molecular probe kits are built with trusted Vysis probes providing

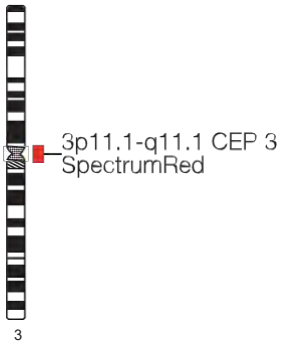
- Specific high-intensity signals without amplification and detection steps
- Low background for easy analysis
- Rapid, convenient, and easy-to-use assays
- Gene amplification detection including internal control probes
- Protocols that offer hybridization as quickly as four hours on the HYBrite and ThermoBrite Denaturation and Hybridization Systems
- Over 10 years of reliable results for researchers and clinicians worldwide

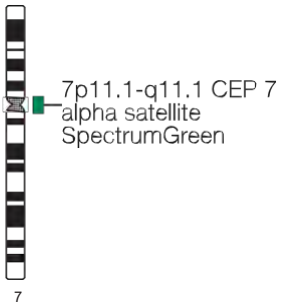
Product description	Quantity	Order No.	Number
UroVysion – FDA Approved	20 Assays	02J27-020	3-3
UroVysion – FDA Approved	100 Assays	02J27-095	3-3
ProbeChek Control Slides for UroVysion Bladder Cancer Kit	3 Slides	02J27-011	3-4
UroVysion Proficiency Panel	5 Slides	02N02-005	3-5
Vysis CDKN2A/CEP 9 FISH Probe Kit previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe	20 µl	04N61-020	3-6
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	3-7
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	3-8
Vysis AURKA SpectrumGold FISH Probe Kit	20 µl	05N93-020	3-9

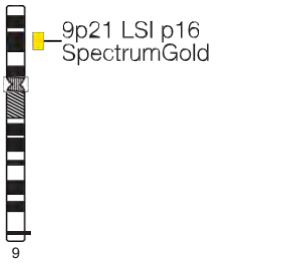
UroVysion

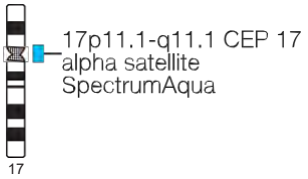
FDA APPROVED











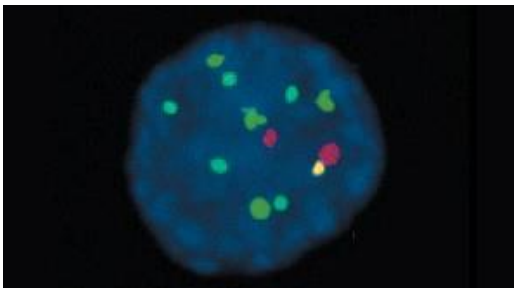
The UroVysion Bladder Cancer Kit (UroVysion Kit) is FDA approved and designed to detect aneuploidy for chromosomes 3, 7, 17, and homozygous loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens. Results from the UroVysion Kit are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

The UroVysion Bladder Cancer Kit probes are directly labeled with one of the Vysis fluorophores; SpectrumRed, SpectrumGreen, SpectrumAqua or SpectrumGold. The UroVysion Bladder Cancer Kit consists of three alpha-satellite repeat sequence probes; CEP 3 SpectrumRed, CEP 7 SpectrumGreen, and CEP 17 SpectrumAqua that hybridize to the pericentromeric regions of chromosomes 3, 7, and 17, respectively. In addition, a unique sequence probe, LSI p16 (9p21) SpectrumGold, is included that hybridizes to the p16 gene at 9p21. This probe set is premixed in Hybridization Buffer.

Results of Hybridization

Hybridization is viewed using a fluorescence microscope equipped with appropriate excitation and emission filters allowing visualization of the red, green, aqua, and gold fluorescent signals. Determination of results is conducted by enumeration of CEP 3, 7, 17, and LSI p16 (9p21) signals through microscopic examination of the nucleus. Processing The UroVysion Bladder Cancer Kit can be used with the Vysis VP2000 Processor for specimen pretreatment and the HYBrite or ThermoBrite Denaturation/Hybridization units for modular automation.

Continuation on the following page >



Aneusomic interphase cell obtained from a sample showing two copies of chromosome 3 (red), four copies of chromosome 7 (green), five copies of chromosome 17 (aqua) and one copy of p16 gene (gold) after the UroVysion Bladder Cancer Kit (UroVysion Kit) hybridization.

Continuation:
UroVysion

Vysis Microscope Filter Recommendations

UroVysion probe signals and DAPI counterstain should be viewed with the following Vysis filter sets:

- DAPI single bandpass (DAPI counterstain)
- Aqua single bandpass (chromosome 17)
- Yellow single bandpass (p16 gene)
- Red/Green dual bandpass (chromosomes 3 and 7)

An epi-fluorescence microscope equipped with a 100-watt mercury lamp is strongly recommended. **Probe Mixture #2**

Ordering Information	Quantity	Order No.
UroVysion	20 Assays	02J27-020
UroVysion	100 Assays	02J27-095
ProbeChek Control Slides for UroVysion Bladder Cancer Kit	3 Slides	02J27-011

References

1. Cairns, P. et al. (1995) Nat Genet 11:210-2.
2. Cajulis, RS. et al. (1997) Diagn Cytopathol 13:214-24.
3. Halling, KC. et al. (2000) J Urol 164, 1768-75.
4. Hopman, AHN. et al. (1991) Cancer Res 51:644-51.
5. Matsuyama, H. et al. (1994) Cancer Genet Cytogenet 77:118-24.
6. Meloni, AM. et al. (1993) Cancer Genet Cytogenet 71:105-18.
7. Sauter, G. et al. (1995) Cancer Genet Cytogenet 82:163-9.
8. Smeets, W. et al. (1993) Cancer Genet Cytogenet 71:97-9.
9. Sokolova, I. et al. (2001) Proceedings of the 92nd annual Meeting of AACR p. 357, Abstract No. 1923.
10. Waldman FM. et al. (1991) Cancer Res 51:3807-13.
11. Wheeless, LL. et al. (1994) Cytometry 17:319-26.

UroVysion Proficiency Panel

Reassure your staff, administrators and referring clinicians that UroVysion is being optimally performed and interpreted. It is convenient and efficient with the new UroVysion Proficiency Panel. The kit has five specimen slides with a mixture of cultured cell lines and cells obtained from urine samples. The slides mimic the finite set of possible results your lab may observe when performing the UroVysion assay on patient specimens.

- Excellent for training new staff members
- Helpful as a refresher for existing staff
- Insightful when confirming that UroVysion assays are being performed correctly

Submit your results for a complete analysis and recommendations
Once your lab processes the UroVysion Proficiency Panel, complete and forward the Enumeration Report Forms to the Abbott Molecular Technical Services Team for a comprehensive analysis and confirmation of proficiency status. Technical Services will then provide results to you.

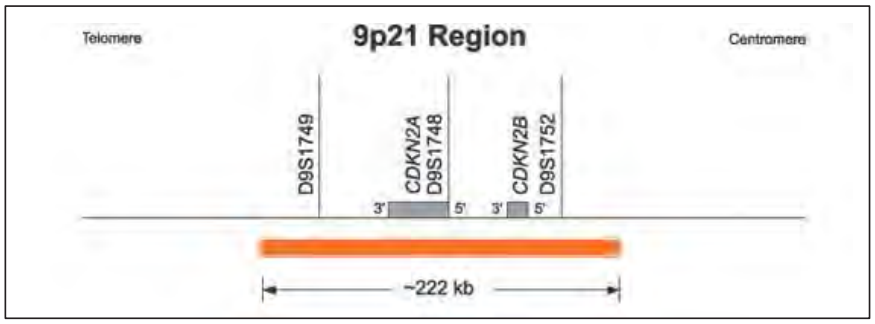
- A Certification of Completion will be issued to your lab if the panel was performed successfully
- If an opportunity to enhance performance is identified, the following services are made available:
  - On-site visit by our Technical Services Team
  - Training at an Abbott Molecular FISH Lab
  - Telephone consultation for labs conducting independent training

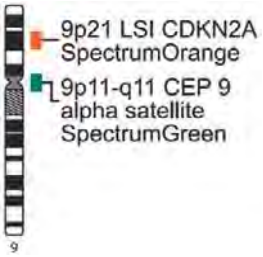
The UroVysion Proficiency Panel kit contains
- Five fixed, voided urine specimens applied to five microscope slides
- Six copies of the Enumeration Report Form for use in determining the results of the five specimens; one extra form is included for convenience
- A copy of the UroVysion Bladder Cancer Kit product insert which includes a complete hybridization protocol, direction for enumeration, clinical trial data, troubleshooting guide and intended use statement

Ordering Information	Quantity	Order No.
UroVysion Proficiency Panel	5 slides	02N02-005

Vysis CDKN2A/CEP 9 FISH Probe Kit

previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe





Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A (p16) are implicated in different Meningiomas and Gliomas[1–4]. Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that is is a marker of worse prognosis in anaplastic oligodendroglimas.[5–6]

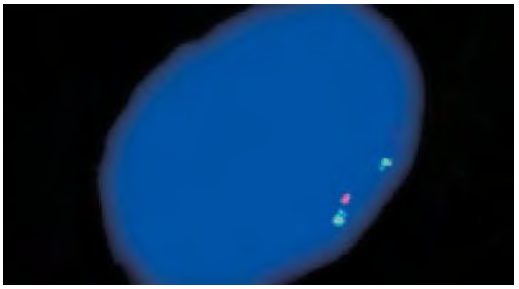
The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in serval cytogenetic studies to detect losses of the CDKN2A gene.[2, 7–9] Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histologically confirmed glial tumors.7 In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN 2A probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately 222 kb and contains a number of genetic loci including D9S1749, D9S1747, p16 (INK4B), p14 (ARF), D9S1748, p15 (INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9.

Results of Hybridization

In a normal sample, the expected pattern for a nucleus hybridized with the LSI CDKN2A/ CEP 9 probe is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orange, two green (1O2G) signal pattern is expected.Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.

Ordering Information	Quantity	Order No.
Vysis CDKN2A/CEP 9 FISH Probe Kit	20 µl	04N61-020

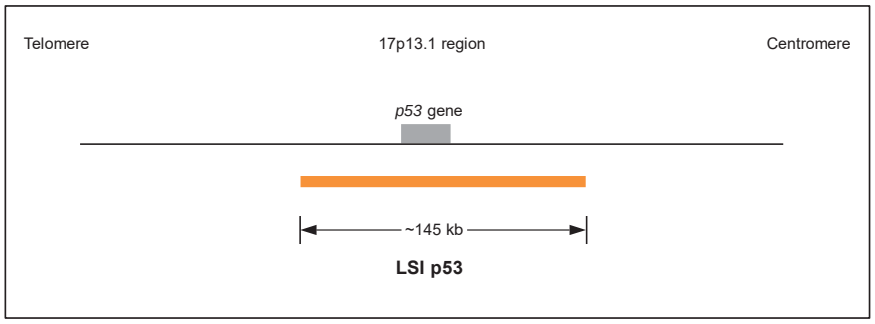


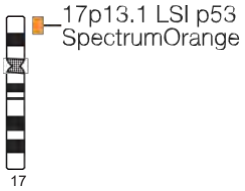
Vysis LSI CDKN2A/CEP 9 Dual Color Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively.

References

1. Ruas M, Peters G. The p16INK4a/CDKN2A tumor suppressor and its relatives. Biochimic Biophys Acta. 1998;1378(2):F115–F177.
2. Perry A, Banerjee R, Lohse CM, et al. A role for chromosome 9p21 deletions in the malignant progression of meningiomas and the prognosis of anaplastic meningiomas. Brain Pathol. 2002;12(2):183–190.
3. Boström J, Meyer-Puttlitz B, Wolter M, et al. Alterations of the tumor supressor genes CDKN2A (p16INK4a) p14ARF, CDKN2B (p15INK4b), and CDKN2C (p18INK4c) in atypical and anaplastic meningiomas. Am J Pathol. 2001;159(2):661–669.
4. Smith JS, Jenkins RB. Genetic alterations in adult diffuse glioma: occurrence, significance, and prognostic implications. Front in Biosci. 2000;5:D213–D231.
5. Cairncross JG, Ueki K, Zlatescu MC, et al. Specific genetic predictors of chemotherapeutic response and survival in patients with anaplastic oligodendrogliomas. J Natl Cancer Inst. 1998;90(19):1473–1479.
6. Bortolotto S, Chiadó-Piat L, Cavalla P, et al. CDKN2A/p16 Inactivation in the prognosis of oligodendrogliomas. Int J Cancer. 2000;88(4):554-557.
7. Kramar F, Zemanova Z, Michalova K, et al. Cytogenetic analyses in 81 patients with brain gliomas: correlation with clinical outcome and morphological data. J Neurooncol. 2007;84(2):201–211.
8. Rajaram V, Leuthardt EC, Singh PK, et al. 9p21 and 13q14 dosages in ependymomas. A clinicopathologic study of 101 cases. Mod Pathol. 2004;17(1):9–14.
9. Korshunov A, Sycheva R, Golanov A. The prognostic relevance of molecular alterations in glioblastomas for patients age < 50 years. Cancer. 2005;104(4):825–832.

Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



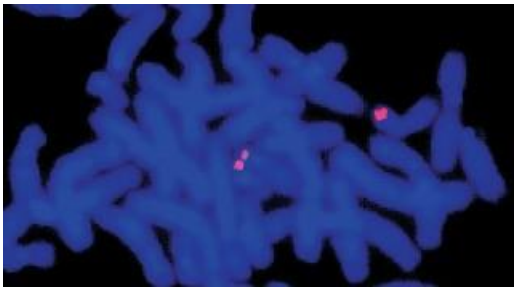


The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.

The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

Results of Hybridization

In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.



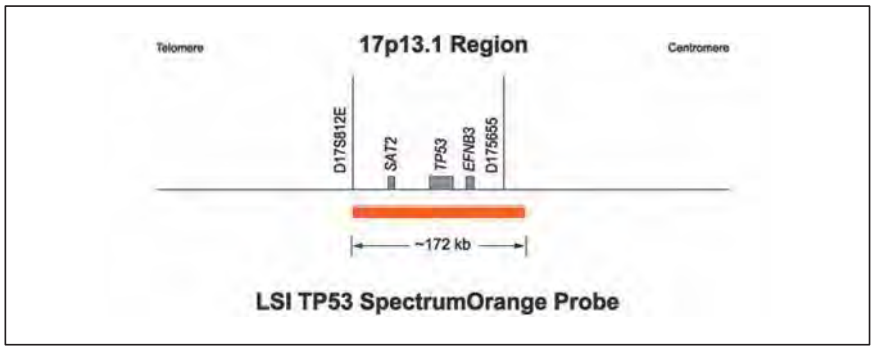
LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

Ordering Information	Quantity	Order No.
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020

References

1. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed. New York City, NY, JohnWiley & Sons, Inc.

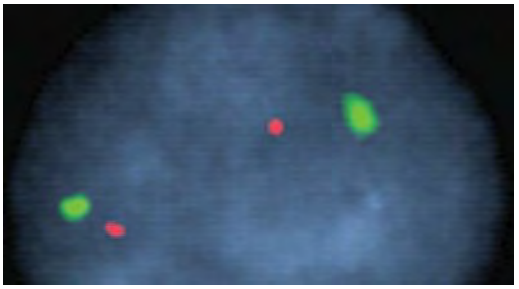
Vysis LSI TP53/CEP 17 FISH Probe Kit



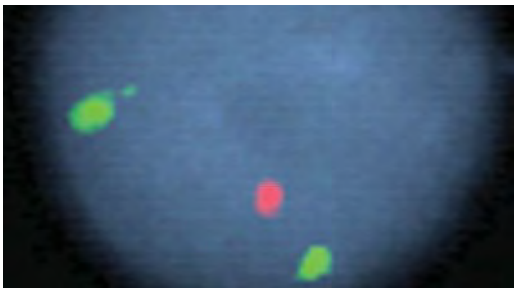
The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma.[1, 2] The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.[3, 4, 5]

The approximately 172 kb SpectrumOrange TP53 probe contains the complete TP53 gene and is located at chromosome 17p13.1. The SpectrumGreen CEP 17 probe is a control probe which hybridizes to the centromere region of chromosome 17p11.1-q11.1.



Normal nucleus showing the two green and two orange signals.



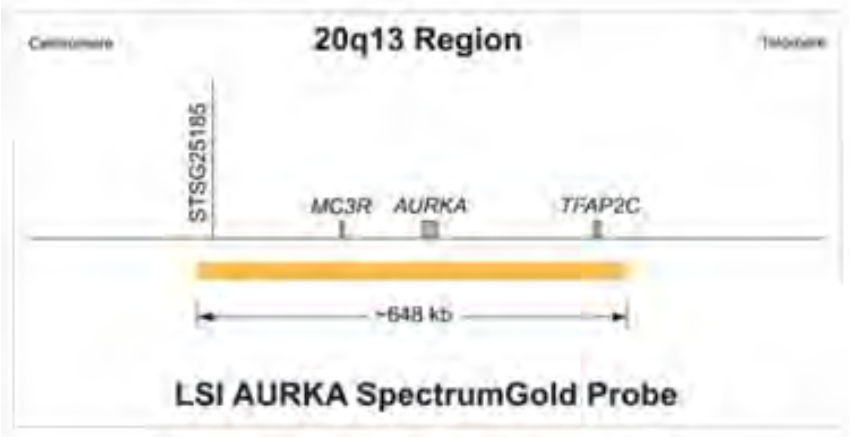
Abnormal nucleus showing the two green and one orange signal.

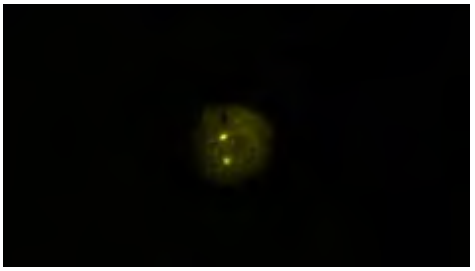
Ordering Information	Quantity	Order No.
Vysis LSI TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020

References

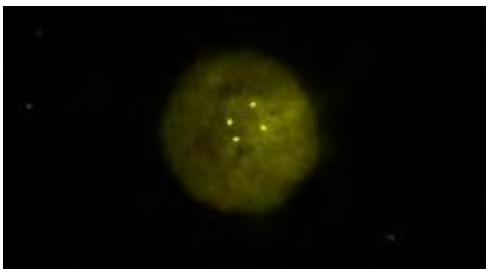
1. Shanafelt T, Geyer SM, and Kay NE. Blood. 2004;103(4):1202–10.
2. Avet-Loiseau H, Attal M, Moreau P, et al. Blood. 2007;109(8):3489–95.
3. Dewald GW, Brockman SR, Paternoster SF, et al. Br J Haematol. 2003;121:287–95.
4. Grever MR, Lucas DM, Dewald GW, et al. J Clin Oncol. 2007;25(7):799–804.
5. Fonseca R, Blood E, Rue M, et al. Blood. 2003;101(11):4569–75.
6. Wiktor AE, Van DL, Stupca PJ, et al. Genet Med. 2006;8(1):16–23

Vysis AURKA SpectrumGold FISH Probe Kit





In a nucleus with a normal copy number of the AURKA gene, two gold signals will be observed.



Abnormal copy number of the AURKA gene is indicated by more than two copies of the gold probe signal. Disregard nuclei with less than 2 copies of the gold probe signal.

The Vysis AURKA SpectrumGold FISH Probe Kit is designed to detect the copy number of Aurora Kinase A (AURKA) locus localized in chromosome 20 at the 20q13.2 band via fluorescence in situ hybridization (FISH) in human urine specimens.

The Vysis AURKA SpectrumGold FISH assay is based on the ability of the Aurora Kinase A Locus-Specific Identifier (LSI) probe to identify copy number changes of the 20q13.2 chromosomal locus using a FISH test. Experimental data suggest that inappropriately high or low levels of Aurora Kinase activity are linked to genetic instability[1] and that a high level of expression of Aurora Kinase A is often associated with amplification of the region of chromosome 20 encoding AURKA, indicating that deregulated expression of at least one gene in the amplified region provides a survival/proliferation advantage to a tumor cell and is therefore linked directly to neoplasia.[2] Over-expression of the Aurora Kinase A gene has also been shown to be associated with aneuploidy, chromosome instability and promotion of tumorigenic transformation and progression in mammalian cells and in several human tumors, including urothelial carcinoma.[3,4] AURKA amplification has been demonstrated in breast, colon, brain, bladder, head/neck and endometrium cancers, and its expression in tumors is often associated with genetic instability and poor prognosis.[2] FISH data on voided urine samples from patients with bladder cancer indicate that amplification of AURKA is frequent in bladder cancer and can be detected in urothelialcells.[5,6] Further, amplification of chromosome 20q has been associated with clinically aggressive variants of several common malignancies, including bladder cancer.[7]

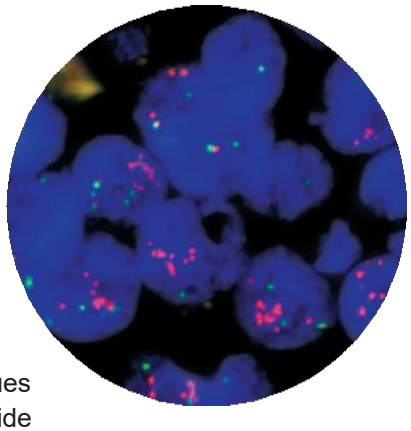
Ordering Information	Quantity	Order No.
Vysis AURKA SpectrumGold FISH Probe Kit	20 µl	05N93-020

References
1. Giet et al. (2005) Trends in Cell Biology 15: 241-50.
2. Gautschi et al. (2008) Clinical Cancer Research 14(6): 1639-1648.
3. Bischoff et al. (1998) EMBO J. 17 (11): 3052-3065.
4. Zhou et al. (1998) Nature Genetics 20 (2): 189-193.
5. Park et al. (2008) Journal of the National Cancer Institute 100:1401-1411.
6. Sen et al. (2002) Journal of the National Cancer Institute 94(17):1320-1329.
7. Knuutila et al. (1998) American Journal of Pathology 152 (5): 1107-1123.

Oncology

Breast Cancer

Advances in breast cancer testing and treatment have greatly improved patient outcomes. With DNA Fluorescence *in situ* Hybridization (FISH) probe technology, pathologists accurately and reliably detect genetic aberrations to help guide more confident diagnoses and treatment decisions. Abbott Molecular's PathVysion HER-2 DNA probe kit is among the first examples of genomic disease management, or personalized medicine. Abbott Molecular also provides directly labeled Vysis DNA probes for additional biomarkers that have been linked to breast cancer.



Abbott Molecular probe kits are built with trusted Vysis probes providing

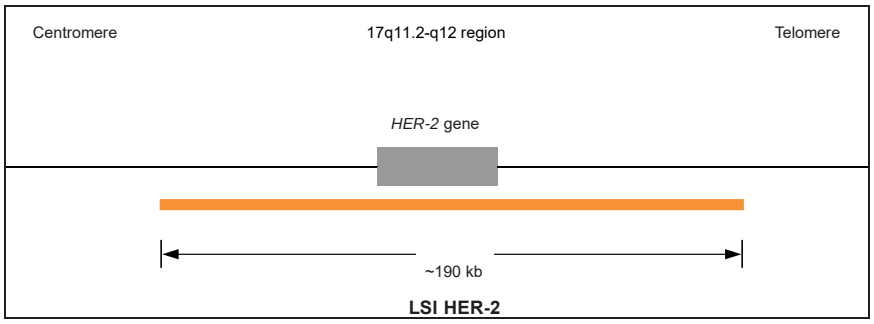
- Specific high-intensity signals without amplification and detection steps
- Low background for easy analysis
- Rapid, convenient, and easy-to-use assays
- Many probes designed for gene amplification detection include internal control probes
- Protocols that offer hybridization as quickly as four hours on the HYBrite and ThermoBrite Denaturation and Hybridization Systems
- Solid tumor probes have been optimized for paraffin-embedded tissues
- Over 10 years of reliable results for researchers and clinicians worldwide

Product description	Quantity	Order No.	Number
PathVysion HER-2 DNA Probe Kit FDA Approved	20 Assays	02J01-030	4-3
PathVysion HER-2 DNA Probe Kit FDA Approved	50 Assays	02J01-035	4-3
PathVysion HER-2 DNA Probe Kit FDA Approved	100 Assays	02J01-036	4-3
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Normal Control – FDA Approved	5 Slides	02J05-030	4-4
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Cut-Off Control – FDA Approved	5 Slides	02J04-030	4-4
Vysis CCND1/CEP11 FISH Probe Kit previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen	20 µl	03N88-020	4-5
Vysis EGFR/CEP 7 FISH Probe Kit	200 µl	01N35-020	4-6
Vysis MYC SpectrumOrange FISH Probe Kit	20 µl	03N87-020	4-7
Vysis TOP2A/CEP 17 FISH Probe Kit	200 µl	03N89-020	4-8
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit	200 µl	03N90-020	4-9
Vysis ZNF217 SpectrumGold FISH Probe Kit	20 µl	05N15-020	4-11
Vysis ZNF217 SpectrumOrange FISH Probe Kit	20 µl	03N91-020	4-11
Vysis ZNF217 SpectrumRed FISH Probe Kit	10 µl	05N16-010	4-11

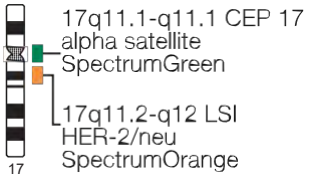
Quantities of 200 µl are prediluted with Hybridisation Buffer

PathVysion HER-2 DNA Probe Kit

FDA APPROVED



PATHVYSION®



Advances in breast cancer testing and treatment have greatly improved patient outcomes. Knowing a woman's HER-2 status is an essential component to understanding how to treat her breast cancer and potentially extend survival. The PathVysion HER-2 DNA Probe Kit is a vital tool in the fight against breast cancer. It is a precise test that provides clinicians and their patients with accurate and reliable HER-2 results.

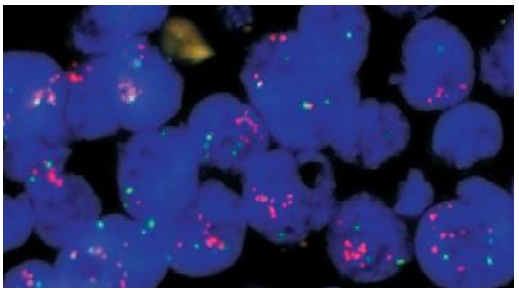
The PathVysion HER-2 DNA probe kit is among the first examples of genomic disease management, or personalized medicine. The test enables the accurate assessment of a patient's HER-2 status at the DNA level and guides doctors to make the most appropriate therapy decisions based on the patient's genetic profile.

Intended Use

The PathVysion HER-2 DNA Probe Kit (PathVysion Kit) which is FDA approved is designed to detect amplification of the HER-2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from the PathVysion Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy.

The PathVysion Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN (Trastuzumab) treatment is being considered (see HERCEPTIN package insert).

HER-2/neu, also known as c-erbB2 or HER-2, is a gene that has been shown to play a key role in the regulation of cell growth. The gene codes for a 185 kd transmembrane cell surface receptor that is a member of the tyrosine kinase family. HER-2 has been shown to be amplified in human breast, ovarian, and other cancers.



PathVysion HER-2 DNA Probe Kit hybridized to breast tissue showing multiple copies of the HER-2 gene as represented by multiple orange signals. The ratio of orange to green probe signals is greater than 2.0 indicating HER-2 amplification.

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Continuation:
PathVysion HER-2 DNA Probe Kit

Warning

The Vysis PathVysion Kit is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients. In making decisions regarding adjuvant CAF treatment, all other available clinical information should also be taken into consideration, such as tumor size, number of involved lymph nodes, and steroid receptor status.No treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu gene amplification status alone.

The PathVysion HER-2 DNA Probe Kit consists of two labeled DNA probes. The LSI HER-2 probe that spans the entire HER-2 gene is labeled in SpectrumOrange. The CEP 17 probe is labeled in SpectrumGreen and hybridizes to the alpha satellite DNA located at the centromere of chromosome 17 (17p11.1-q11.1). Inclusion of the CEP 17 probe allows for the relative copy number of the HER-2 gene to be determined.

Results of Hybridization

Results on enumeration of 20 interphase nuclei from tumor cells per target are reported as the ratio of average HER-2/neu copy number to that of CEP 17. Our clinical study found that specimens with amplification showed a LSI HER-2/neu and CEP 17 signal ratio of greater than or equal to 2.0; normal specimens showed a ratio of less than 2.0. Results at or near the cut-off point (1.8-2.2) should be interpreted with caution.

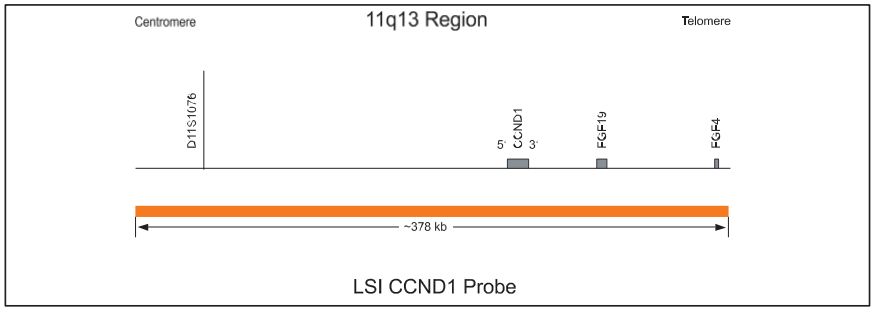
Ordering Information	Quantity	Order No.
PathVysion HER-2 DNA Probe Kit FDA Approved	20 Assay	02J01-030
PathVysion HER-2 DNA Probe Kit FDA Approved	50 Assays	02J01-035
PathVysion HER-2 DNA Probe Kit FDA Approved	100 Assays	02J01-036
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Normal Control FDA Approved	5 Slides	02J05-030
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Cut-Off Control FDA Approved	5 Slides	02J04-030

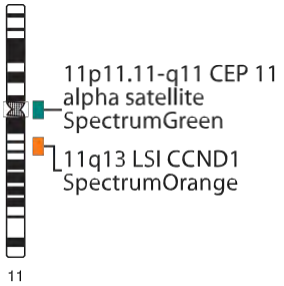
References

1. Press, et al. Clinical Cancer Research 2005; 11(18) September 15, 2005.
2. Mass, R.D. et al. Clinical Breast Cancer, 2005, 6, (3), 240-6.
3. Dybdal, N. et al. Breast Cancer Research and Treatment 2005, 93, (1), 3-11.
4. Pauletti G, et al. Oncogene 1996; 13:63-72.
5. Pauletti G, et al: J Clin Oncol 2000; 18, 21: 3651-3664.

Vysis CCND1/CEP 11 FISH Probe Kit

previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe





Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.[1, 2, 3]

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1 % of cases.[4] CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen.[5] The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al.6 found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

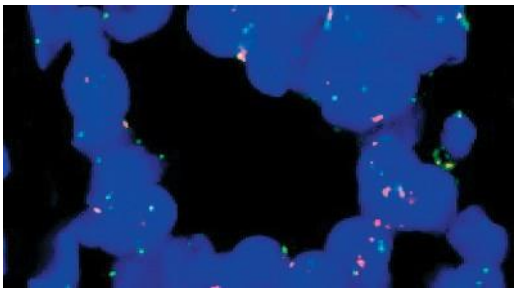
The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

Results of Hybridization

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

Ordering Information	Quantity	Order No.
Vysis CCND1/CEP11 FISH Probe Kit	20 µl	03N88-020

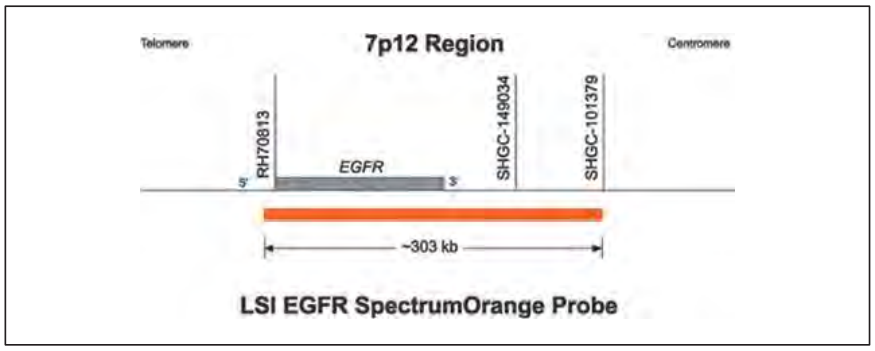


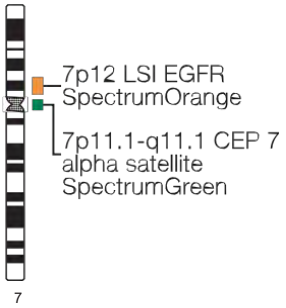
LSI Cyclin D1 SpectrumOrange and CEP 11 SpectrumGreen hybridized to abnormal tissue.

References

1. Schuuring E, Verhoeven E, Tinteren Hv et al. Cancer Research 1992;52:5229–5234.
2. Bieche I, Olivi M, Nogues C et al. P. British Journal of Cancer 20002;86:580–586.
3. Ormandy CJ, Musgrove EA, Hui R, et al. Breast Cancer Research and Treatment 2003;78:323–335.
4. Al-Kuraya K, Schraml P, Torhorst J, et al. Cancer Research 2004;64:8534–8540.
5. Jirström K, Stendahl M, Ryden L, et al. Cancer Research 2005;65(17):8009-8016.
6. Katz RL, Caraway NP, Gu J, et al. American Journal of Clinical Pathology 2000;114:248–257.
7. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genetics in Medicine 2006;8(1):16–23.

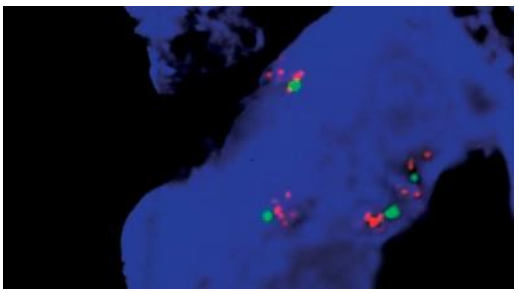
Vysis EGFR/CEP 7 FISH Probe Kit





EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC)[1] which is the leading cause of cancer death worldwide.[2]

NSCLC has a 5-year survival rate of approximately 15%.[3] There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.[1, 4]



An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange/CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

Results of Hybridization

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Simultaneously, the copy number of chromosome 7 can be quantified by enumeration of the green signals observed within the same cell. Therefore, enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.

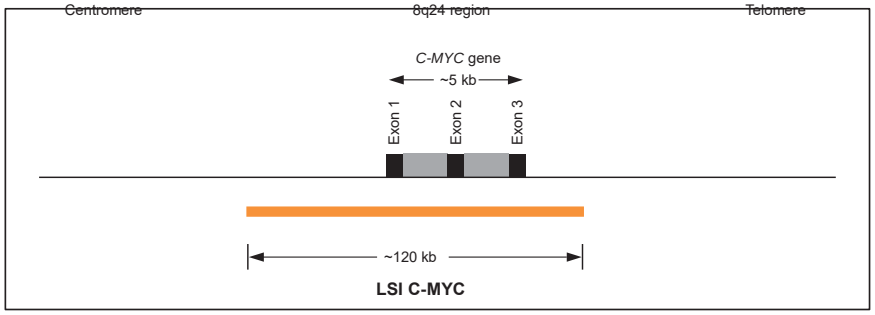
Ordering Information	Quantity	Order No.
Vysis EGFR/ CEP 7 FISH Probe Kit	200 µl*	01N35-020

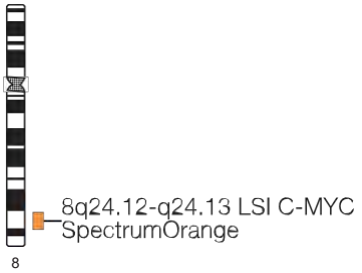
* premixed in Hybridization Buffer

References

1. Parkin MD. Global cancer statistics in the year 2000. Lancet Oncol 2001;2:533–432.
2. Jemal A, Thomas A, Murray T, et al. Cancer Statistics 2002. CA CancerJ Clin 2002;52:23–47.
3. Hirsch FR, Varella-Garcia M, Bunn PA Jr, et al. J Clin Oncol 2006;21(20):3798–807.
4. Wiktor AE, Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16–23.

Vysis MYC SpectrumOrange FISH Probe Kit

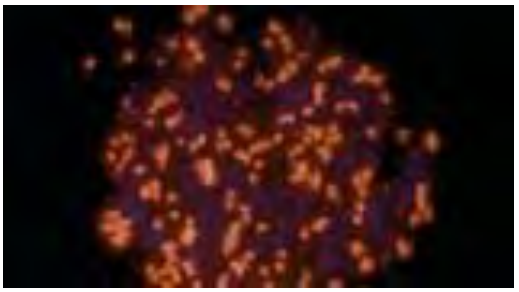




The MYC (C-MYC) oncogene has been reported to be amplified in >20% of breast carcinoma and various other malignancies and is a prognostic factor for breast cancer.1, 2, 3 FISH is a rapid and reproducible method that allows the accurate measurement of the level of oncogene amplification within interphase nuclei in human tumors.4 This probe may be used to determine the MYC copy number or as a general purpose probe for the 8q24 region.

The Vysis LSI MYC SpectrumOrange Probe was employed in a number of studies. Park et al. used the Vysis LSI MYC Probe to investigate co-amplification of the MYC and HER2 genes in 214 consecutive breast cancers.5 For detecting lung cancer, Sokolava et al. compared a FISH-based assay, that included Vysis LSI MYC, to conventional cytology in 74 bronchial washing specimens, and achieved significantly higher sensitivity with the FISH assay (82% vers. 54%).6 In a recent study, Rygiel et al. used the Vysis LSI MYC (8q24.12-q24.13) SpectrumOrange Probe to evaluate amplification of MYC as a diagnostic marker to identify patients with Barrett's esophagus with high-grade dysplasia or esophageal adenocarcinoma.7

The LSI C-MYC (8q24.12-q24.13) Probe is an approximately 120 kb SpectrumOrange labeled probe.



LSI C-MYC Probe hybridized to an abnormal cell. Multiple orange signals contained within the cell indicate amplification of the C-MYC locus.

Results of Hybridization

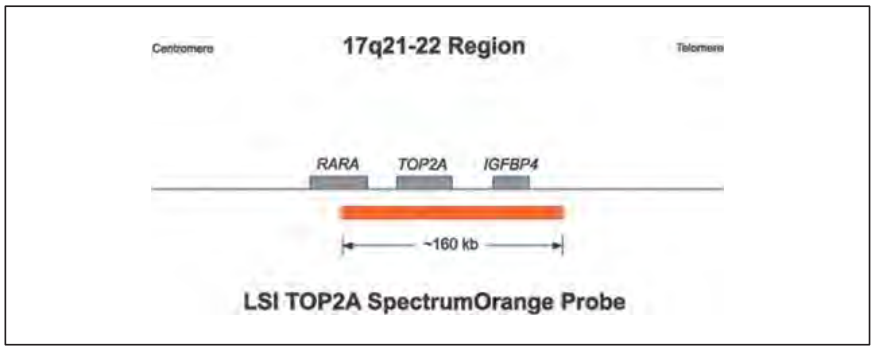
In a cell with amplification of the C-MYC locus, multiple copies of the orange signal may be seen when hybridized with the C-MYC probe.

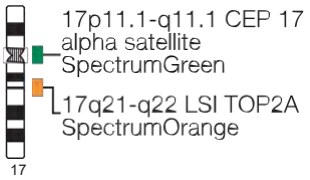
Ordering Information	Quantity	Order No.
Vysis MYC SpectrumOrange FISH Probe Kit	20 µl	03N87-020

References

1. Deming SL, Nass SJ, Dickson RB et al. C-myc amplification in breast cancer: a meta-analysis of its occurence and prognostic relevance. British Journal of Cancer 2000;83(12):1688-1695.
2. Nesbit CE, Tersak JM, and Prochownik EV. MYC oncogenes and human neoplastic disease. Oncogene 1999;18:3004-3016.
3. Schlotter CM, Vogt U, Bosse U, et al. C-myc, not HER-2/ neu, can predict recurrence and mortality of patients with node-negative breast cancer. Breast Cancer Research 2003;5(2):30-36.
4. Persons DL, Borelli KA, Hsu PH. Quantitation of HER-2/neu and c-myc gene amplification in breast carcinoma using fluorescence in situ hybridization. Modern Pathology 1997;10(7):720-727.
5. Park K, Kwak K, Kim J, et al. c-myc amplification is associated with HER2 amplification and closely linked with cell proliferation in tissue miroarray of nonselected breast cancers. Human Pathology 2005;36:634-639.
6. Sokolova IA, Bubendorf L, O'Hare A, et al. A Fluorescence In Situ Hybridization-Based Assay for Improved Detection of Lung Cancer Cells in Bronchial Washing Specimens. Cancer Cytopathology 2002;96(5):307-315.
7. Rygiel AM, Milano F, ten Kate FJ et al. Gains and Amplifications of c-myc, EGFR, and 20.q13 Loci in the No Dysplasia-Dysplasia-Adenocarcinoma Sequence of Barrett's Esophagus. Cancer Epidemiology, Biomarkers & Prevention 2008;17(6)1380-1385.
8. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genetics in Medicine 2006;8(1):16-23.

Vysis TOP2A/CEP 17 FISH Probe Kit





The TOP2A gene, located at 17q21-q22, encodes topoisomerase II- a key enzyme in DNA replication, cell cycle progression, and chromosome segregations. As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors. The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors. The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. This probe set is premixed in Hybridization Buffer.

LSI TOP2A is a single ~160kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene and is directly labeled with SpectrumOrange. The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen.

In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

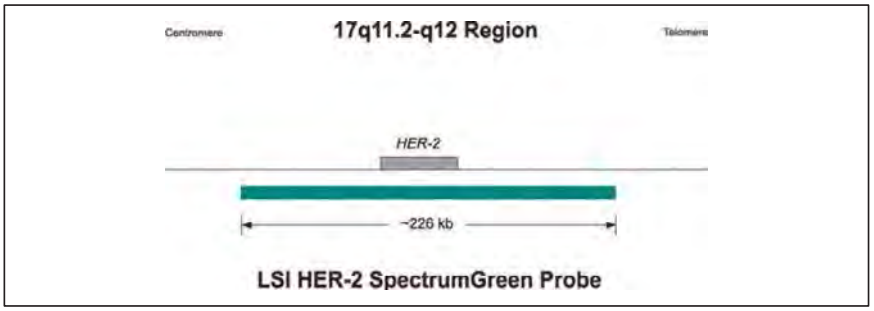
Ordering Information	Quantity	Order No.
Vysis TOP2A/CEP 17 FISH Probe Kit	200 µl*	03N89-020

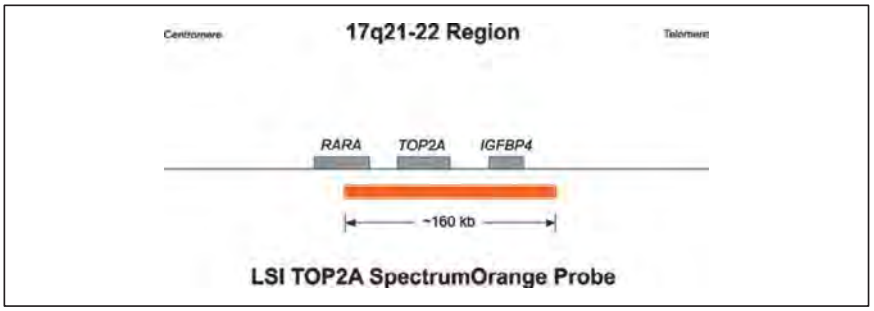
* premixed in Hybridization Buffer

References

1. Tsai-Pflugfelder M, et al. Proceedings of the National Academy of Sciences 1988;85(19):7177-7181.
2. Chen AY, Liu LF. Annu Rev Pharmacol Toxicol 1994;34:191-218.
3. Capranico G, et al. Biochemistry 1990;29(2):562-569.
4. Arriola E, et al. Breast Cancer Research Treatment 2007;106:181-189.
5. Nielsen KV, et al. Acta Oncologica 2008;4(47):725-734.
6. Smith K, et al. Oncogene 1993;8(4):933-938.
7. Beser AR, et al. Pathology Oncology Research 2007;13(3):180-185.
8. Hicks DG, et al. Human Pathology 2005;36:348-356.
9. Wiktor AE, et al. Genetics in Medicine 2006;8(1):16-23.

Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit





The TOP2A gene, located at 17q21-q22 encodes topoisomerase II-α, a key enzyme in DNA replication, cell cycle progression, and chromosome segregation.[1, 2] As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors.[3] The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors.[4, 5] The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. The TOP2A gene has also been shown to be co-amplified with HER-2 in cell lines and in human breast cancers.[6]

The Vysis Locus Specific Identifier (LSI) TOP2A SpectrumOrange/HER-2 SpectrumGreen/CEP17 SpectrumAqua Probe Set utilizes locus specific probes for TOP2A and HER-2 as well as chromosome 17 centromeric probe. Each probe is labeled with a different fluorophore to allow accurate enumeration of each locus within individual nuclei. Simultaneous enumeration of all three probes reveals the copy number gains or losses of HER-2 and TOP2A relative to the copy number of chromosome 17. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi color probe.

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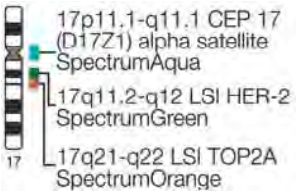
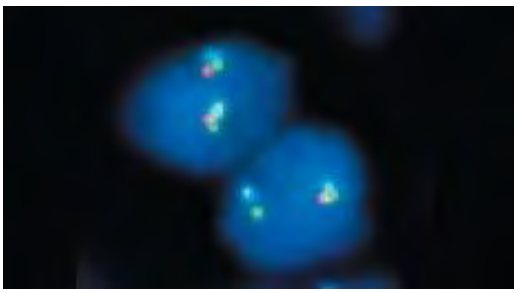
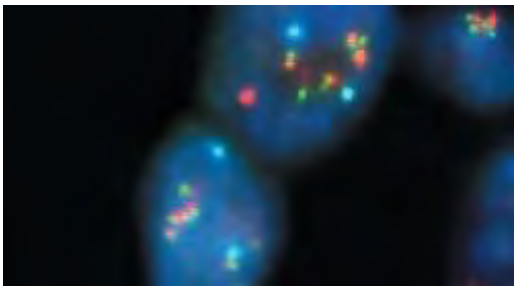




Result of the hybridization of the LSI TOP2A/HER-2/CEP 17 Multi-color Probe as observed in two normal interphase cells. In the nucleus located in the upper left, two copies of each of the three probes are observed: orange (TOP2A), green (HER-2), and aqua (CEP 17). The lower right nucleus exhibits normal hybridization results for LSI HER-2 and CEP 17 but is lacking one TOP2A signal.



Tumor cells hybridized with the LSI TOP2A/HER-2/CEP 17 Multi-color probe. The cells in this image show amplification of both TOP2A (orange signals) and HER-2 (green signals) as indicated by multiple signals of each color. Aqua signals from the CEP 17 probe indicate that chromosome 17 is present in the normal quantity (two copies).

Continuation:
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit

TOP2A and HER-2 gene status is of interest since topoisomerase II-α is a molecular target of anthracycline drugs and HER-2 is targeted by several small molecule tyrosine kinase inhibitors as well as antibodies against the HER-2 receptor protein. Beser et al. used the Vysis TOP2A/HER-2/CEP17 FISH Probe Kit to examine the frequency of TOP2A amplification and deletion relative to the HER-2 gene status and chromosome 17 aneusomy in a series of 50 breast tumors.[7] Hicks et al. used the same probe set to similarly document the relationship between TOP2A and HER-2 genomic alterations and chromosome 17 aneusomy in 138 breast cancers.[8]

LSI TOP2A is a single ~160 kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene. In both products, the probe is directly labeled with SpectrumOrange. The HER-2 probe that spans the entire HER-2 gene at 17q11.2-q12 is an an ~190 kb unique sequence probe. In the LSI TOP2A/HER-2/CEP 17 product, this probe is directly labeled with SpectrumGreen. The The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen or SpectrumAqua SpectrumAqua in the LSI TOP2A/CEP 17 and LSI TOP2A/HER-2/CEP 17 products, respectively.

Results of Hybridization
As with TOP2A and chromosome 17, a nucleus with a normal quantity (two copies) of HER-2 will appear with two green signals. Simultaneous enumeration of all three probes will reveal the copy number of each as well well as the amplification or deletion status of TOP2A and HER-2 relative to chromosome 17 copy number. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

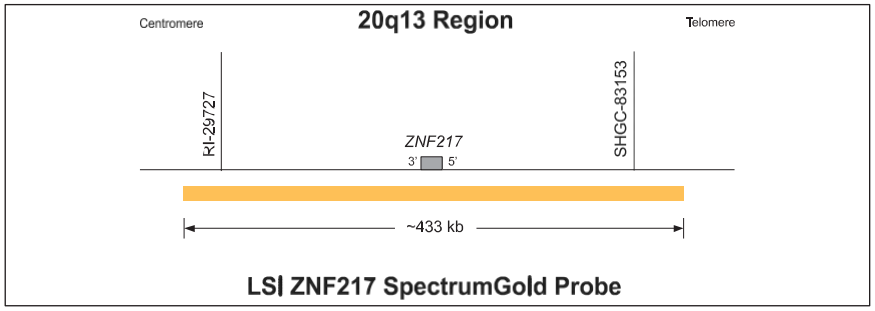
Ordering Information	Quantity	Order No.
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit	200 µl*	03N90-020

* premixed in Hybridization Buffer

References

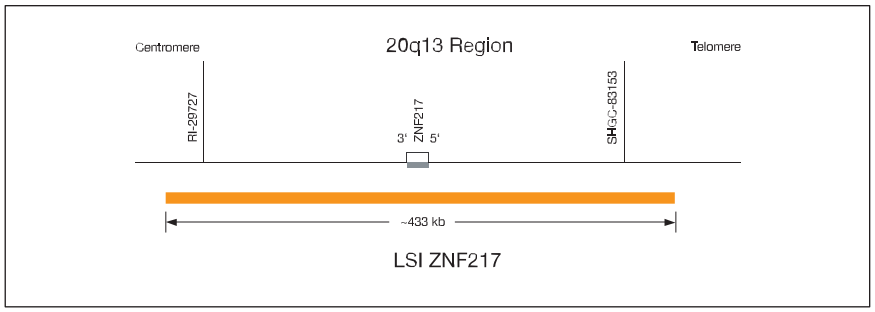
1. Tsai-Pflugfelder M, Liu LF, Liu AA, et al. Cloning and sequencing of cDNA topoisomerase II and localization of the gene to chromosome region 17q21-22. Proceedings of the National Academy of Sciences 1988;85(19):7177-7181.
2. Chen AY, Liu LF. DNA topoisomerases: essential enzymes and lethal targets. Annu Rev Pharmacol Toxicol 1994;34:191-218.
3. Capranico G, Zunino F, Kohn KW, et al. Sequence-selective topoisomerase II inhibition by anthracycline derivatives inSV40 DNA: relationship with DNA binding affinity and cytotoxicity. Biochemistry 1990;29(2):562-569.
4. Arriola E, Socorro MR, Lambros MBK, et al. Topoisomerase II alpha amplification may predict benefit from adjuvant anthracyclines in HER2 positive early breast cancer. Breast Cancer Research Treatment 2007;106:181-189.
5. Nielsen KV, Ejlertsen B, Moller S, et al. The value of TOP2A gene copy number variation as a biomarker in breast cancer: Update of DBCG trial 89D. Acta Oncologica 2008;4(47):725-734.
6. Smith K, Houlbrook S, Greenall M, et al. Topoisomerase II alpha co-amplification with erbB2 in human primary breast cancer and breast cancer cell lines: relationship to m-AMSA and mitoxantrone sensitivity. Oncogene 1993;8(4):933-938.
7. Beser AR, Tuzlali S, Guzey D, et al. HER-2, TOP2A and chromosome 17 alterations in breast cancer. Pathology Oncology Research 2007;13(3):180-185.
8. Hicks DG, Yoder BJ, Pettay J, et al. The incidence of topoisomerase II-alpha genomic alterations in adenocarcinoma of the breast and their relationship to human epidermal growth factor receptor-2 gene amplification: a fluorescence in situ hybridization study. Human Pathology 2005;36:348-356.
9. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genetics in Medicine 2006;8(1):16-23.

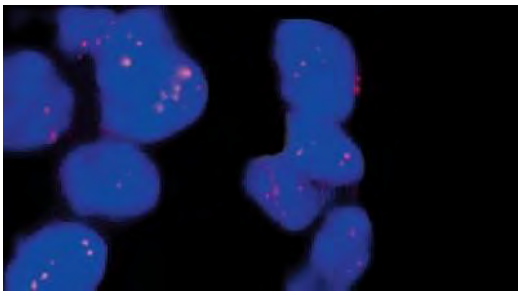
Vysis ZNF217 SpectrumGold FISH Probe Kit



Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumGold FISH Probe Kit	20 µl	05N15-020

Vysis ZNF217 SpectrumOrange FISH Probe Kit

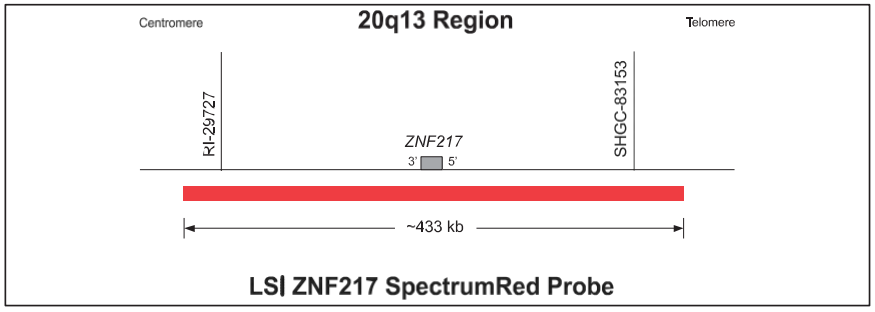




LSI ZNF217 (20q13.2) SpectrumOrange hybridized to abnormal cells. Note multiple orange-pink signals contained within some cells indicate amplification of the ZNF217.

Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumOrange FISH Probe Kit **CE marked**	20 µl	03N91-020

Vysis ZNF217 SpectrumRed FISH Probe Kit



Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumRed FISH Probe Kit	10 µl	05N16-010

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Continuation:
Vysis ZNF217 SpectrumGold, SpectrumOrange & SpectrumRed FISH Probe Kit

The ZNF217 gene is a candidate oncogene suggested to play a key role during neoplastic transformation. ZNF217 is located at 20q13, a region that is frequently amplified in a variety of tumor types.[1–6] Amplification of ZNF217 in breast cancer is associated with aggressive tumor behaviour and poor clinical prognosis.[7]

The Vysis LSI ZNF217 (20q13.2) SpectrumOrange Probe was used in a study that indicated distinct differences in the role of genes known to be amplified in female breast cancer and their relevance for the pathogenesis of male breast cancer. In another study, fluorescence in situ hybridization was performed on 128 male breast tumors using the Vysis SpectrumOrange LSI ZNF217 in addition to other Vysis probes including, LSI HER-2, LSI CCND1, LSI MYC, and the corresponding centromeric probes to evaluate the frequencey of amplification of the genes in MBC.[8] A third study used the Vysis LSI ZNF217 SpectrumOrange** Probe to identify gain of ZNF217 as an important abnormality and prognostic factor in larynx tumorigenesis. For this study a tissue microarray consisting of 863 larynx carcinomas was analysed.[9]

The LSI ZNF217 SpectrumGold and SpectrumRed Probes are single approximatelly 433 kb unique sequence probes directly labeled in SpectrumGold or SpectrumRed and hybridize to the 20q13.2 region of Chromosome 20 and include the 17.5 kb ZNF217 gene.

** Vysis LSI ZNF217 SpectrumOrange was used in studies, which are referenced here. Vysis LSI ZNF217 SpectrumGold Probe and SpectrumRed hybridzes t the same sequence as the Vysis LSI ZNF217 SpectrumOrange Probe, but labeled with another Fluorophore.

Results of Hybridization

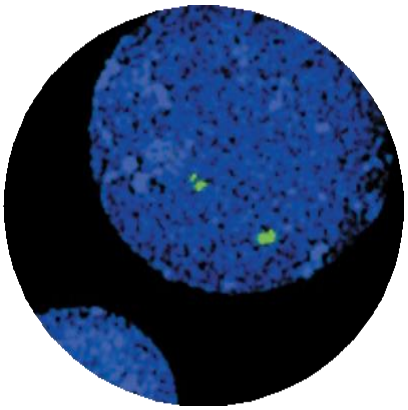
When hybridized with the LSI ZNF217 Probe, a normal cell containing two copies of the 20q13.2 region will exhibit two signals. In a cell harboring amplification of the ZNF217 gene or 20q13.2 region, multiple copies of the gold, orange or red signal will be observed.

References
1. Collins C, Rommens JM, Kowbel D, et al. Proceedings of the National Academy of Sciences USA 1998;95:8703-8708.
2. Yang SH, Seo MY, Jeong HJ, et al. Clinical Cancer Research 2005;11:612-620.
3. Iwabuchi H, Sakamoto M, Sakunaga H, et al. Cancer Research 1995;55(24):6172-6180.
4. Zhu H, Lam DC, Han KC, et al. et al. Cancer Letters 2007;245:303-314.
5. Bar-Shira A, Pinthus JH, Rozovsky U, et al. Cancer Research 2002;62(23):6803-6807.
6. Lassmann S, Weis R, Markowiec F, et al. Journal of Molecular Medicine 2007;85(3):293-304.
7. Tanner MM, Tirkkonen M, Kallioniemi A, et al. Clinical Cancer Research 1995;1:1455-1461.
8. Bärlund M, Kuukasjärvi T, Syrjäkoski K, et al. International Journal of Cancer 2004;111:968-971.
9. Koynova D, Tsenova V, Kunev K, et al. Biotechnology & Biotechnological Equipment 2006;128-131.
10. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genetics in Medicine 2006;8(1):16-23.

Oncology

Solid Tumor Probes

Accurate and reliable detection of genetic aberrations in solid tumors with DNA fluorescence *in situ* Hybridization (FISH) probe technology is a powerful means to guide more confident diagnoses and treatment decisions. Abbott Molecular offers a comprehensive line of direct labeled Vysis DNA probes for solid tumor assessment. Single- and multi-color probe sets offer researchers and clinicians a variety of ways to identify chromosome or locus deletions, gains, or translocations that have been associated with specific types of solid tumors. These probes can be applied to a variety of sample types prepared for metaphase or interphase analysis.



Vysis FISH technology for oncology, cytology, and pathology provides the following advantages:

- Specific high-intensity signals with direct-labelled probes
- Low background for easy analysis
- Rapid, convenient, and easy-to-use assays
- Many probes designed for gene amplification detection include internal control probes
- Protocols that offer hybridization as quickly as four hours on the HYBrite and ThermoBrite Denaturation and Hybridization System
- Solid tumor probes have been optimized for paraffin-embedded tissues

Alphabetical Listing

Product description	Quantity	Order No.	Number
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020	5-6
Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit	2 x 200 µl	04N60-020	5-7
Vysis LSI 22 (BCR) SpectrumGreen Probe	20 µl	05J17-024	5-9
Vysis LSI ALK Break Apart Rearrangement Probe Kit IVD	200 µl	06N38-033	5-10
Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe	20 µl	05J44-011	5-11
Vysis LSI BRAF SpectrumGold FISH Probe Kit	20 µl	06N09-020	5-12
Vysis CCND1/CEP 11 FISH Probe Kit previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe	20 µl	03N88-020	5-13
Vysis CDKN2A/CEP 9 FISH Probe Kit previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe	20 µl	04N61-020	5-14
Vysis DDIT3 Break Apart FISH Probe Kit previously: Vysis LSI CHOP (12q13) Dual Color, Break Apart Rearrangement Probe	20 µl	03N57-020	5-15
Vysis LSI D5S23, D5S721 SpectrumGreen Probe	20 µl	04N30-020	5-16
Vysis LSI EGFR SpectrumRed Probe	20 µl	04N31-020	5-17
Vysis EGFR/CEP7 FISH Probe Kit	200 µl	01N35-020	5-17
Vysis EWSR1 Break Apart FISH Probe Kit	20 µl	03N59-020	5-18
Vysis FGFR1 SpectrumRed Probe	20 test	08N21-020	5-47
Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH	20 µl	08N21-060	5-19
Vysis 10q26 FGFR2 Break Apart FISH Probe	20 µl	09N23-060	5-20
Vysis 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit	20 µl	08N42-060	5-21
Vysis FOXO1 Break Apart FISH Probe Kit previously: Vysis LSI FKHR (13q14) Dual Color, Break Apart Rearrangement Probe	20 µl	03N60-020	5-22
Vysis FUS Break Apart FISH Probe Kit	20 µl	03N58-020	5-23
Vysis LSI LPL SpectrumOrange Probe	20 µl	04N34-020	5-24
Vysis LSI MDM2 / CEP 12 FISH Probe Kit	10 µl	01N15-010	5-27
Vysis LSI MDM2 SpectrumOrange Probe	20 µl	01N15-020	5-28
Vysis Melanoma FISH Probe Kit	200 µl	01N89-020	5-24
Vysis LSI MET SpectrumRed FISH Probe Kit	20 µl	06N05-020	5-26
Vysis LSI MYC SpectrumGold Probe	20 µl	04N35-020	5-29
Vysis LSI MYC SpectrumGreen Probe	20 µl	04N36-020	5-29
Vysis MYC SpectrumOrange FISH Probe Kit	20 µl	03N87-020	5-30
Vysis LSI N-MYC (2p24) SpectrumGreen/CEP 2 SpectrumOrange Probe	20 µl	07J72-001	5-31
Vysis LSI N-MYC (2p24) SpectrumOrange Probe	20 µl	05J50-001	5-32
Vysis LSI 1q23 NTRK1 Break Apart FISH Probe	20 µl	08N43-60	5-33
Vysis LSI PIK3CA SpectrumGreen FISH Probe Kit	20 µl	06N10-020	5-34
Vysis ProbeChek ALK Negative Control Slides IVD	5 slides	06N38-005	5-10
Vysis ProbeChek ALK Positive Control Slides IVD	5 slides	06N38-010	5-10
Vysis PTEN/CEP 10 FISH Probe Kit	20 µl	04N62-020	5-35
Vysis LSI RET Probe (Cen) SpectrumGreen	20 µl	08N31-040	5-48
Vysis LSI RET Probe (Tel) SpectrumRed	20 µl	08N31-020	5-48
Vysis LSI RET Probe (Tel) SpectrumOrange	20 µl	08N31-030	5-48
Vysis 10q11.21 RET Break Apart FISH Probe	20 µl	08N31-060	5-36
Vysis LSI ROS1 (Tel) SpectrumOrange and	20 µl	08N05-020	5-46
Vysis LSI ROS1 (Cen) Spectrum Green Probe	20 µl	08N07-020	5-46
Vysis 6q22 ROS1 Break Apart FISH Probe	20 µl	08N29-020	5-37
Vysis LSI SS18 Break Apart FISH Probe Kit previously: Vysis LSI SYT (18q11.2) Dual Color, Break Apart Rearrangement Probe	20 µl	03N61-020	5-38
Vysis LSI TERC SpectrumGold Probe	20 µl	02N11-030	5-39
Vysis TOP2A/CEP 17 FISH Probe Kit	200 µl	03N89-020	5-39
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit	200 µl	03N90-020	5-40
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	5-42
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	5-43

Vysis ZNF217 SpectrumGold FISH Probe Kit	20 µl	05N15-020	5-44
Vysis ZNF217 SpectrumOrange FISH Probe Kit	20 µl	03N91-020	5-44
Vysis ZNF217 SpectrumRed FISH Probe Kit	10 µl	05N16-010	5-44

Quantities of 200 µl are prediluted with Hybridisation Buffer

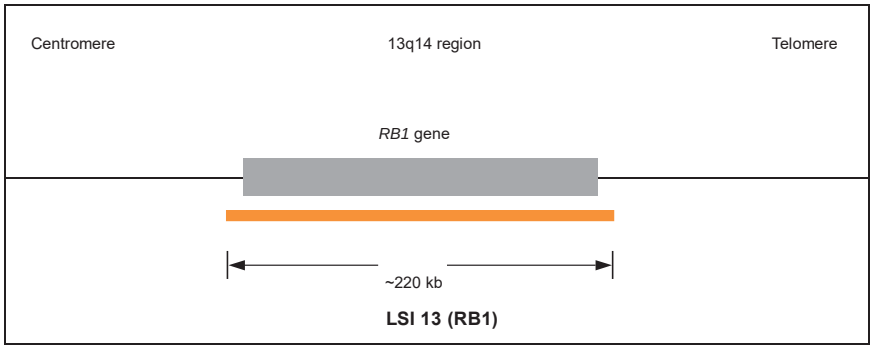
Listing By Disease State

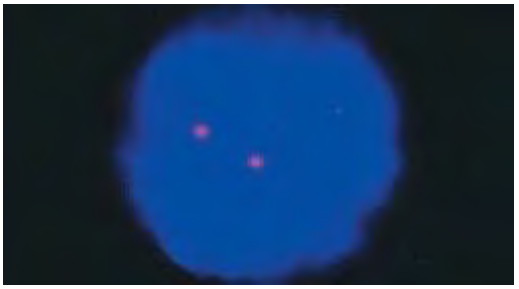
Product description	Quantity	Order No.	Page Number
Gliomas			
Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit	2 x 200 µl	04N60-020	5-7
Vysis CDKN2A/CEP 9 FISH Probe Kit previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe	20 µl	04N61-020	5-14
Vysis EGFR/CEP7 FISH Probe Kit	200 µl	01N35-020	5-17
Vysis PTEN/CEP 10 FISH Probe Kit	20 µl	04N62-020	5-35
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	5-42
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	5-43
Lung Cancer			
Vysis EGFR/CEP7 FISH Probe Kit	200 µl	01N35-020	5-17
Vysis FGFR1 SpectrumRed Probe	20 test	08N21-020	5-47
Vysis 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit	20 µl	08N42-060	5-21
Vysis LSI ALK Break Apart Rearrangement Probe Kit IVD	200 µl	06N38-020	5-10
Vysis ProbeChek ALK Negative Control Slides IVD	5 slides	06N38-005	5-10
Vysis ProbeChek ALK Positive Control Slides IVD	5 slides	06N38-010	5-10
Vysis LSI BRAF SpectrumGold FISH Probe Kit	20 µl	06N09-020	5-12
Vysis LSI MET SpectrumRed FISH Probe Kit	20 µl	06N05-020	5-26
Vysis 1q23 NTRK1 Break Apart FISH Probe	20 µl	08N43-060	5-33
Vysis LSI PIK3CA SpectrumGreen FISH Probe Kit	20 µl	06N10-020	5-34
Vysis LSI RET Probe (Cen) SpectrumGreen	20 µl	08N31-040	5-48
Vysis LSI RET Probe (Tel) SpectrumRed	20 µl	08N31-020	5-48
Vysis LSI RET Probe (Tel) SpectrumOrange	20 µl	08N31-030	5-48
Vysis LSI ROS1 (Tel) SpectrumOrange and	20 µl	08N05-020	5-46
Vysis LSI ROS1 (Cen) Spectrum Green Probe	20 µl	08N07-020	5-46
Melanoma			
Vysis Melanoma FISH Probe Kit	200 µl	01N89-020	5-24
Prostate Cancer			
Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe	20 µl	05J44-011	5-11
Vysis MYC SpectrumOrange FISH Probe Kit	20 µl	03N87-020	5-30
Sarcomas			
Vysis DDIT3 Break Apart FISH Probe Kit previously: Vysis LSI CHOP (12q13) Dual Color, Break Apart Rearrangement Probe	20 µl	03N57-020	5-15
Vysis EWSR1 Break Apart FISH Probe Kit	20 µl	03N59-020	5-18
Vysis FOXO1 Break Apart FISH Probe Kit previously: Vysis LSI FKHR (13q14) Dual Color, Break Apart Rearrangement Probe	20 µl	03N60-020	5-22
Vysis FUS Break Apart FISH Probe Kit	20 µl	03N58-020	5-23
Vysis LSI SS18 Break Apart FISH Probe Kit previously: Vysis LSI SYT (18q11.2) Dual Color, Break Apart Rearrangement Probe	20 µl	03N61-020	5-38
Other Cancers			
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020	5-6
Vysis LSI 22 (BCR) SpectrumGreen Probe	20 µl	05J17-024	5-9
Vysis CCND1/CEP 11 FISH Probe Kit previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe	20 µl	03N88-020	5-13
Vysis LSI D5S23, D5S721 SpectrumGreen Probe	20 µl	04N30-020	5-16
Vysis EGFR/CEP7 FISH Probe Kit	200 µl	01N35-020	5-17
Vysis LSI EGFR SpectrumRed Probe	20 µl	04N31-020	5-17
Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH	20 µl	08N21-060	5-19
Vysis 10q26 FGFR2 Break Apart FISH Probe	20 µl	09N23-060	5-20
Vysis LSI LPL SpectrumOrange Probe	20 µl	04N34-020	5-24

Vysis LSI MDM2 / CEP 12 FISH Probe Kit	20 µl	01N15-010	5-27
Vysis LSI MDM2 SpectrumOrange Probe	20 µl	01N15-020	5-28
Vysis MYC SpectrumOrange FISH Probe Kit	20 µl	03N87-020	5-30
Vysis 10q11.21 RET Break Apart FISH Probe	20 µl	08N31-060	5-36
Vysis 6q22 ROS1 Break Apart FISH Probe	20 µl	08N29-020	5-37
Vysis LSI TERC SpectrumGold Probe	20 µl	02N11-030	5-39
Vysis TOP2A/CEP 17 FISH Probe Kit	200 µl	03N89-020	5-39
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit	200 µl	03N90-020	5-40
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	5-42
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	5-43
Vysis ZNF217 SpectrumGold FISH Probe Kit	20 µl	05N15-020	5-44
Vysis ZNF217 SpectrumOrange FISH Probe Kit	20 µl	03N91-020	5-44
Vysis ZNF217 SpectrumRed FISH Probe Kit	10 µl	05N16-010	5-44

Quantities of 200 µl are prediluted with Hybridisation Buffer

Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe





LSI 13 (RB1) 13q14 Probe hybridized to a normal nucleus showing a two orange (2O) signal pattern.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene.

Results of Hybridization

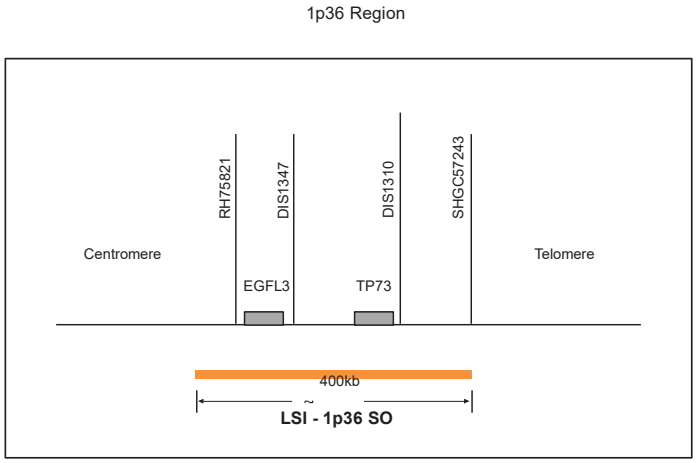
In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

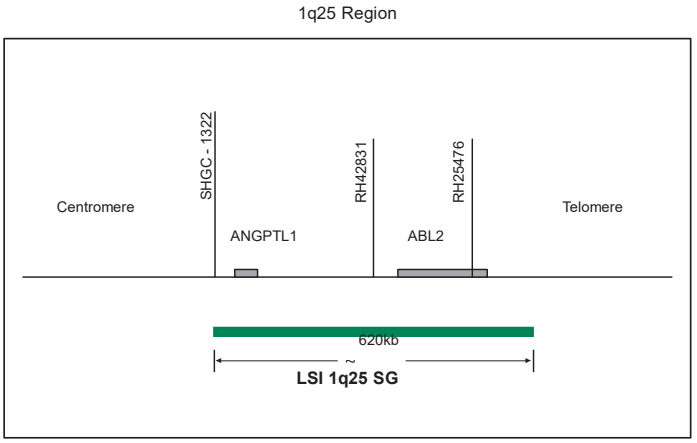
Ordering Information	Quantity	Order No.
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020

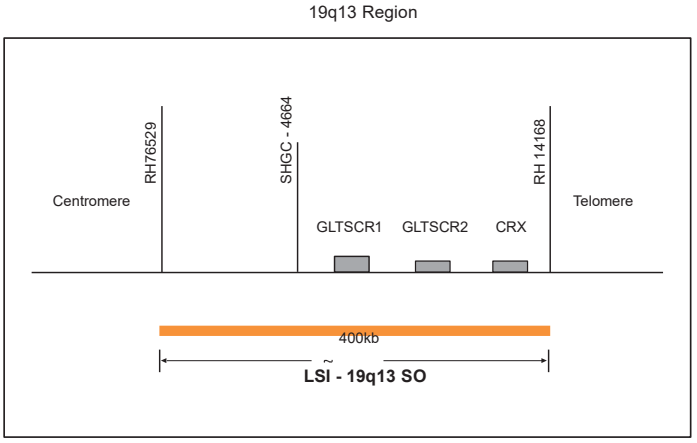
References

1. Heim, S., et al. Cancer Cytogenetics 2nd ed. (1995): 377.

Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit







Diffuse gliomas of the central nervous system are classified based on their histological appearance as astrocytomas, oli- godendrogliomas and mixed oligoastrocytomas. Fluorescence in situ hybridization using 1p36 and 19q13 LSI FISH probes showed that the oligodendroglial phenotype was also associated with the 1p deletion and that allelic loss of 1p was a powerful predictor of chemotherapeutic response. Combined 1p36-19q13 deletions were highly associated with classic oligodendroglioma histology and a longer survival rate.[1–5]

The Vysis LSI 1p36/1q25 and 19q13/19p13 probes performed successfully in several studies to detect losses in 1p36 and 19q13.6-7 FISH testing using this probe set in an analysis of 81 histologically confirmed patient samples (glial tumors, WHO grade I-IV) supported previous study findings that loss of 1p36 and 19q13 is highly correlated with tumors with oligodendroglial component.[6] Wharton et al. detected 1p and 19q deletions in the majority of samples graded as oligodendrogliomas, WHO grade II and III.[7]

These and other studies established FISH analysis using LSI 1p36/LSI 19q13 as a useful tool to complement morphological diagnosis of malignant tumors with a oligodendroglial component.

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Continuation:
Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit

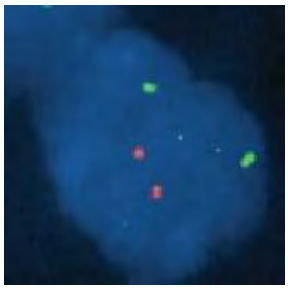
The Vysis LSI 1p36 SpectrumOrange/1q25 SpectrumGreen Probes are provided in one vial as a mixture of a ~435 kb SpectrumOrange-labeled 1p36 probe and a ~618 kb SpectrumGreen-labeled 1q25 probe premixed in hybridization buffer. The LSI 1p36 probe contains sequences that extend from near SHGC 57243 locus, through the TP73 and MEGF6 genes, and ends at a point telomeric to the MEGF6 locus. The LSI 1q25 probe contains sequences that extend from a point telomeric to the ABL2 gene, through the ABL2 and ANGPTL1 genes, and ends proximally near the SHGC-1322 locus.

The Vysis LSI 19q13 SpectrumOrange/19p13 SpectrumGreen Probes are provided in one vial as a mixture of a ~380 kb SpectrumOrange-labeled 19q13 probe and a ~502 kb SpectrumGreen-labeled 19p13 probe premixed in hybridization buffer. The LSI 19p13 probe contains sequences that extend from a point centromeric to the MAN2B1 locus, through MAN2B1, ZNF443 and ZNF44 genes, and ends at a point telomeric to the ZNF44 locus. The LSI 19q13 probe contains sequences that extend from a point telomeric to the CRX locus, through the CRX, GLTSCR2 and GLTSCR1 genes, and ends proximally at a point centromeric to the GLTSCR1 locus.

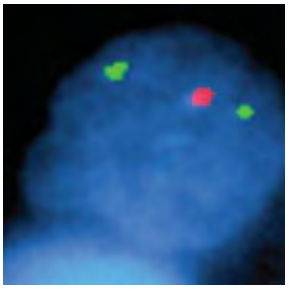
Results of Hybridization
As indicated above, this product contains two vials containing dual color probes. A description of the hybridization results expected with each probe probe set follows below:

Vial 1
This probe allows status assessment of the following two chromosome regions: 1p36 and 1q25. In a normal cell hybridized with the LSI 1p36 and LSI 1q25, two orange and two green signals will be observed indicative of two intact copies of chromosome 1. In an abnormal cell with a deletion in the 1p36 region fewer than two orange signals will be observed.

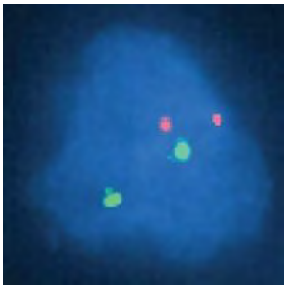
Vial 2
This probe allows status assessment of the following two chromosome regions: 19q13 and 19p13. In a normal cell with two intact copies of chromosome 19, two orange and two green signals will be observed. In an an abnormal cell with a deletion in the 19q13 region fewer than two orange orange signals will be observed.



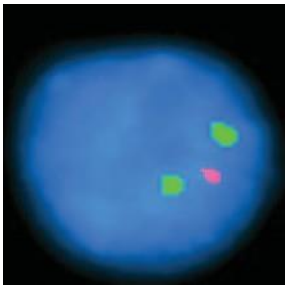
Result of the hybridization of the 1p36/1q25 FISH Probe Kit vial 1 as observed in normal interphase cells.



An abnormal cell hybridized with the 1p36/1q25 FISH Probe Kit vial 1. The cell in this image shows the one orange, two green signal pattern indicative of the 1p36 deletion.



Result of the hybridization of the 19p13/19q13 FISH Probe Kit vial 2 as observed in normal interphase cells.



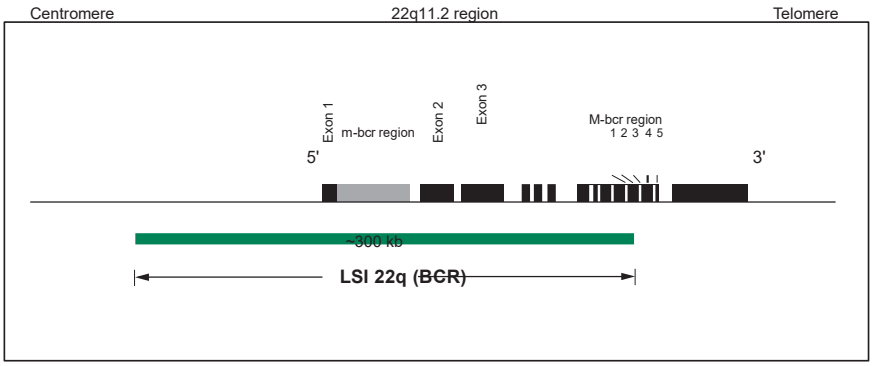
An abnormal cell hybridized with the19p13/19q13 FISH Probe Kit vial 2. The cell in this image shows the one orange, two green signal pattern indicative of the 19q13 deletion.

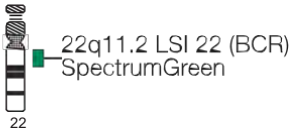
Ordering Information	Quantitiy	Order No.
Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit	2x 200 µl*	04N60-020

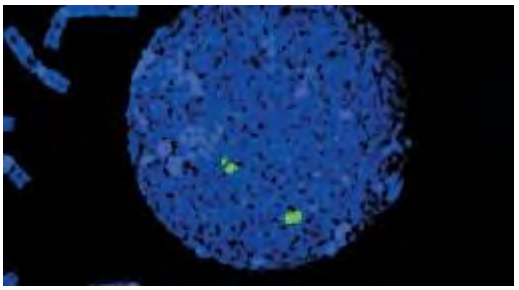
*premixed in Hybridizaton Buffer

References
1. Cairncross J et al. (1998) J. of the National Cancer Institute 90(19): 1473-1479.
2. Smith J et al. (1999) Oncogene 18: 4144-4152
3. Ino Y et al. (2001) Clinical Cancer Research 7: 839-845.
4. Perry A et al. (2003) Frontiers in Bioscience 8: 1-9.
5. Buckner J et al. (2003) J of Clinical Oncology 21 (2): 251-255.

Vysis LSI 22 (BCR) SpectrumGreen Probe







LSI 22 (BCR) SpectrumGreen hybridized to a normal interphase cell.

The LSI 22 (BCR) Probe is an approximately 300 kb SpectrumGreen probe corresponding to 22q11.2.

Results of Hybridization

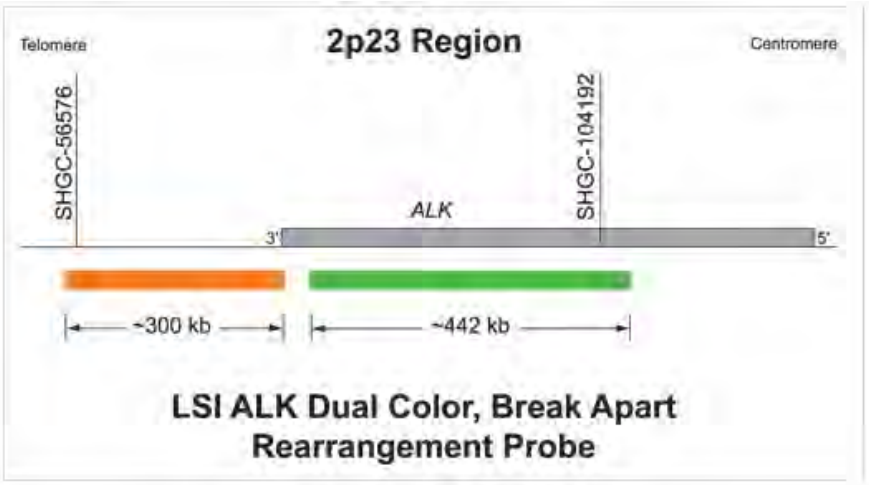
In a normal cell, the expected results for a nucleus hybridized with the LSI 22 (BCR) probe is a two green signal pattern.

Ordering Information	Quantity	Order No.
Vysis LSI 22 (BCR) SpectrumGreen Probe	20 µl	05J17-024

References

1. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed. New York City, NY, JohnWiley & Sons, Inc.

Vysis LSI ALK Break Apart Rearrangement Probe Kit



The Vysis ALK Break Apart FISH Probe Kit is intended to detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens.

Reduce variability with ready-to-use components

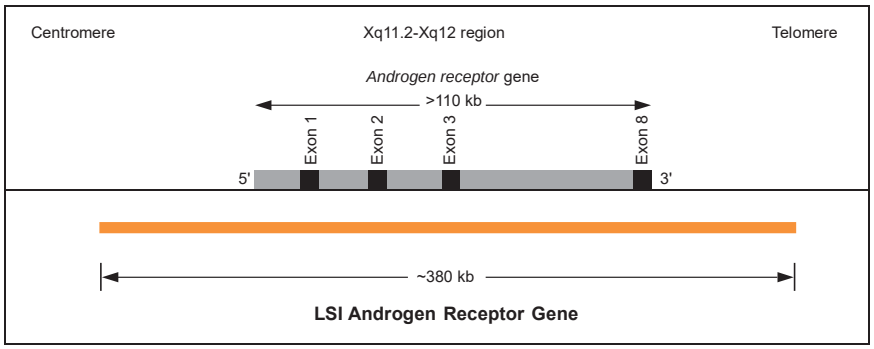
- Premixed, optimized probes
- ALK positive control slides
- ALK negative control slides
- Ready-to-use slide preparation reagents

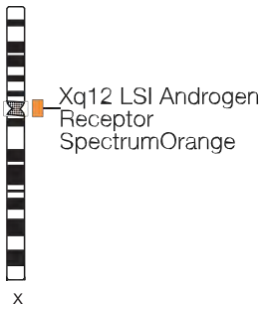
Ordering Information	Quantity	Order No.
Vysis LSI ALK Break Apart Rearrangement Probe Kit **IVD**	200 µl	06N38-033
Vysis ProbeChek ALK Negative Control Slides	5 slides	06N38-005
Vysis Probechek ALK Positive Control Slides	5 slides	06N38-010

References
Kwak EL, Bang YJ, Camidge DR, et al. Anaplastic lymphoma kinase inhibition in non-small-cell lung cancer. N Engl J Med. 2010;363(18):1693-1703

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). Non-Small Cell Lung Cancer (Version 3.2011). ©2011 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Accessed (March 28, 2011)

Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe



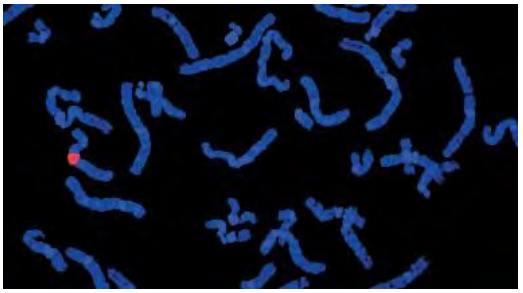


The LSI Androgen Receptor Gene (Xq12) Probe may be used to detect copy number of the androgen receptor (AR) gene.

LSI Androgen Receptor (Xq12) Probe is an approximately 380 kb SpectrumOrange labeled probe.

Results of Hybridization

In a normal male cell hybridized with LSI Androgen Receptor Gene (Xq12) Probe, the expected signal pattern is one orange (1O) signal. In a cell harboring amplification of the LSI Androgen Receptor Gene multiple copies of the orange signal will be observed.



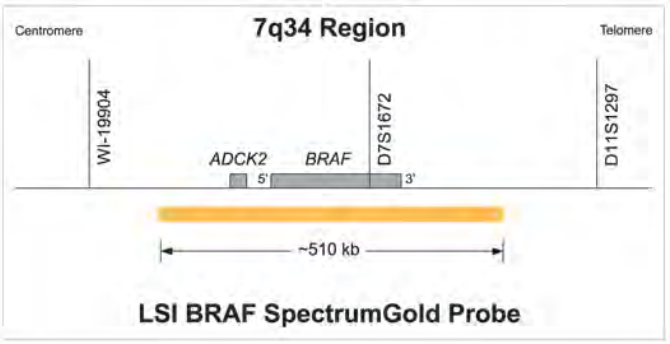
LSI Androgen Receptor Gene (Xq12) Probe hybridized to a normal male cell showing the one orange (1O) signal pattern.

Ordering Information	Quantity	Order No.
Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe	20 µl	05J44-011

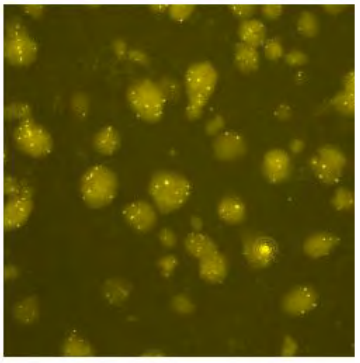
References

1. Heim, S., et al. Cancer Cytogenetics 2nd ed. (1995): 377.
2. Visakorpi, et al. Nat. Genet. 9 (1995): 401-6.
3. Wilson, J. N.Engl. J.Med. 332 (1995): 1440-1.

Vysis BRAF SpectrumGold FISH Probe Kit



The approximately 510 kb LSI BRAF (7q34) SpectrumGoldprobe contains the entire BRAF gene on chromosome 7.[8]



The Vysis BRAF FISH assay is based on the ability of BRAF locus specific identifier (LSI) probe to identify copy number changes of 7q34 chromosomal locus, using a FISH test.

BRAF is one of three serine/threonine RAF-regulated kinases that have an important role in cellular proliferation, differentiation, and programmed cell death.[1] It alsoparticipates in the RAS-RAF-MEK-ERK-BRAF in promoting tumorigenesis (malignant transformation of kinase BRAFs).[1]

Mutationally activated BRAF-V600E is detected in melanoma (70%), colorectal (15%), papillary thyroid (40%), ovarian (30%), and non-small-cell lung cancers (NSCLCs) (3%). [2,3] Melanoma with activating mutation of BRAF is more likely tohave copy gains at the BRAF locus.[4] BRAF copy number gains have been identified in both follicular thyroid cancer and malignant melanoma, and may occur through either gene amplification or chromosome 7 polysomy. [5,6,7] The BRAF copy number gains are expected in lung cancer, where chromosome 7 is also amplified.

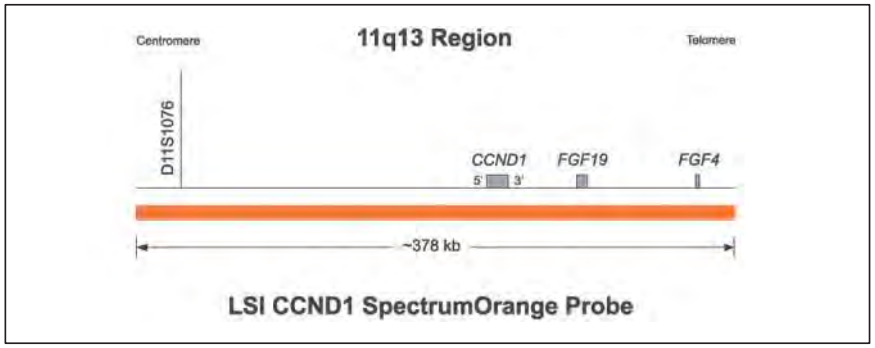
Results of Hybridization
Normal diploid nuclei or metaphase chromosome sets are expected to exhibit two gold fluorescent BRAF signals, which correspond to two target loci on chromosome homologues to which the BRAF fluorescent probe is bound: 7q34. A chromosome set that has an extra copy (copies) of BRAF (7q34) will exhibit more than two gold fluorescent signals.

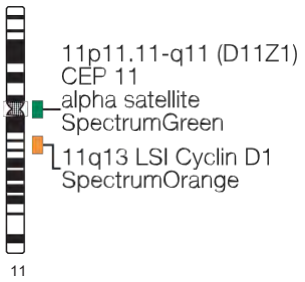
References
1. Flaherty KT, McArthur G. BRAF, a target in melanoma: implications for solid tumor drug development. Cancer. 2010;116(21):4902–13.
2. Davies H, Bignell GR, Cox C, et al. Mutations of the BRAF gene in human cancer. Nature. 2002;417(6892): 949–54.
3. Zebisch A, Troppmair J. 2006. Back to the roots: The remarkable RAF oncogene story. Cell Mol Life Sci. 2006;63(11): 1314–30.
4. Modrek B, Ge L, Pandita A, et al. Oncogenic activating mutations are associated with local copy gain. Mol Cancer Res. 2009;7(8):1244-52.
5. Ciampi R, Zhu Z, Nikiforov YE. BRAF copy number gains in thyroid tumors detected by fluorescence in situ hybridization. Endocr Pathol. 2005;16(2):99–105.
6. Tanami H, Imoto I, Hirasawa A, et al. Involvement of overexpressed wild-type BRAF in the growth of malignant melanoma cell lines. Oncogene. 2004;23(54):8796–804.
7. Willmore-Payne C, Holden JA, Hirschowitz S, Layfield LJ. BRAF and c-kit gene copy number in mutation-positive malignant melanoma. Hum Pathol. 2006;37(5):520–7.
8. Kent WJ, Sugnet CW, Furey TS, et al. The Human Genome Browser at UCSC. Genome Res. 2002:12(6):996-1006.

Ordering Information	Quantity	Order No.
Vysis BRAF SpectrumGold FISH Probe Kit	20 µl	06N09-020

Vysis CCND1/CEP 11 FISH Probe Kit

previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe





Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15 % of breast cancers. CCND1 amplification has been reported to be a prognostic marker. 1[,2,3]

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1 % of cases.[4] CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen.[5] The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

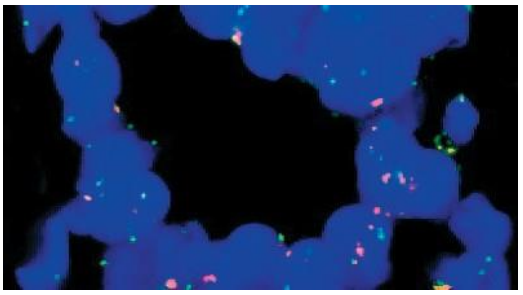
The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al.[6] found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

Results of Hybridization

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange signals. Other patterns may be observed if additional genetic alterations are present.

Ordering Information	Quantity	Order No.
Vysis CCND1/CEP 11 FISH Probe Kit	20 µl	03N88-020



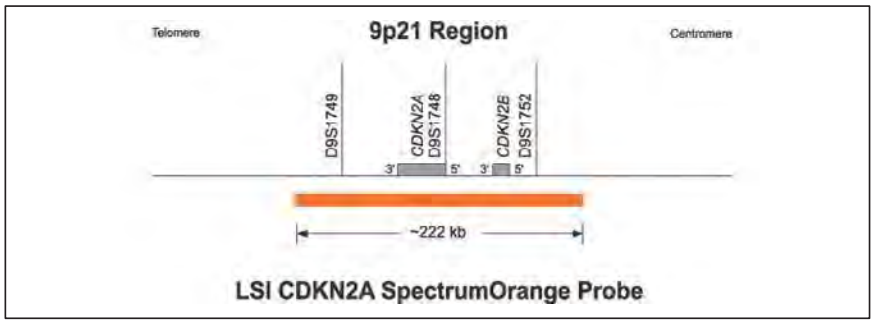
Vysis CCND1/CEP 11 FISH Probe hybridized to abnormal tissue.

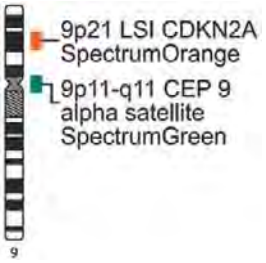
References

1. Schuuring E, Verhoeven E, Tinteren Hv et al. Cancer Research 1992;52:5229-5234.
2. Bieche I, Olivi M, Nogues C et al. British Journal of Cancer 2002;86:580-586.
3. Ormandy CJ, Musgrove EA, Hui R, et al. BreastCancer Research and Treatment 2003;78:323-335.
4. Al-Kuraya K, Schraml P, Torhorst J, et al. Cancer Research 2004;64:8534-8540.
5. Jirstrom K, Stendahl M, Ryden L, et al. Cancer Research 2005;65(17):8009-8016.
6. Katz RL, Caraway NP, Gu J, et al. American Journal of Clinical Pathology 2000;114:248-257.
7. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genetics in Medicine 2006;8(1):16-23.

Vysis CDKN2A/CEP 9 FISH Probe Kit

previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe

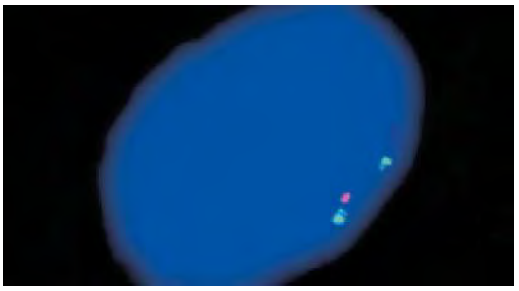




Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A (p16) are implicated in different Meningiomas and Gliomas.[1–4] Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that it is a marker of worse prognosis in anaplastic oligodendrogliomas.[5–6]

The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in several cytogenetic studies to detect losses of the CDKN2A gene.[2, 7–9] Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histolgically confirmed glial tumors.[7] In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.[9]

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN2A (p16) probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately222 kb and contains a number of genetic loci including D9S1749, DS1747, p16 (INK4B), p14 (ARF), D9S1748, p15(INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9.



Vysis LSI CDKN2A/CEP 9 Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively

Results of Hybridization

In a normal sample, the expected pattern for a nucleus hybridized with the Vysis LSI CDKN2A/CEP 9 Probe is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orangte, two green (1O2G) signal pattern is expected. Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.

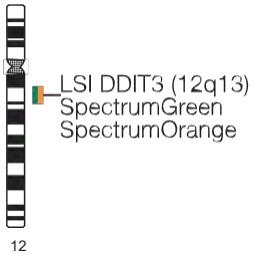
Ordering Information	Quantity	Order No.
Vysis CDKN2A/CEP 9 FISH Probe Kit	20 µl	04N61-020

References

1. Ruas M, Peters G. Biochimic Biophys Acta. 1998;1378(2):F115-F177.
2. Perry A, Banerjee R, Lohse CM, et al. Brain Pathol. 2002;12(2):183-190.
3. Boström J, Meyer-Puttlitz B, Wolter M, et al. Am J Pathol. 2001;159(2):661-669.
4. Smith JS, Jenkins RB. Frontin Biosci. 2000;5:D213-D231.
5. Cairncross JG, Ueki K, Zlatescu MC, et al. J Natl Cancer Inst. 1998;90(19):1473-1479.
6. Bortolotto S, Chiadó-Piat L, Cavalla P, et al. Int J Cancer. 2000;88(4):554-557.
7. Kramar F, Zemanova Z, Michalova K, et al. J Neurooncol. 2007;84(2):201-211.
8. Rajaram V, Leuthardt EC, Singh PK, et al. Mod Pathol. 2004;17(1):9-14.
9. Korshunov A, Sycheva R, Golanov A. Cancer. 2005;104(4):825-832.

Vysis DDIT3 Break Apart FISH Probe Kit

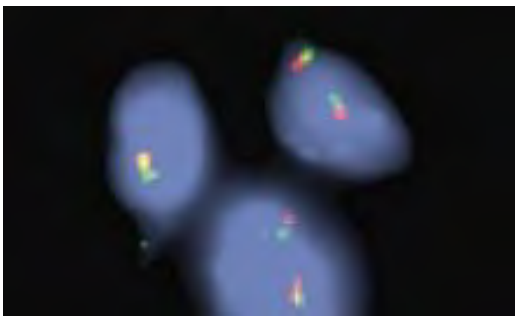
previously: Vysis LSI CHOP (12q13) Dual Color, Break Apart Rearrangement Probe



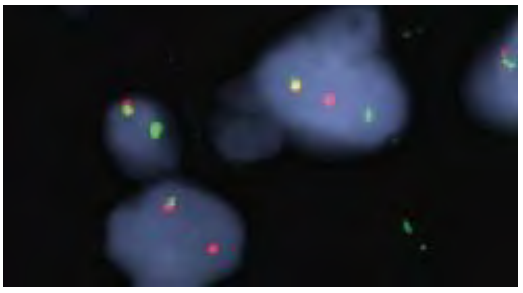
Chromosomal rearrangements involving the DDIT3 gene located on chromosome 12q13, are common in myxoid liposarcomas (MLS) and have also been identified in round cell (RC) and mixed liposarcomas (combined myxoid and round cell). A unique translocation t(12;16)(q13;p11) is present in > 95 % of MLS cases and is thus regarded as a diagnostic marker for MLS/RC. t(12;16) results in the fusion (and transcriptional deregulation) of the genes TLS (FUS) and DDIT3, a C/EBP-family transcription factor implicated in adipocyte differentiation.[1, 2, 4] Hybridization with the LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe will identify chromosomal rearrangement in the DDIT3 gene but not a specific gene-fusion partner.

The DDIT3 Dual Color, Break Apart Rearrangement Probe has been used in different studies to detect DDIT3 (12q13) gene rearrangements. Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe successfully detected rearrangment of the DDIT3 (CHOP) gene in 18/18 formalin-fixed, paraffin-emmbedded tissues from myxoid liposarcoma.[3] Matsui et al. used the LSI DDIT3 (CHOP) Dual Color, Break Apart Rearrangement Probe (Abbott Molecular, Inc.) to confirm rearrangement of the DDIT3 gene in a rare case of MLS bearing a variant chromosomal translocation t(12;22)(q13;q12) resulting in EWS-DDIT3 fusion gene.[4]

The Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a 700 kb probe labeled in SpectrumOrange lies proximal to the DDIT3 gene. The second probe labeled in SpectrumGreen extends distally from the DDIT3 gene and is approximately 660 kb in length. The centromeric SpectrumOrange probe contains most of the GLI1 oncogene, and this probe may be useful in detecting GLI amplification. The telomeric SpectrumGreen probe contains the CDK4 gene. CDK4 can be amplified in sarcoma and glioblastoma. Not all the genes within the probes are shown on the map.



Result of the hybridization of the Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe, showing the two fusion signal pattern as observed in normal interphase cells



Abnormal cells hybridized with the Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe. Two of the cells in this image show the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the DDIT3 gene region.

Results of Hybridization

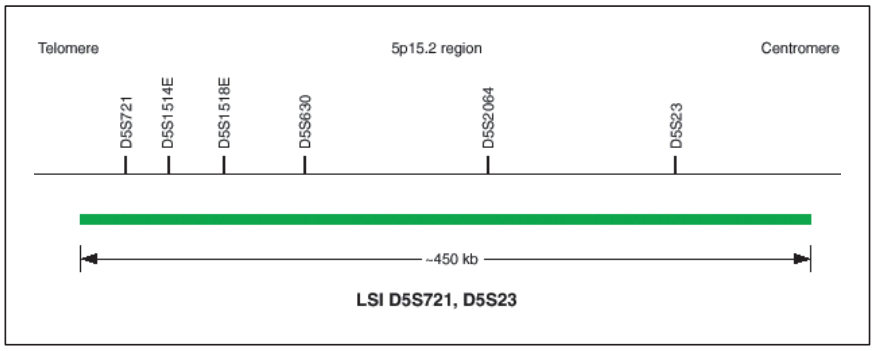
In a normal cell that lacks a t(12q13) in the DDIT3 gene region, a two fusion signal pattern will be observed which reflects the two intact copies of DDIT3. In an abnormal cell with a simple t(12q13), a one fusion, one green, and one orange signal pattern will be expected.

Ordering Information	Quantity	Order No.
Vysis DDIT3 Break Apart FISH Probe Kit	20 µl	03N57-020

References

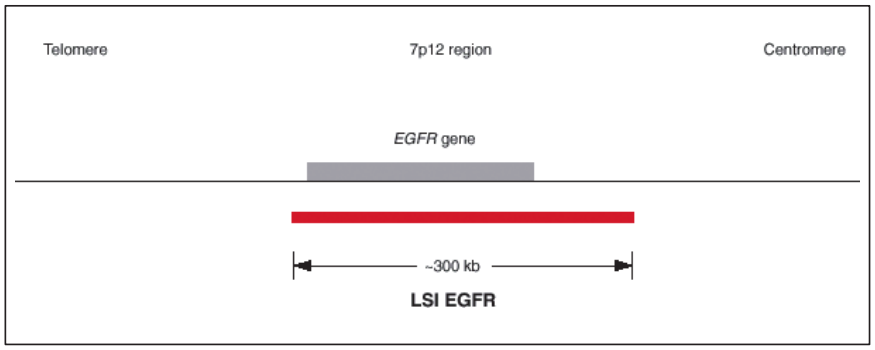
1. Antonescu, C., et al. Clinical Cancer Research 7 (2001): 3977-3987.
2. Knight, J. C., et al. Cancer Research 55 (1995): 24-27.
3. Downs-Kelly E, et al. Am J Surg Pathol 2008;32(1):8-13.
4. Matsui Y, et al. Bioch Biophys Res Com 2006;348:437-440.
5. Wiktor AE, et al. Genet Med 2006;8(1):16-23.

Vysis LSI D5S23, D5S721 SpectrumGreen Probe



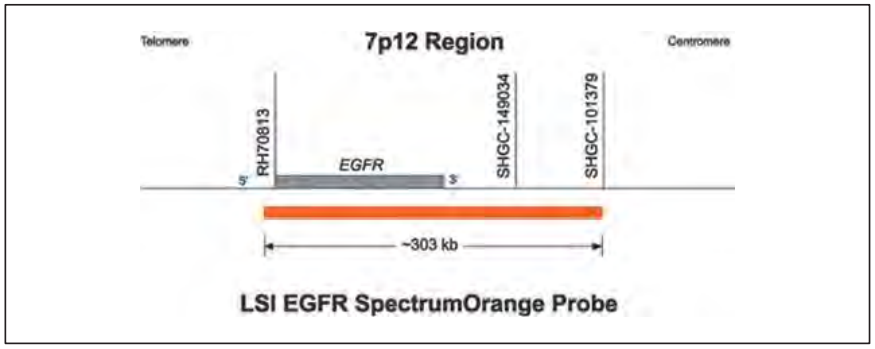
Ordering Information	Quantity	Order No.
Vysis LSI D5S23, D5S721 SpectrumGreen Probe	20 µl	04N30-020

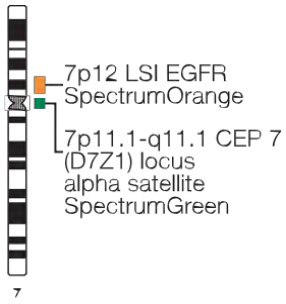
Vysis LSI EGFR SpectrumRed Probe



Ordering Information	Quantity	Order No.
Vysis LSI EGFR SpectrumRed Probe	20 µl	04N31-020

Vysis EGFR/CEP7 FISH Probe Kit





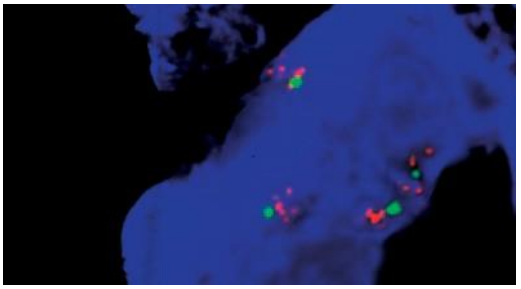
EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC)[1] which is the leading cause of cancer death worldwide.[2]

NSCLC has a 5-year survival rate of approximately 15%.[3] There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.[1, 4]

This probe set is premixed in Hybridization Buffer.

Results of Hybridization

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.



An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange/CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

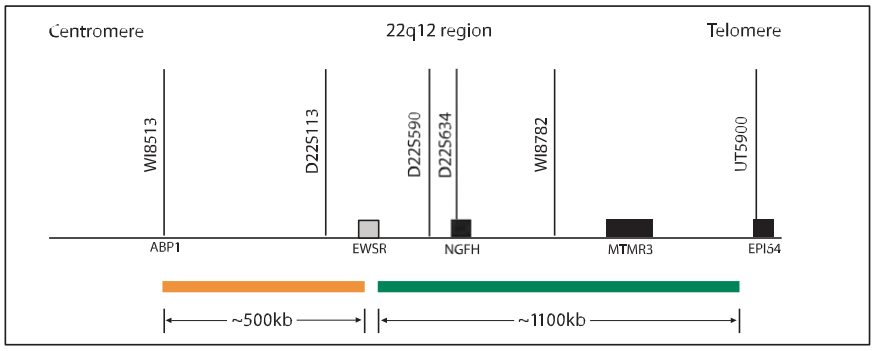
Ordering Information	Quantity	Order No.
Vysis EGFR/CEP 7 FISH Probe Kit	200 µl*	01N35-020

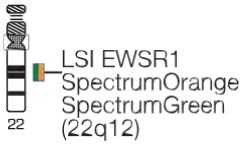
* Premixed in Hybridizaton Buffer

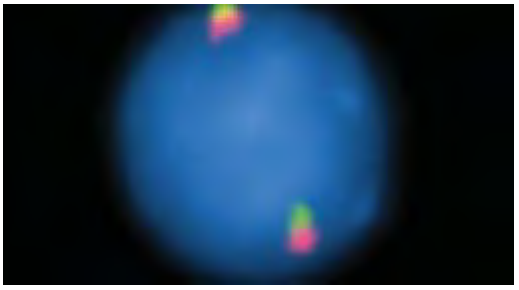
References

1. Parkin MD. Lancet Oncol 2001;2:533-43.
2. Jemal A, et al. CA Cancer J Clin 2002;52:23-47.
3. Hirsch FR, et al. J Clin Oncol 2005;23(28):6838-45.
4. Hirsch FR,et al. J Clin Oncol 2005;21(20):3798-3807.
5. Cappuzzo F, et al. J Natl Cancer Inst 2005;97(9):643-55.

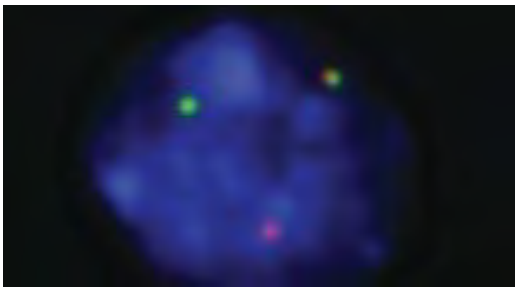
Vysis EWSR1 Break Apart FISH Probe Kit







Result of the hybridization of the LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe as observed in a normal interphase cell.



An abnormal cell hybridized with the LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe. The cell in this image shows the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the EWSR1 region.

The Vysis EWSR1 Break Apart FISH probe kit contains the LSI EWSR 1 (22q12) Dual Color, Break Apart Rearrangement Probe.

Chromosome rearrangements involving the EWSR1 (Ewing sarcoma breakpoint region 1) gene on chromosome 22q12 have been observed in several types of tumors1. Approximately 90% of the translocations involving the EWSR1 gene result in the t(11;22) (q24;q12), which juxtaposes the EWSR1 with the FLI1 (Friend leukemia virus integration 1) gene on chromosome 11q24. The resulting fusion produces chimeric transcripts and proteins that consist of the N-terminus of EWSR1 and the C-terminal portion of FLI1. The next most common translocation partner of the EWSR1 gene is the ERG (v-ets erythroblastosis virus E26 oncogene like) on chromosome 21q22. While extremely rare, translocations with ETV1 (ets variant gene 1) on chromosome 7p22, FEV (FEV protein) on chromosome 2q33, and E1VF on chromosome 17q12 and several other genes have also been observed. Hybridization with the LSI EWSR1 (22q12) Break Apart Rearrangement Probe will identify t(22q12) but not the specific translocation partner. The probe will also identify aneuploidy of chromosome 22.

The LSI EWSR1 Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a ~500 kb probe labeled in SpectrumOrange, flanks the 5' side of the EWSR1 gene, and extends inward into intron 4. The second probe, a ~1100 kb probe labeled in SpectrumGreen, flanks the 3' side of the EWSR1 gene. The known break points within the EWSR1 gene are restricted to introns 7 through 10.

Results of Hybridization

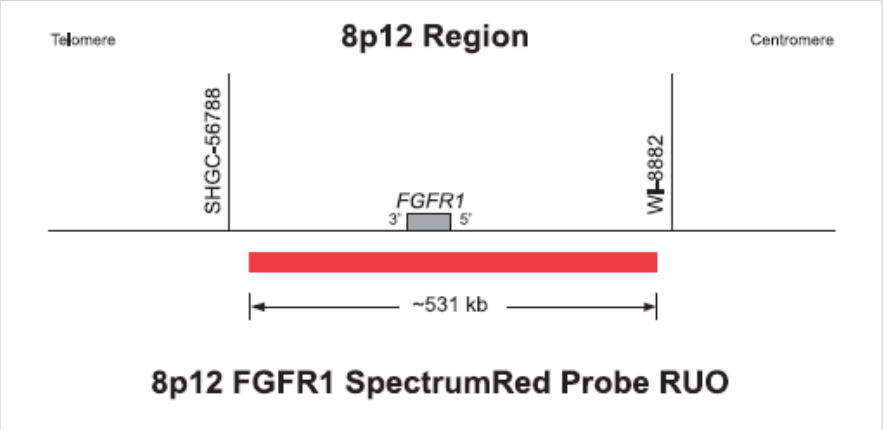
In a normal cell that lacks a t(22q12) in the EWSR1 gene region, a two fusion signal pattern will be observed reflecting the two intact copies of EWSR1. In an abnormal cell with a simple t(22q12), a one fusion, one green, one orange signal pattern will be expected.

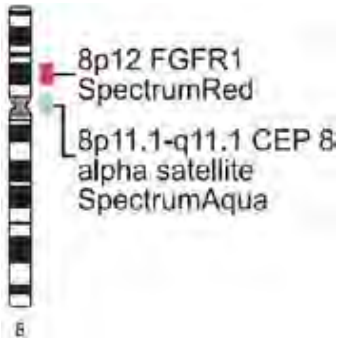
Ordering Information	Quantity	Order No.
Vysis EWSR1 Break Apart FISH Probe Kit	20 µl	03N59-020

References

1. Antonescu, C., et al. Clinical Cancer Research 7 (2001): 3977-3987.
2. Knight, J. C., et al. Cancer Research 55 (1995): 24-27.
3. Downs-Kelly E, et al. Am J Surg Pathol 2008;32(1):8-13.
4. Matsui Y, et al. Bioch Biophys Res Com 2006;348:437-440.
5. Wiktor AE, et al. Genet Med 2006;8(1):16-23.

Vysis 8p12 FGFR1 SpectrumRed/ CEP 8 SpectrumAqua FISH



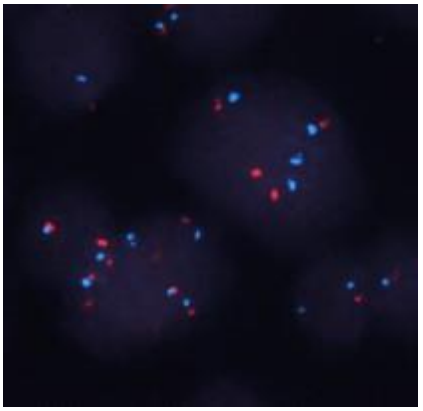


PRODUCT DESCRIPTION

The SpectrumRed 8q12 FGFR1 Fluorescence in situ hybridization (FISH) probe is targeted to the 8q12 region on chromosome 8. The probe is approximately 531 kb in size and contains the entire FGFR1 gene.

The CEP 8 SpectrumAqua probe hybridizes to the alpha satellite DNA located at the centromere of chromosome 8 (8p11.1-q11.1).

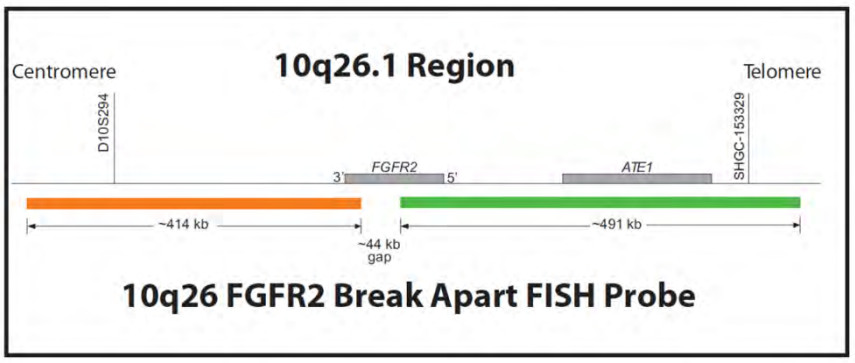
The hybridized probe fluoresces both in interphase nuclei and metaphase chromosomes.

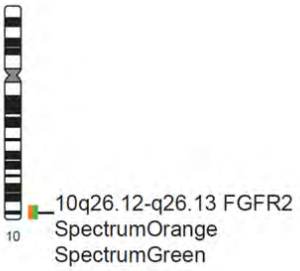


Merged Image viewed under Vysis single- band Red, single-band Aqua and single-band DAPI filters

PRODUCT	QUANTITY	ORDER #	GTIN
Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH **(RUO)**	20 µL	08N21-060	00884999038059

Vysis 10q26 FGFR2 Break Apart FISH Probe

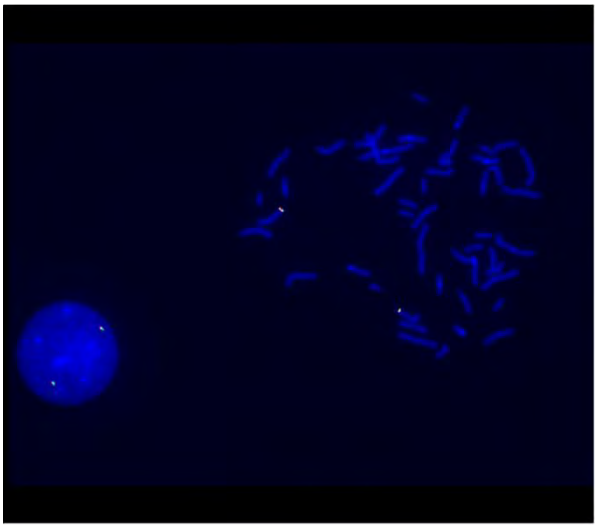




PRODUCT DESCRIPTION

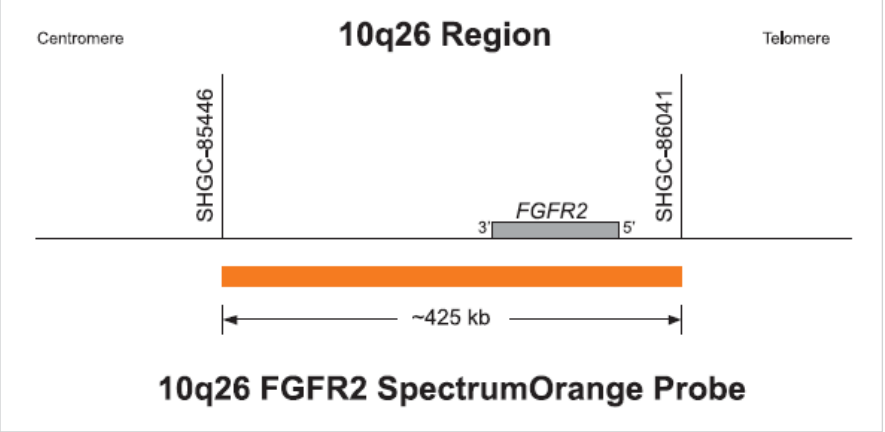
The Vysis LSI FGFR2 (Cen) SpectrumOrange probe is positioned centromeric of the FGFR2 gene and is approximately 414 kb in size spanning chr10:122,841,555-123,255,766 on 10q26.12-q26.13 (February 2009, UCSC Genome Browser1).

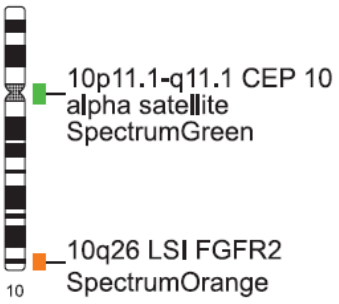
The Vysis LSI FGFR2 (Tel) SpectrumGreen probe is positioned telomeric of the FGFR2 gene and is approximately 491 kb in size spanning chr10:123,300,014-123,791,418 on 10q26.13 (February 2009 UCSC Genome Browser1).



PRODUCT	QUANTITY	ORDER #	GTIN
10q26 FGFR2 Break Apart FISH Probe **(RUO)**	20 µL	09N23-060	00884999046092

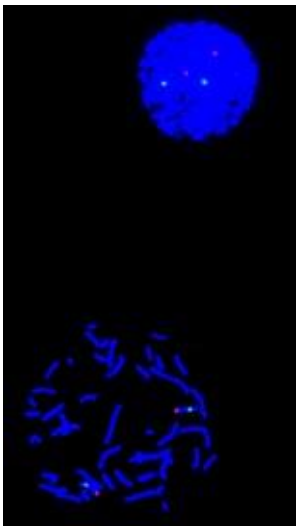
10q26 FGFR2 SpectrumOrange/ CEP 10 SpectrumGreen FISH Probe Kit





PRODUCT DESCRIPTION

The 10q26 FGFR2 SpectrumOrange probe is approximately 425 kb in size and contains the entire FGFR2 gene. The CEP 10 SpectrumGreen probe hybridizes to the alpha satellite DNA located at the centromere of chromosome 10 (10p11.1-q11.1).

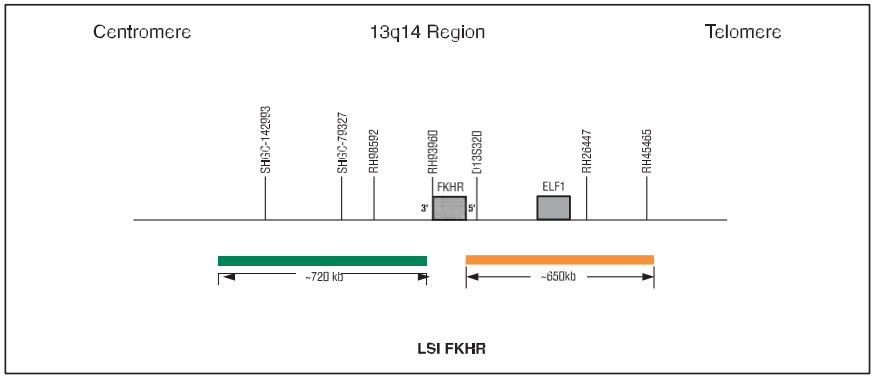


Metaphase and Interphase images of hybridized cell using the 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit

PRODUCT	QUANTITY	ORDER #	GTIN
10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit	20 µL	08N42-060	00884999042582

Vysis FOXO1 Break Apart FISH Probe Kit

previously: Vysis LSI FKHR (13q14) Dual Color, Break Apart Rearrangement Probe



Chromosomal rearrangements involving the FOXO1 gene on chromosome 13q14 are associated with alveolar rhabdomyosarcoma (ARMS). Identification of RMS is a diagnostic dilemma for pathologists, requiring a significant amount of rule out testing for this and other soft-tissue cancers. ARMS is characterized by two consistent chromosomal translocations, the common t(2;13)(q35.2;q14) and the variant t(1;13)(p36;q14) resulting in the formation of PAX3-FOXO1 and PAX7-FOXO1fusion genes respectively (~80% of cases of ARMS). Hybridization with the Vysis LSI FOXO1 (13q14) Dual Color, Break Apart Rearrangement Probe will identify a chromosomal rearrangement at the FOXO1 gene but not a specific gene-fusion partner.

The Vysis LSI FOXO1 (13q14) Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a 720 kb probe labeled in SpectrumGreen lies proximal to the FOXO1 gene. The second probe labeled in SpectrumOrange extends distally from the FOXO1 gene and is approximately 650 kb in length.

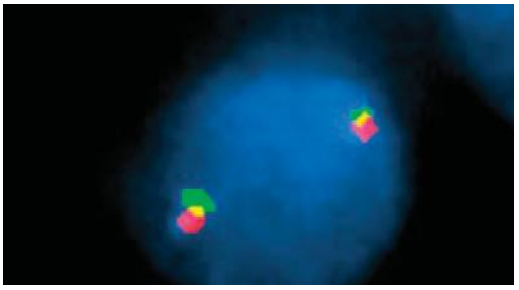
Results of Hybridization

In a normal cell that lacks a t(13q14) in the FOXO1 gene region, a two fusion signal pattern will be observed.

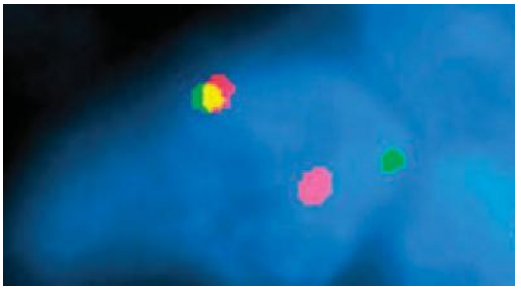
Ordering Information	Quantity	Order No.
Vysis FOXO1 Break Apart FISH Probe Kit	20 µl	03N60-020

References

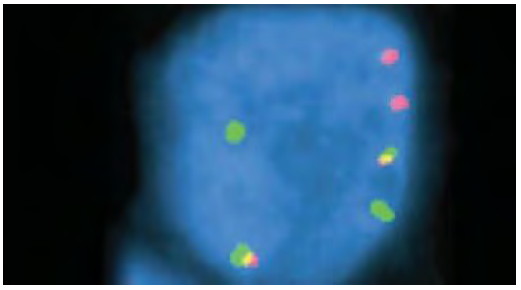
1. Anderson, J., et al. Br J Cancer 85 (6) (2001): 831-835.
2. Biegel, et al.Genes Chrom Cancer 12 (3) (1995): 186-192.
3. Slominski, A., et al. Arch Pathol Lab Med. 123 (1999): 1246-1259.
4. Womer, R. B., Eur J of Cancer 33 (13) (1997): 2230-2236.
5. Nishio J., et al. Lab Invest 2006;86:547-556.
6. Mehra S., et al. Diagn Mol Pathol 2008;17(1):14-20.
7. Matsumura T., et al. Virchows Arch 2007.
8. Das k, et al. Diagn Cytoopath 2006;34(10):704-706.
9. Wiktor EA., et al. Genet Med 2006;8(1):16-23.



Result of the hybridization of the LSI FOXO1 (13q14) Dual Color Break Apart Rearrangement Probe, showing the two fusion signal pattern as observed in normal interphase cells.

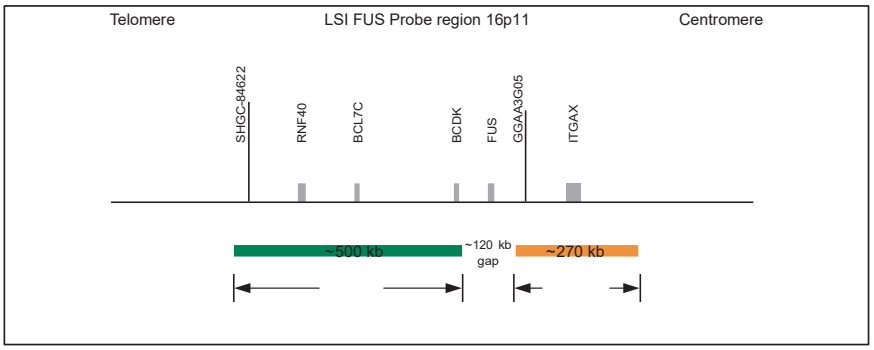


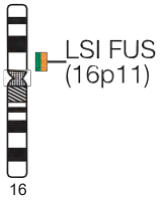
Abnormal cells hybridized with the LSI FOXO1 (13q14) Dual Color Break Apart Rearrangement Probe. The cells in this image show the one fusion, one orange and one green signal pattern indicative of a rearrangement of one copy of the FOXO1 gene region.



Abnormal cells hybridized with the LSI FOXO1 (13q14) Dual Color Break Apart Rearrangement Probe. The cells in this image show the one fusion, one orange and one green signal pattern indicative of a rearrangement of one copy of the FOXO1 gene region. In addition, there are often extra signals in the abnormal cases suggesting that perhaps they are also highly aneuploid or polyploid.

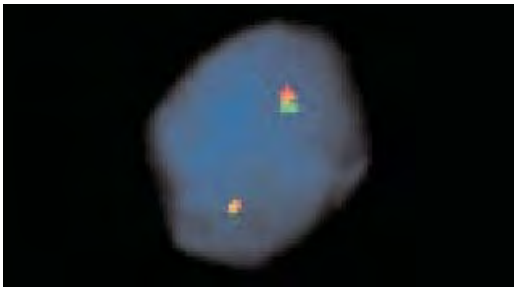
Vysis FUS Break Apart FISH Probe Kit



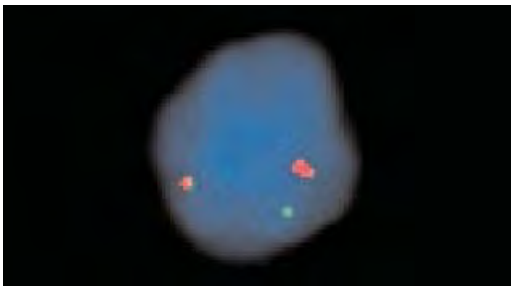


Chromosomal rearrangements involving the FUS gene located on chromosome 16p11 have been observed in many tumor types including several soft tissue sarcomas (STS). Different types of STS are characterized by specific chromosomal translocations including t(12;16)(q13;p11) FUS-DDIT3 (Myxoid liposarcoma), t(16;21)(p11;q22) FUS-ERG (Acute myeloid leukemia), t(12;16)(q13;p11) FUS-ATF1 (Angiomatoid-fibrous histiocytoma) and t(7;16)(q32-34;p11) FUS-CREB3L2 (Low grade fibromyxoid sarcoma). The resulting chimeric fusion proteins are mainly transactivators exerting deregulation of differentiation control on the tumor-target cell.1,2 Hybridization with the LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe will identify a chromosomal rearrangement in the FUS gene region but not a specific gene-fusion partner.

FUS FISH-probes were successfully used to confirm diagnosis of different sarcomas as demonstrated by several studies. The Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe detected rearrangement of the FUS gene in 7/10 formalin-fixed, paraffin-embedded tissues from low-grade fibromyxoid sarcomas.3 In another study the Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe was used to detect rearrangement of the FUS gene in a rare case of Ewing bone sarcoma bearing a variant chromosomal translocation t(2;16)(q35;p11) resulting in a FUS-FEV fusion gene.4



Normal cell hybridization using the LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe.



Abnormal cell hybridization using the LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe.

Results of Hybridization

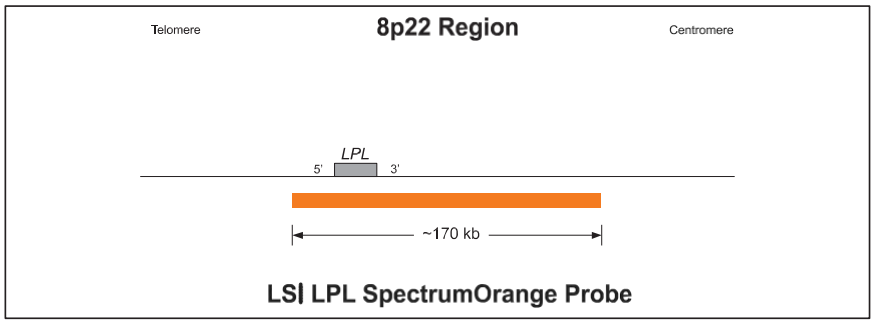
Hybridization of this probe to interphase nuclei of normal cells is expected to produce a two fusion signal pattern. The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 16 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

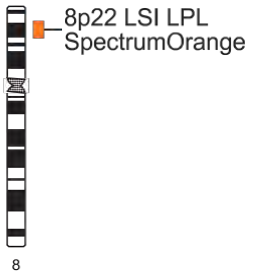
Ordering Information	Quantity	Order No.
Vysis FUS Break Apart FISH Probe Kit	20 µl	03N58-020

References

1. Perez-Mancera PA., et al., (2005) Seminar Cancer Biol. 2005;15: 206-14.
2. Mertens F., et al., (2005) Lab Invest. 2005;85: 408-15.
3. Downs-Kelly E, et al. Am J Surg Pathol 2008;32(1):8-13.
4. Ng TL, et al. J Mol Diagn 2007;9(4):459-463.

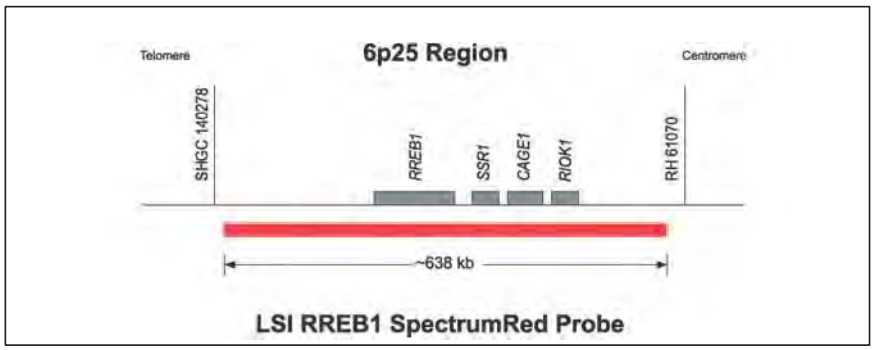
Vysis LSI LPL SpectrumOrange Probe

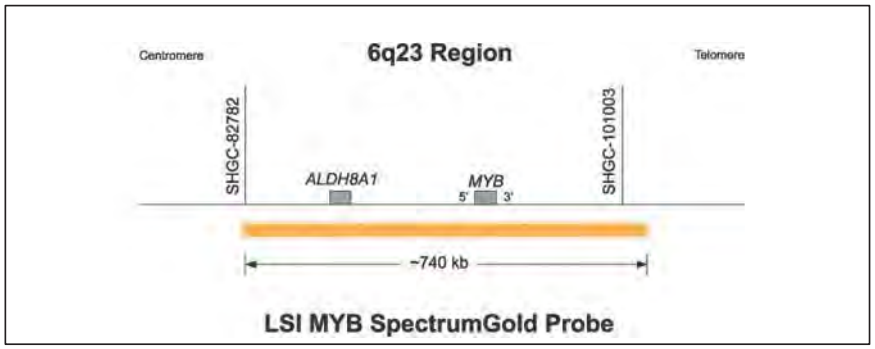


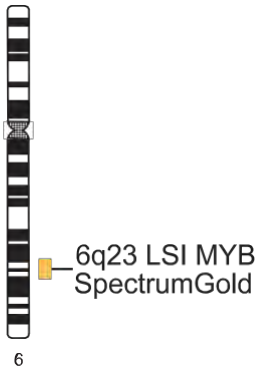


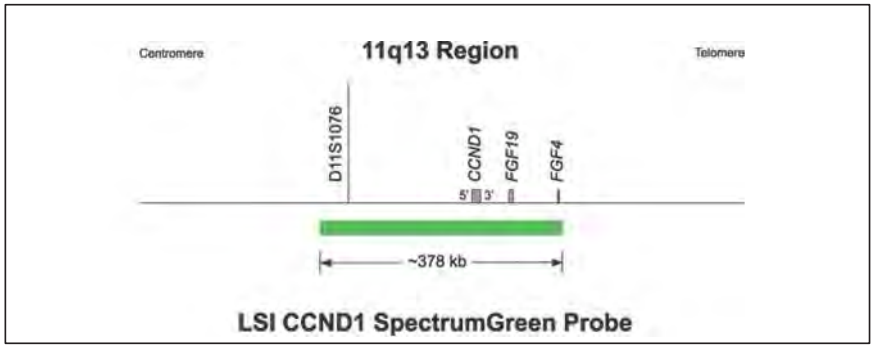
Ordering Information	Quantity	Order No.
Vysis LSI LPL SpectrumOrange Probe	20 µl	04N34-020

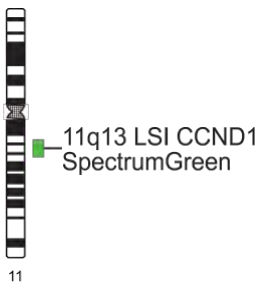
Vysis Melanoma FISH Probe Kit











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Continuation:
Vysis Melanoma FISH Probe Kit

The Vysis Melanoma FISH Probe Kit is designed to detect copy number of the RREB1 (6p25), MYB (6q23), CCND1 (11q13) genes and of centromere 6 via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin embedded human skin tissue specimens. The Vysis Melanoma FISH Probe Kit is indicated as an aid in the diagnosis of melanoma in skin biopsy specimens.

The RREB1 (6p25) Probe is labeled with SpectrumRed and covers an approximately 638 kb region that contains the entire RREB1 gene. The MYB (6q23) probe is labeled with SpectrumGold and covers an approximately 740 kb region that contains the entire MYB gene. The CCND1 (11q13) probe is labeled with SpectrumGreen and covers an approximately 378 kb region that contains the entire CCND1 gene. The CEP 6 probe, labeled with SpectrumAqua, hybridizes to the alpha satellite DNA located at the centromere of chromosome 6 (6p11.1-q11.1).

Results of Hybridization
In a normal cell, two copies of each signal will be observed.

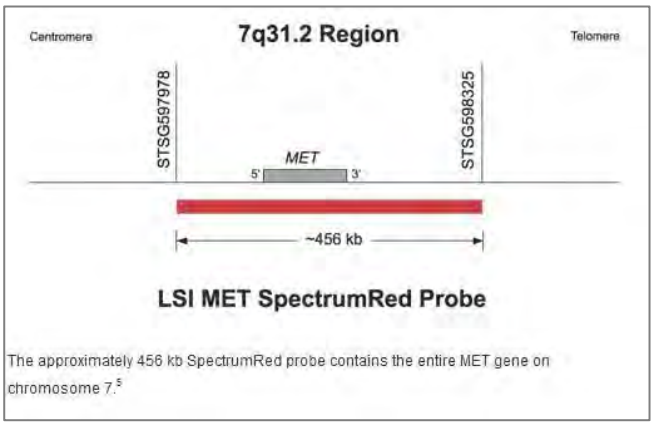
Ordering Information	Quantity	Order No.
Vysis Melanoma FISH Probe Kit	200 µl*	01N89-020

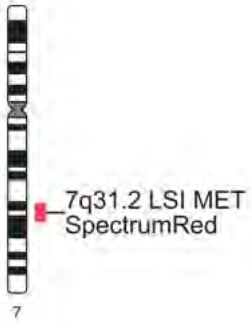
* premixed in Hybridizaton Buffer

References

1. Jewell, Susan et. al. Identification of markers RREB1, MYB, CCND1 and centromere 6 for the discrimination between melanoma and nevi FFPE skin biopsies using FISH. Proceedings of the 2007 Annual Meeting of the American Association for Cancer Research; 2007 April 14-18; Los Angeles, CA. Abstract #135.
2. Gerami, Pedram et. al. Fluorescence In Situ Hybridization (FISH) as an Ancillary Diagnostic Tool in the Diagnosis of Melanoma. Am J Surg Pathol 2009; 33(8):1146-1156.
3. Thomas JM. The place of sentinel node biopsy in melanoma after the Multicenter Selective Lymphadenectomy Trial. ANZ J Surg. 2006;76:98–99.

Vysis MET SpectrumRed FISH Probe Kit





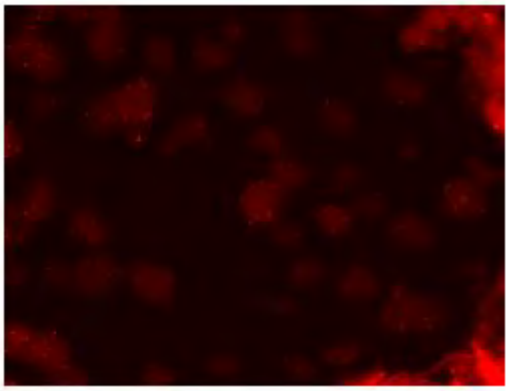
The Vysis MET SpectrumRed FISH Probe Kit is based on the ability of MET locus-specific identifier (LSI) probe to identify copy number changes of 7q31.2 chromosomal locus, using a FISH test.

MET is a Receptor Tyrosine Kinase. It binds to the ligand, Hepatocyte Growth Factor (HGF). The MET pathway regulates many cellular responses including cell proliferation, survival, motility, invasion and morphogenesis. This pathway is one of the most frequently dysregulated pathways in human cancer for both solid tumors and hematological malignancies including gastric, head and neck, liver, ovarian, non-small cell lung (NSCL) and thyroid cancers, as well as in metastases of some of these cancers[1].

MET has been shown to be frequently overexpressed or amplified in many cancers, including brain, colorectal, gastric, lung, head and neck and stomach cancers where it is correlated with poor clinical outcomes[1].

The MET locus has been found to have potential utility for the prognosis of lung cancer,[3,4] where FISH positive MET status predicted worse survival in patients with non-small cell lung cancer (NSCLC).

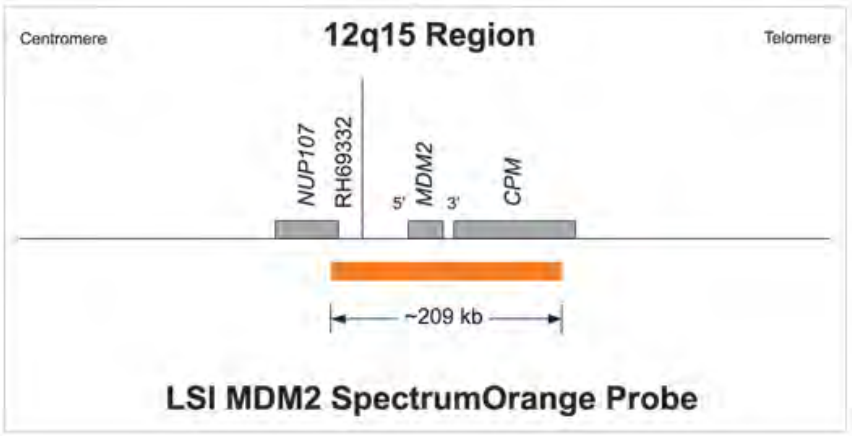
Results of Hybridisation
In a nucleus with normal copy number of the MET gene, two red signals will be observed. Abnormal copy number of the MET gene is indicated by more than two copies of the red probe signal.

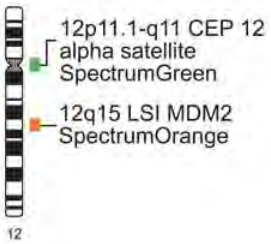


References
1. Liu X, Newton RC, Scherle PA. Developing c-MET pathway inhibitors for cancer therapy: progress and challenges. Trends Mol Med. 2010;16(1):37-45.
2. Kubo T, Yamamoto H, Lockwood WW, et al. MET gene amplification or EGFR mutation activate MET in lung cancers untreated with EGFR tyrosine kinase inhibitors. Int J Cancer. 2009 Apr 15;124(8):1778-84.
3. Cappuzzo F, Marchetti A, Skokan M, et al. Increased MET gene copy number negatively affects survival of surgically resected non–small-cell lung cancer patients. J Clin Oncol. 2009;27(10):1667-74.
4. Okuda K, Sasaki H, Yukiue H, Yano M, Fujii Y. Met gene copy number predicts the prognosis for completely resected non-small cell lung cancer. Cancer Sci. 2008 Nov;99(11):2280-5.
5. Kent WJ, Sugnet CW, et al. the Human Genome Browser at UCSC. Genome Res. 2002 12 (16): 996-1006.

Ordering Information	Quantity	Order No.
Vysis MET SpectrumRed FISH Probe Kit	20 µl	06N05-020

Vysis LSI MDM2/CEP 12 FISH Probe Kit

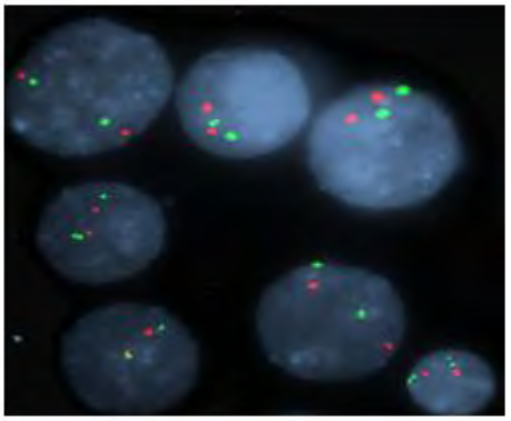




The approximately 209 kb SpectrumOrange probe spans MDM2 gene on 12q15.The SpectrumGreen CEP 12 probe hybridizes to alphoid sequences found within the centromere of chromosome 12 (12p11.1-q11).

The Vysis MDM2/CEP 12 FISH Probe Kit uses a dual-color probe designed to detect the copy number of the LSI MDM2 probe target located at chromosome 12q15 using FISH.

The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma [1] and chronic lymphocyticleukemia [2-5] in humans. This region includes the mouse double minute2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm. [1] This results ininactivation of the tumor suppressor and the formation of tumors, which ultimately leads to cancer.



Results of Hybridization

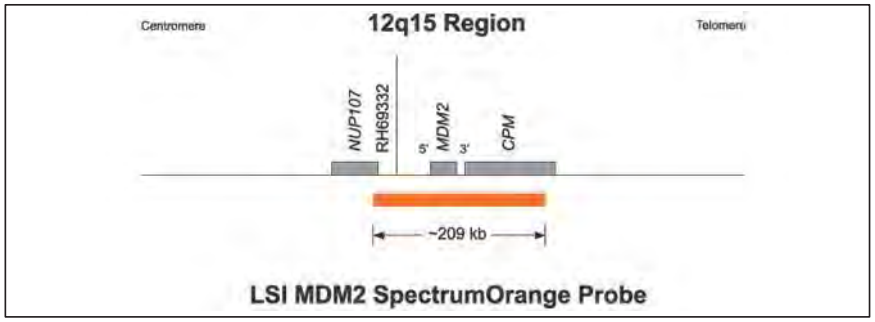
Nuclei or metaphase chromosome sets lacking the MDM2 amplification are expected to exhibit two orange and two green signals. Amplification of MDM2 would exhibit more than two orange signals and amplification of centromere 12 would exhibit more than two green signals.

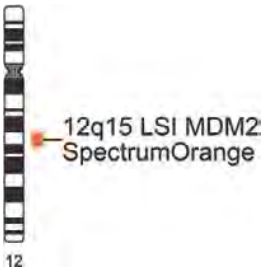
Ordering Information	Quantity	Order No.
Vysis MDM2/CEP 12 FISH Probe Kit	10 µl	01N15-010

References

1. Chene P. Inhibiting the p53-MDM2 interaction: an important target for cancer therapy. Nat Rev Cancer. 2003;3(2):102-9.
2. Dewald GW, Brockman SR, Paternoster SF, et al. Chromosome anomalies detected by interphase fluorescence in situ hybridization: correlation with significant biological features of B-cell chronic lymphocytic leukemia. Br J Haematol. 2003;121(2):287-95.
3. Fink SR, Paternoster SF, Smokey SA, et al. Fluorescent-labeled DNA probes applied to novel biological aspects of B-cell chronic lymphocytic leukemia. Leuk Res. 2005;29(3):253-62.
4. Nelson BP, Gupta R, Dewald GW, Paternoster SF, Rosen ST, Peterson LC. Chronic lymphocytic leukemia FISH panel: impact on diagnosis. Am J Clin Pathol. 2007;128(2):323-32.
5. Shanafelt TD, Witzig TE, Fink SR, et al. Prospective evaluation of clonal evolution during long-term follow-up of patients with untreated early-stage chronic lymphocytic leukemia. J Clin Oncol.2006;24(28):4634-41.

Vysis LSI MDM2 SpectrumOrange Probe





The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma in humans. This region includes the mouse double minute 2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm.[1] This results in inactivation of the tumor suppressor and the formation of tumors which ultimately leads to cancer. The use of MDM2 as an aid in differential diagnosis of sarcomas has been documented.[2, 3]

The SpectrumOrange Vysis LSI MDM2 fluorescence in situ hybridization (FISH) probe is targeted to the 12q15 region on chromosome 12. The probe is ~209 kb in size and spans the MDM2 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and on metaphase chromosomes.

Results of Hybridization

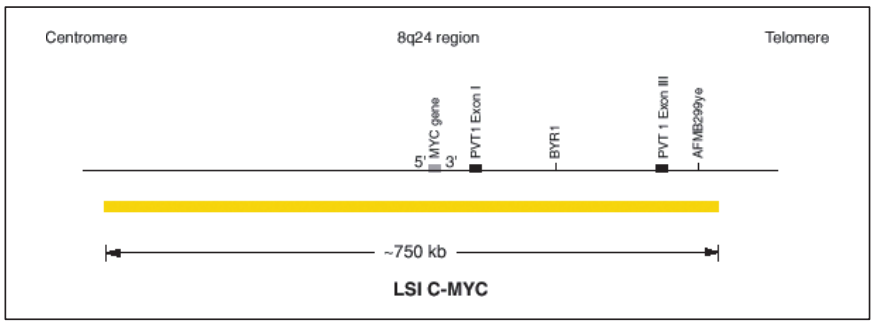
In a cell with normal copy number of the MDM2 gene, two orange signals will be observed.

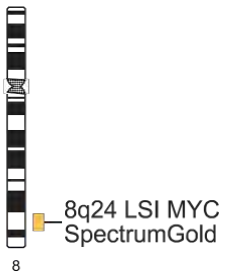
Ordering Information	Quantity	Order No.
Vysis LSI MDM2 SpectrumOrange Probe	20 µl	01N15-020

References

1. Chene, Inhibiting the p53-MDM2 Interaction: An important target for cancer therapy, Nature Reviews 3: 102-109 (2003).
2. Sirvent N, Detection of MDM2-CDK4 amplification by FISH in 200 paraffin-embedded tumor samples: utility in diagnosis adipocytic lesions and comparison with IHC and real-time PCR, AM J Surg Pathol, 2007 Oct 31 (10):1476-89.
3. Weaver J, FISH for MDM2 gene amplification as a diagnostic tool in lipomatous neoplasms, Mod Pathol (2008) 21, 943-949.

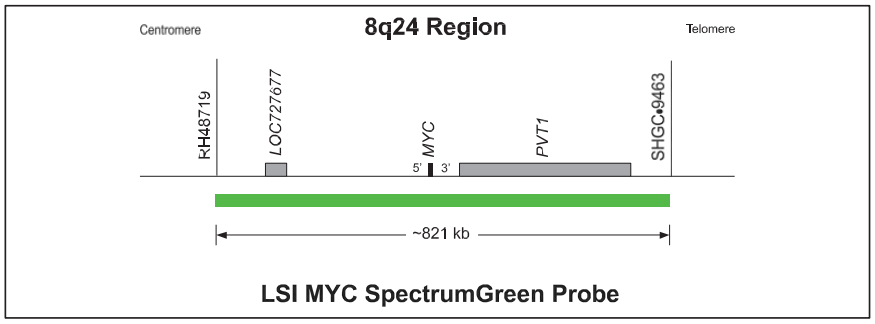
Vysis LSI MYC SpectrumGold Probe

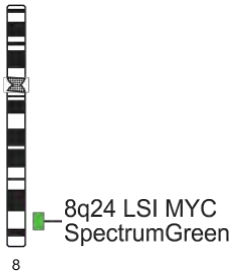




Ordering Information	Quantity	Order No.
Vysis LSI MYC SpectrumGold Probe	20 µl	04N35-020

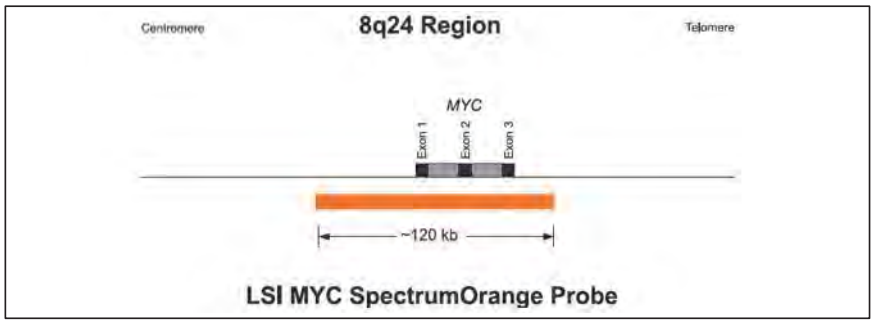
Vysis LSI MYC SpectrumGreen Probe





Ordering Information	Quantity	Order No.
Vysis LSI MYC SpectrumGreen Probe	20 µl	04N36-020

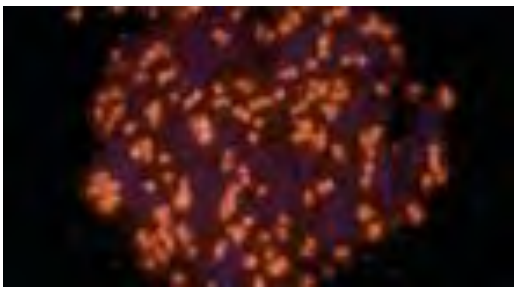
Vysis MYC SpectrumOrange FISH Probe Kit



The MYC (C-MYC) oncogene has been reported to be amplified in > 20 % of breast carcinoma and various other malignancies and is a prognostic factor for breast cancer.[1, 2, 3] FISH is a rapid and reproducible method that allows the accurate measurement of the level of oncogene amplification within interphase nuclei in human tumors.[4] This probe may be used to determine the MYC copy number or as a general purpose probe for the 8q24 region.

The Vysis LSI MYC SpectrumOrange Probe was employed in a number of studies. Park et al. used the Vysis LSI MYC Probe to investigate co-amplification of the MYC and HER2 genes in 214 consecutive breast cancers.[5] For detecting lung cancer, Sokolava et al. compared a FISH-based assay, that included Vysis LSI MYC, to conventional cytology in 74 bronchial washing specimens, and achieved significantly higher sensitivity with the FISH assay (82 % vers. 54 %).[6] In a recent study, Rygiel et al. used the Vysis LSI MYC (8q24.12-q24.13) SpectrumOrange Probe to evaluate amplification of MYC as a diagnostic marker to identify patients with Barrett's esophagus with high-grade dysplasia or esophageal adenocarcinoma.[7]

The LSI C-MYC (8q24.12-q24.13) Probe is an approximately 120 kb SpectrumOrange labeled probe.



LSI C-MYC Probe hybridized to an abnormal cell. Multiple orange signals contained within the cell indicate amplification of the C-MYC locus.

Results of Hybridization

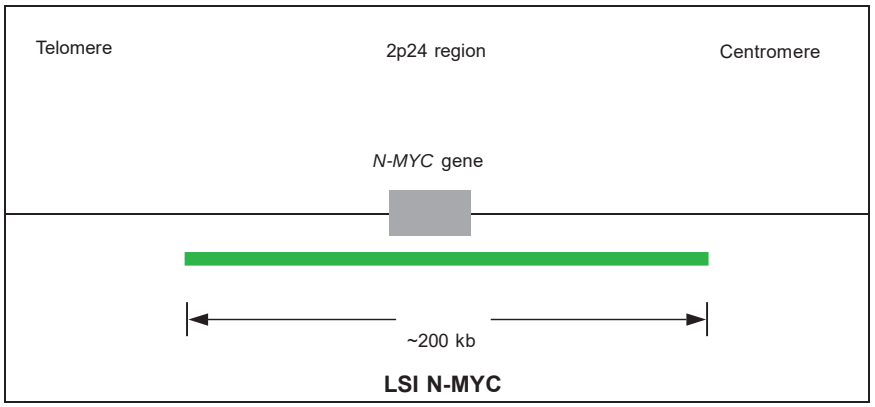
In a cell with amplification of the C-MYC locus,multiple copies of the orange signal may be seen when hybridized with the C-MYC probe.

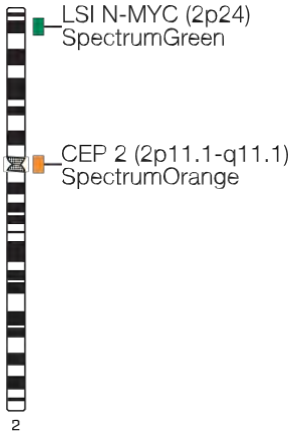
Ordering Information	Quantity	Order-No.
Vysis MYC SpetrumOrange FISH Probe Kit	20 µl	03N87-020

References

1. Deming SL, Nass SJ, Dickson RB et al. British Journal of Cancer 2000;83(12):1688-1695.
2. Nesbit CE, Tersak JM, and Prochownik EV. Oncogene 1999;18:3004-3016.
3. Schlotter CM, Vogt U, Bosse U, et al. Breast Cancer Research 2003;5(2):30-36.
4. Persons DL, Borelli KA, Hsu PH. Modern Pathology 1997;10(7):720-727.
5. Park K, Kwak K, Kim J, et al. Human Pathology 2005;36:634-639.
6. Sokolova IA, Bubendorf L, O?Hare A, et al. Cancer Cytopathology 2002;96(5):307-315.
7. Rygiel AM, Milano F, ten Kate FJ et al. Cancer Epidemiology, Biomarkers & Prevention 2008;17(6)1380-1385.
8. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genetics in Medicine 2006;8(1):16-23.

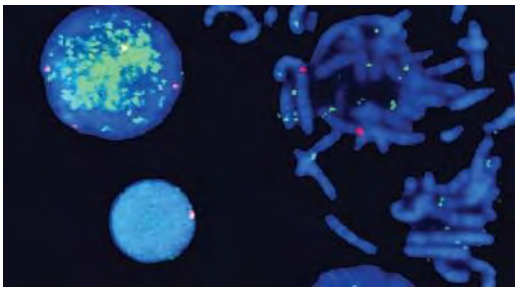
Vysis LSI N-MYC (2p24) SpectrumGreen/CEP 2 SpectrumOrange Probe





The LSI N-MYC (2p24) probe contains unique DNA sequences specific to the N-MYC oncogene (HUGO name MYCN) located within the 2p24 region of chromosome 2. This probe may be used to detect the MYCN oncogene copy number.

The LSI N-MYC (2p24)/CEP 2 (2p11.1-q11.1) Dual ColorProbe Set is a mixture of LSI N-MYC (2p24) labeled with SpectrumGreen and CEP 2 (2p11.1-q11.1) labeled with SpectrumOrange. The LSI N-MYC (2p24) SpectrumGreen probe is an approximately 200 kb probe that hybridizes to the 2p24 region on chromosome 2 and contains sequences that flank both 5' and 3' ends of the MYCN gene. The CEP 2 (2p11.1-q11.1) SpectrumOrange probe hybridizes to alpha satellite sequences specific to chromosome 2.



An abnormal sample hybridized with the LSI N-MYC (2p24)/CEP 2 (2p11.1-q11.1) Dual Color Probe showing a high level of amplification of the N-MYC oncogene.

Results of Hybridization

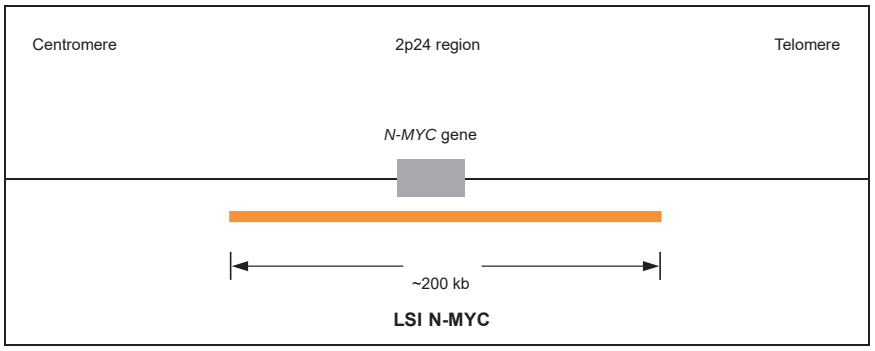
In a normal cell with two intact copies of chromosome 2, two green and two orange signals will be observed. In an abnormal cell containing amplification of the MYCN oncogene, greater than two green signals will be observed.

Ordering Information	Quantity	Order No.
Vysis LSI N-MYC (2p24) SpectrumGreen/ CEP 2 SpectrumOrange Probe	20 µl	07J72-001

References

1. Brodeur, GM (2003) Nat Rev Cancer 3: 203-216.
2. Brodeur, GM et al. (1984) Science 224: 1121-1124.
3. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed.
4. Maris, J., et al. (1999) J Clin Oncol 17: 2264-2279.
5. Schwab, M. (2002) Ann NY Acad Sci 963: 63-73.
6. Seeger, RC et al. (1985) NEJM 313:1111-1116.

Vysis LSI N-MYC (2p24) SpectrumOrange Probe



The LSI N-MYC (2p24) Probe contains unique DNA sequences specific to the N-MYC (HUGO name MYCN) oncogene located within the 2p24 region of chromosome 2. This probe may be used to detect the MYCN oncogene copy number.

The N-MYC (2p24) Probe is an approximately 200 kb SpectrumOrange labeled probe.

Results of Hybridization

In a normal cell, the expected pattern for a nucleus hybridized with the LSI MYCN Probe is the two orange (2O) signal pattern. In an abnormal cell containing amplification of the MYCN oncogene, greater than two orange signals will be observed.

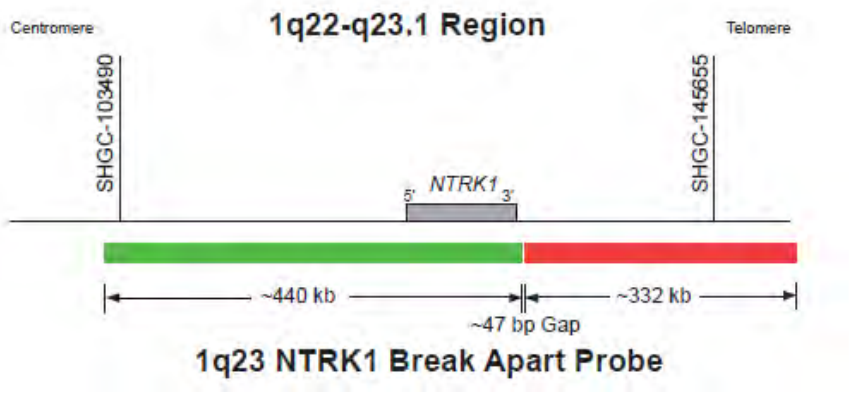
LSI N-MYC Probe hybridized to an abnormal cell showing a high level of amplification of the N-MYC oncogene.

Ordering Information	Quantity	Order No.
Vysis LSI N-MYC (2p24) SpectrumOrange Probe	20 µl	05J50-001

References

1. Heim, S., et al. Cancer Cytogenetics 2nd ed. (1995): 377.

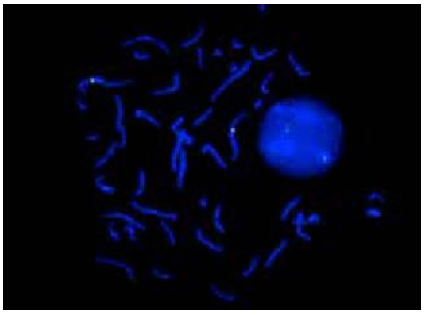
Vysis 1q23 NTRK1 Break Apart FISH Probe



PRODUCT DESCRIPTION

The 1q23 NTRK1 (Tel) SpectrumRed probe is approximately 332 kb in size and is positioned telomeric of the NTRK1 gene.

The 1q23 NTRK1 (Cen) SpectrumGreen probe is approximately 440 kb in size and contains the entire NTRK1 gene.

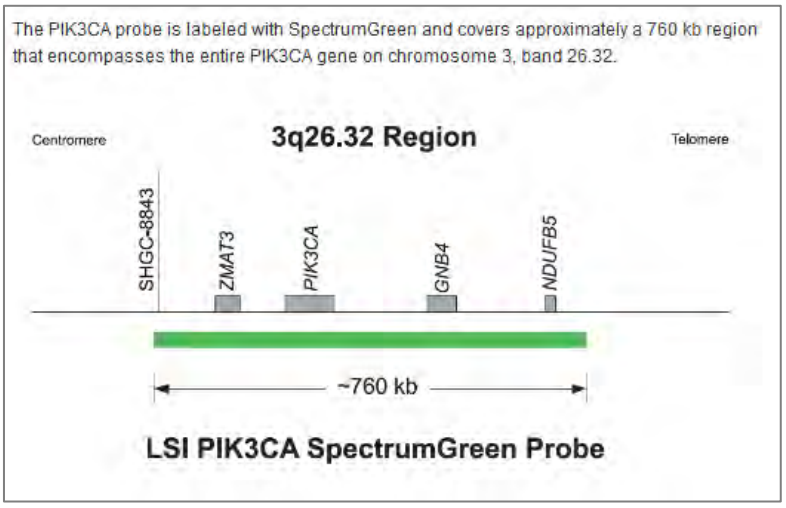


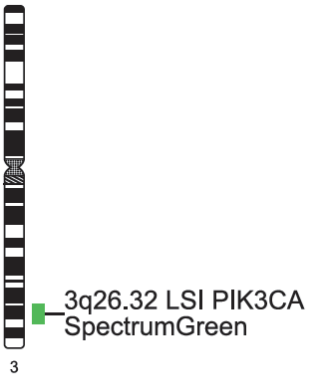
RESULTS OF HYBRIDIZATION

The signal pattern observed in cells containing the NTRK1 rearrangement is the expected pattern of at least one green/red (yellow) fusion signal. In addition, a single green (1G) and a single red (1R) may also be also visible.

PRODUCT	QUANTITY	ORDER #	GTIN
Vysis LSI NTRK1 Break Apart FISH Probe Kit **(RUO)**	20 µL	08N43-60	00884999042612

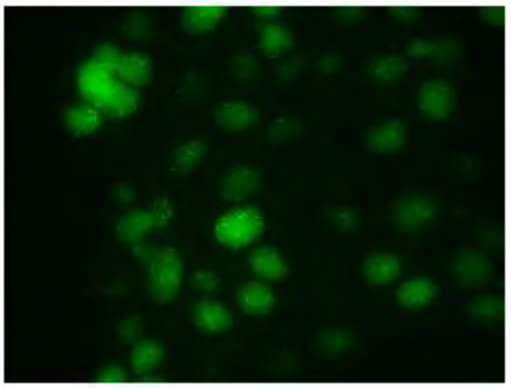
Vysis PIK3CA SpectrumGreen FISH Probe Kit





The Vysis PIK3CA SpectrumGreen FISH Probe Kit is designed to detect copy number of 3q26.32 via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded (FFPE) lung cancer tissue.

The PIK3CA gene locus has been shown to be frequently amplified in many cancers, including lung, ovarian, cervical, gastric, colorectal, breast, head and neck [1-3].



Results of Hybridization

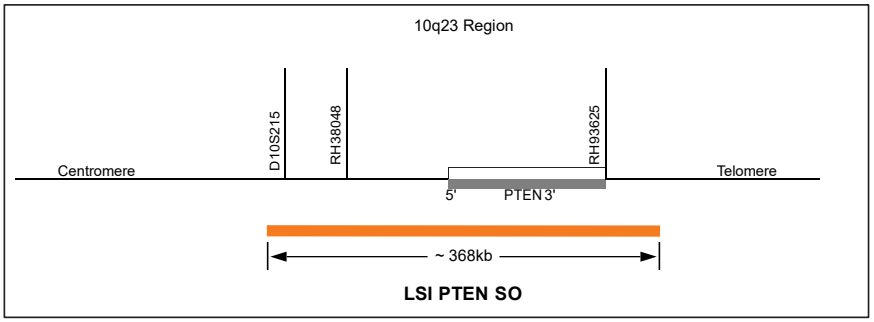
Normal diploid nuclei are expected to exhibit two green fluorescent PIK3CA signals. A chromosome set that has an extra copy (copies) of PIK3CA will exhibit more than two green fluorescent signals.

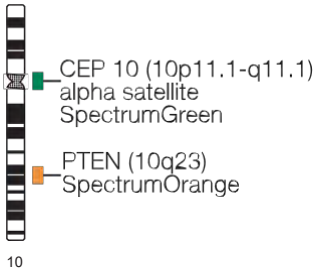
Ordering Information	Quantity	Order No.
Vysis PIK3CA SpectrumGreen FISH Probe Kit	20 µl	06N10-020

References

1. Angulo B, Suarez-Gauthier A, Lopez-Rios F, et al. Expression signatures in lung cancer reveal a profile for EGFR-mutant tumours and identify selective PIK3CA overexpression by gene amplification. J Pathol. 2008;214(3):347–356.
2. Shayesteh L, Lu Y, Kuo WL, et al. PIK3CA is implicated as an oncogene in ovarian cancer. Nat Genet. 1999;21(1):99–102.
3. Psyrri A, Papageorgiou S, Liakata E, et al. Phosphatidylinositol 3′-kinase catalytic subunit alpha gene amplification contributes to the pathogenesis of mantle cell lymphoma. Clin Cancer Res. 2009;15(18):5724–5732.

Vysis PTEN/CEP 10 FISH Probe Kit





The gene for the phosphatase and tensin homolog (PTEN) on chromosome 10q23 is mutated in a wide range of human cancers with comparable frequency to the gene for p53.[1] The PTEN tumor suppressor gene is mutated in multiple cancers that undergo 10q loss. The PTEN gene encodes a lipid phosphatase that negatively regulates the phosphoinositol-3-kinase/Akt pathway.[2] Allelic loss of chromosome 10q is one of the most common events in gliomas.[3]

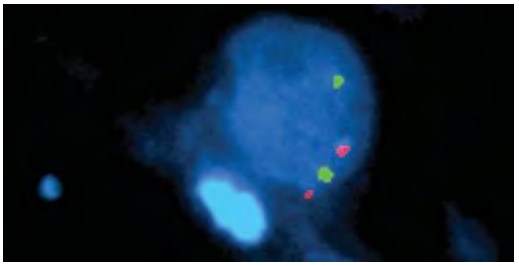
The Vysis LSI PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes performed successfully in several cytogenetic studies to detect losses of the PTEN gene.[4–8] Evaluation of this probe set in a study using diffusely infiltrating astrocytoma samples from 159 patients correlated significantly with histological grade. The clinical findings emphasized the utility of combining histological interpretation and molecular testing.[4] Korshunov et al. successfully used the Vysis PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes and Vysis FISH probes for other relevant markers (EGFR, CDKN2A, 1p/19q) to obtain clinically useful information for 114 morphologically ambiguous high-grade gliomas composed small cells.[5] Another study using the Vysis FISH probes for PTEN and EGFR, including biopsy-proved tissue samples from 63 anaplastic astrocytoma and 111 glioblastoma multiforme cases, demonstrated the clinical significance of both markers.[6]

Vysis LSI PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes are provided in one vial as a mixture of LSI PTEN (10q23) probe, labeled with SpectrumOrange, and the CEP 10 probe, labeled with SpectrumGreen. The LSI PTEN (10q23) SpectrumOrange Probe is a ~368 kb probe that hybridizes to the 10q23 region on chromosome 10 and contains sequences that flank both the 5' and 3' ends of the PTEN gene. The CEP 10 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 10.

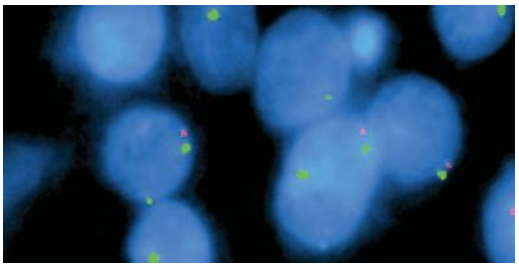
Results of Hybridization

In a normal cell with two intact copies of chromosome 10, two green and two orange signals will be observed. In an abnormal cell with a deletion of the PTEN (10q23) gene region, fewer than two orange signals will be observed.

Ordering Information	Quantity	Order No.
Vysis PTEN/CEP 10 FISH Probe Kit	20 µl	04N62-020



Result of the hybridization of the LSI PTEN (10q23)/ CEP10 Dual Color Probe as observed in normal interphase cells. (Photo courtesy of Dr. Arie Perry, Washington University.)



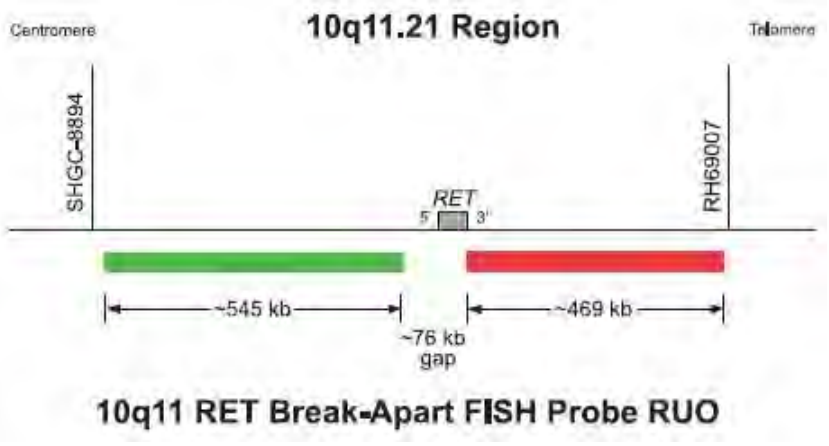
An abnormal cell hybridized with the LSI PTEN (10q23)/ CEP10 Dual Color Probe. The cell in this image shows the one orange, two green signal pattern indicative of a PTEN (10q23) deletion. (Photo courtesy of Dr. Arie Perry, Washington University.)

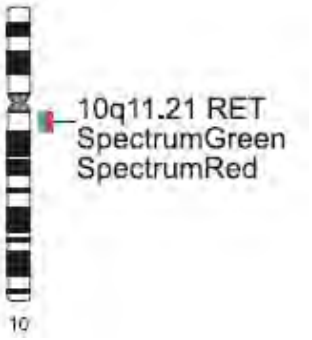
References

1. Goberdhan DCI, Wilson C. PTEN: tumour suppressor, multifuctional growth regulator and more. Hum Mol Genet. 2003;12(2):239-248.
2. Eng C. PTEN: One gene, many syndromes. Hum Mutat. 2003;22(3):183-198.
3. Sasaki H, Zlatescu MC, Betensky RA, et al. PTEN is a target of chromosome 10q loss in anaplastic oligodendrogliomas and PTEN alterations are associated with poor prognosis. Am J Pathol. 2001;159(1):359-367.
4. Mott RT, Turner KC, Bigner DD, et al. Utility of EGFR and PTEN numerical aberrations in the evaluation of diffusely infiltrating astrocytomas. J Neurosurg. 2008;108(2):330-335.
5. Korshunov A, Sycheva R, Golanov A. Molecular stratification of diagnostically challenging high-grade gliomas composed of small cells: The utility of Fluorescence In situ hybridization. Clin Cancer Res. 2004;10(23):7820-7826.
6. Smith JS, Tachibana I, Passe SM, et al. PTEN mutation, EGFR amplification, and outcome in patients with anaplastic astrocytoma and glioblastoma multiforme. J Natl Cancer Inst. 2001;93(16):1246-1256.
7. Pollack IF, Hamilton RL, James CD, et al. Rarity of PTEN deletions and EGFR amplification in malignant gliomas of childhood: results from the Children's Cancer Group 945 cohort. J Neurosurg. 2006;105(5 suppl):418-424.
8. Korshunov A, Sycheva R, Golanov A. The prognostic relevance of molecular alterations in glioblastomas for patients age < 50 years. Cancer. 2005;104(4):825-832.
9. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice.

Genet Med. 2006;8(1):16-23.

Vysis 10q11.21 RET Break Apart FISH Probe

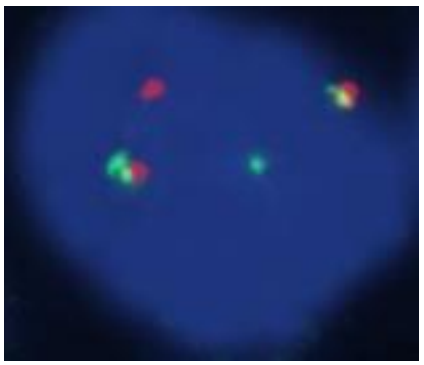




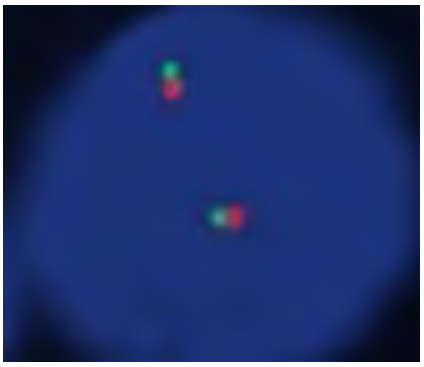
PRODUCT DESCRIPTION

The 10q11 RET (Tel) SpectrumRed probe is approximately 469 kb in size and is positioned telomeric of the RET gene.

The 10q11 RET (Cen) SpectrumGreen probe is approximately 545 kb in size and is positioned centromeric of the RET gene.



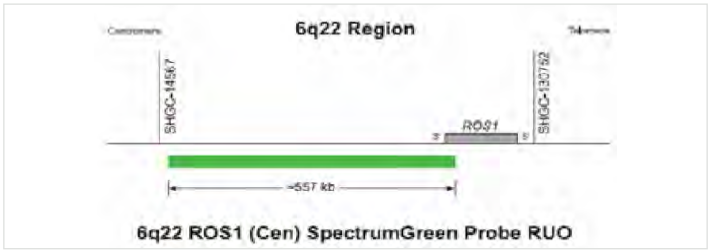
Positive

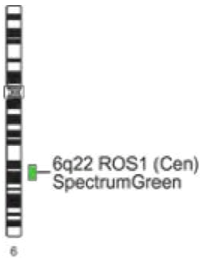


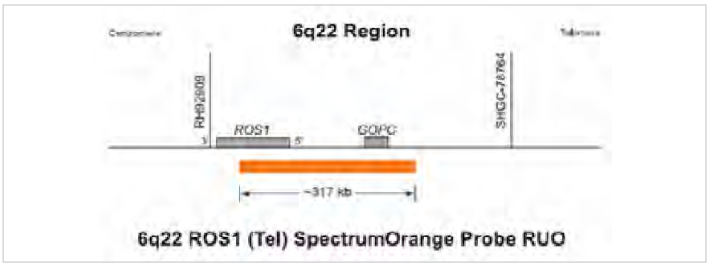
Negative

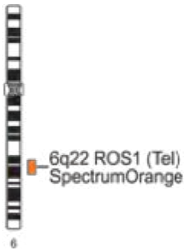
PRODUCT	QUANTITY	ORDER #	GTIN
Vysis 10q11 RET Break-Apart FISH Probe **(RUO)**	20 µL	08N31-060	00884999038097

Vysis 6q22 ROS1 Break Apart FISH Probe









PRODUCT DESCRIPTION

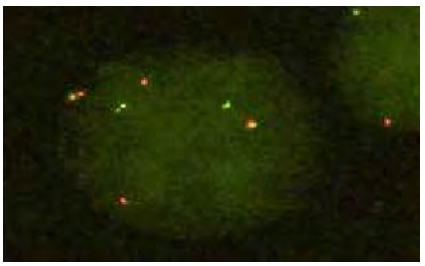
6q22 ROS1 Break Apart FISH Probe RUO Kit is comprised of two probes necessary to identify ROS1 genetic rearrangements. The SpectrumOrange 6q22 ROS1 (Tel) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 317 kb in size and positioned telomeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes. The SpectrumGreen Vysis LSI ROS1 (Cen) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6.

The probe is approximately 557 kb in size and positioned telomeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

The 6q22 ROS1 Break Apart FISH Probe RUO Kit is available for Research Use Only (RUO), and not for use in diagnostic procedures.

RESULTS OF HYBRIDIZATION

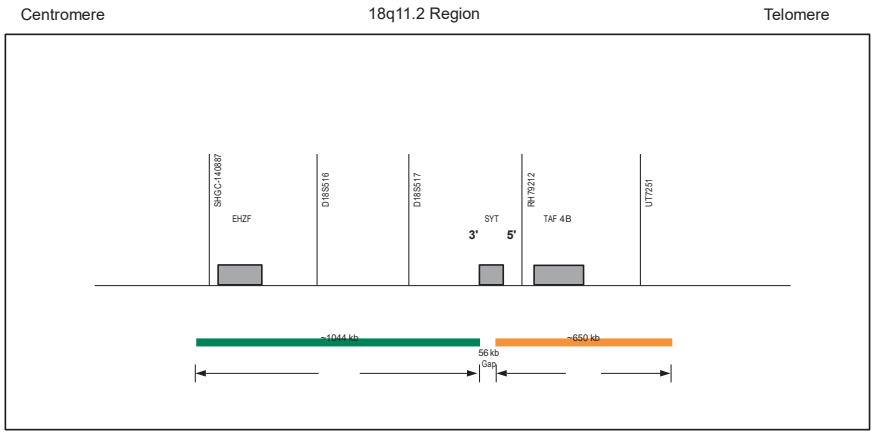
The signal pattern observed in a cell line containing the ROS1 rearrangement is the expected pattern of at least one green/orange (yellow) fusion signal. In addition, a single green (1G) and a single orange (1O) is also visible.



PRODUCT	QUANTITY	ORDER #	GTIN
Vysis 6q22 ROS1 Break Apart FISH Probe **(RUO)**	20 µL	08N29-020	00884999037892

Vysis SS18 Break Apart FISH Probe Kit

previously: Vysis LSI SYT (18q11.2) Dual Color, Break Apart Rearrangement Probe

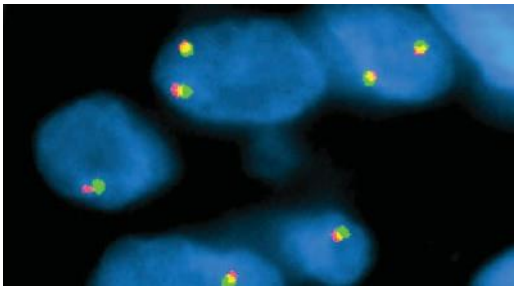


Chromosomal rearrangements involving the SS18 gene located in the breakpoint region of chromosome 18q11.2 are common among synovial sarcoma soft tissue tumors.[1] Several studies have indicated that the t(X;18)(p11.2;q11.2) translocation arises exclusively in synovial sarcoma (SS).[2] Hybridization with the Vysis LSI SS18 (18q11.2) Dual Color, Break Apart Rearrangement probe will identify t(18q11.2) but not the specific translocation partner.

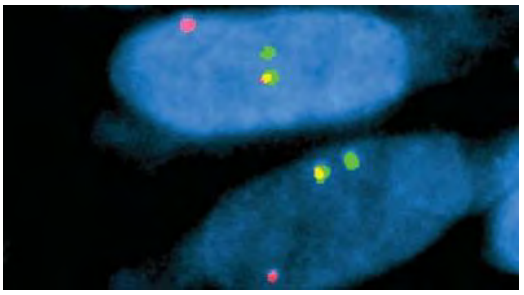
The LSI SS18 Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, an ~650 kb probe labeled in SpectrumOrange, extends distally from the SS18 gene. The second probe labeled in SpectrumGreen lies 3' or proximal to the SS18 gene and is approximately ~1040 kb in length.

Results of Hybridization

In a normal cell that lacks a t(18q11.2) in the SS18 gene region, a two fusion signal pattern will be observed, reflecting the two intact copies of SS18. In an abnormal cell with a simple t(18q11.2), a one fusion, one green and one orange signal pattern will be expected.



Result of the hybridization of the LSI SS18 Break Apart FISH Probe showing the two fusion signal pattern as observed in normal interphase cells. (Photo courtesy of Arie Perrry, M.D., Washington University School of Medicine.)



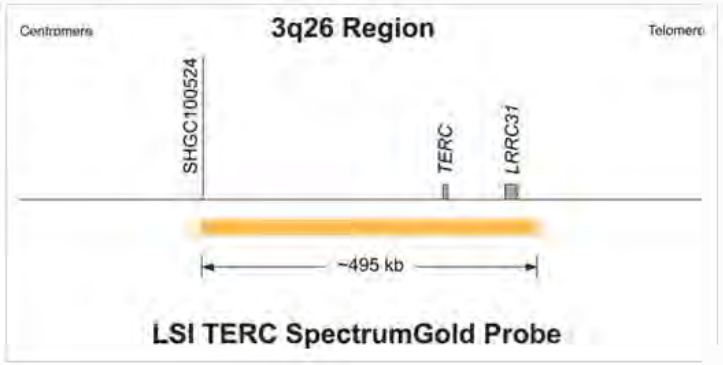
Abnormal cells hybridized with the LSI SS18 Dual Color, Break Apart Rearrangement Probe. The cells in this image show the one fusion, one orange and one green signal pattern indicative of a rearrangement of one copy of the SYT gene region. (Photo courtesy of Arie Perry, M.D., Washington University School of Medicine.)

Ordering Information	Quantity	Order No.
Vysis SS18 Break Apart FISH Probe Kit	20 µl	03N61-020

References

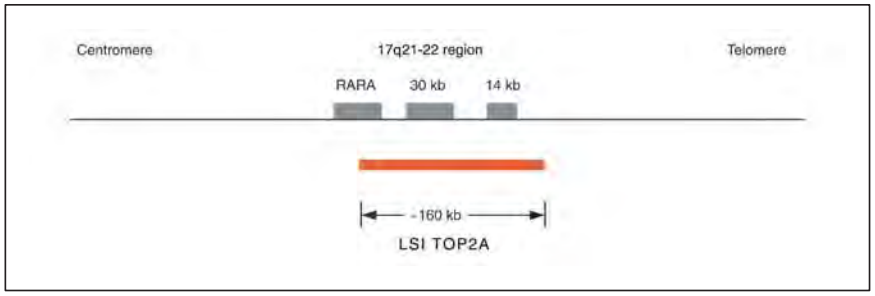
1. Sandberg A., et al. Cancer Genetics and Cytogenetics 133 (2002): 1-23.
2. Dos Santos N., et al.Genes, Chromosomes and Cancer 30 (2001): 1-14.
3. Terry J., et al. Diagnostic Molecular Pathology 2005;14(2):77-82.
4. Ten Heuvel SE, et al. Applied Immunohistochemistry & Molecular Morphology 2008;16(3):246-250.
5. Laza A, et al. Archives of Pathology and Laboratory Medicine 2006;130:1199-1207.
6. Subramaniam MM., et al. Cancer Genetics and Cytogenetics 2007;172:23-28.
7. Amary MFC, et al. Modern Pathology 2007;20:482-496.

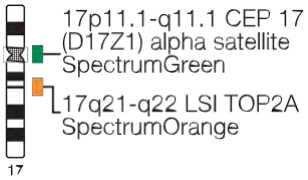
Vysis TERC SpectrumGold Probe



Ordering Information	Quantity	Order No.
Vysis TERC SpectrumGold Probe	20 µl	02N11-030

Vysis TOP2A/CEP 17 FISH Probe Kit





The TOP2A gene, located at 17q21-q22 encodes topoisomerase II

Results of Hybridization

In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present

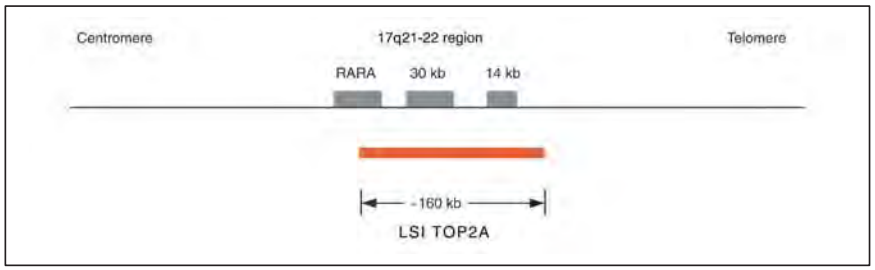
Ordering Information	Quantity	Order No.
Vysis TOP2A/CEP 17 FISH Probe Kit	200 µl*	03N89-020

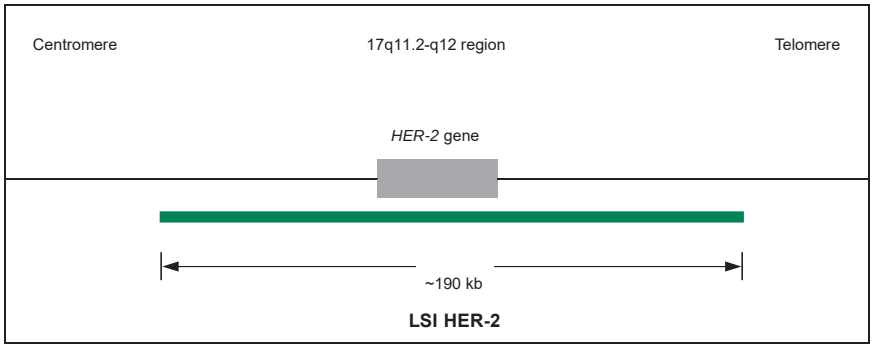
* premixed with Hybridization Buffer

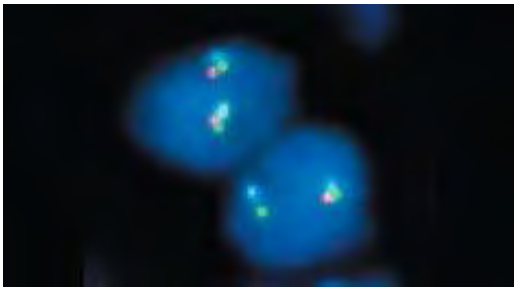
References

1. Tsai-Pflugfelder M, et al. Proceedings of the National Academy of Sciences 1988;85(19):7177-7181.
2. Chen AY, Liu LF. Annu Rev Pharmacol Toxicol 1994;34:191-218.
3. Capranico G, et al. Biochemistry 1990;29(2):562-569.
4. Arriola E, et al. Breast Cancer Research Treatment 2007;106:181-189.
5. Nielsen KV, et al. Acta Oncologica 2008;4(47):725-734.
6. Smith K, et al. Oncogene 1993;8(4):933-938.
7. Beser AR, et al. Pathology Oncology Research 2007;13(3):180-185.
8. Hicks DG, et al. Human Pathology 2005;36:348-356.
9. Wiktor AE, et al. Genetics in Medicine 2006;8(1):16-23.

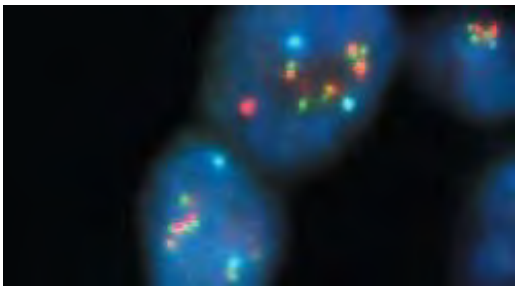
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit







Result of the hybridization of the TOP2A/HER-2/CEP 17 probe as observed in two normal interphase cells. In the nucleus located in the upper left, two copies of each of the three probes are observed: orange (TOP2A), green (HER-2), and aqua (CEP 17). The lower right nucleus exhibits normal hybridization results for LSI HER-2 and CEP 17 but is lacking one TOP2A signal.



Abnormal cells hybridized with the TOP2A/HER-2/CEP 17 probe. The cells in this image show amplification of both TOP2A (orange signals) and HER-2 (green signals) as indicated by multiple signals of each color. Aqua signals from the CEP 17 probe indicate that chromosome 17 is present in the normal quantity (two copies).

The TOP2A gene, located at 17q21-q22 encodes topoisomerase II-α, a key enzyme in DNA replication, cell cycle progression, and chromosome segregation.[1, 2] As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors.[3] The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors.[4, 5] The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. The TOP2A gene has also been shown to be co-amplified with HER-2 in cell lines and in human breast cancers.[6]

The Vysis Locus Specific Identifier (LSI) TOP2A SpectrumOrange/HER-2 SpectrumGreen/CEP17 SpectrumAqua Probe Set utilizes locus specific probes for TOP2A and HER-2 as well as chromosome 17 centromeric probe. Each probe is labeled with a different fluorophore to allow accurate enumeration of each locus within individual nuclei. Simultaneous enumeration of all three probes reveals the copy number gains or losses of HER-2 and TOP2A relative to the copy number of chromosome 17. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi color probe.

TOP2A and HER-2 gene status is of interest since topoisomerase II-α is a molecular target of anthracycline drugs and HER-2 is targeted by several small molecule tyrosine kinase inhibitors as well as antibodies against the HER-2 receptor protein. Beser et al. used the Vysis TOP2A/HER-2/CEP17 FISH Probe Kit to examine the frequency of TOP2A amplification and deletion relative to the HER-2 gene status and chromosome 17 aneusomy in a series of 50 breast tumors.[7] Hicks et al. used the same probe set to similarly document the relationship between TOP2A and HER-2 genomic alterations and chromosome 17 aneusomy in 138 breast cancers.[8]

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Continuation:
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit

LSI TOP2A is a single ~160 kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene. In both products, the probe is directly labeled with SpectrumOrange. The HER-2 probe that spans the entire HER-2 gene at 17q11.2-q12 is an an ~190 kb unique sequence probe. In the LSI TOP2A/HER-2/CEP 17 product, this probe is directly labeled with SpectrumGreen. The The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen or SpectrumAqua SpectrumAqua in the LSI TOP2A/ CEP 17 and LSI TOP2A/HER-2/CEP 17 products, respectively.

Results of Hybridization
A nucleus with a normal quantity (two copies) of HER-2 will appear with two green signals. In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occurred, more or less than two signals will be present. Simultaneous enumeration of all three probes will reveal the copy number of each as well as the amplification or deletion status of TOP2A and HER-2 relative to chromosome 17 copy number. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

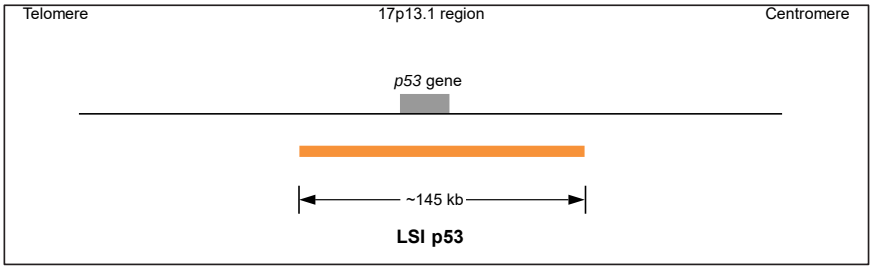
Ordering Information	Quantity	Order No.
Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit	200 µl*	03N90-020

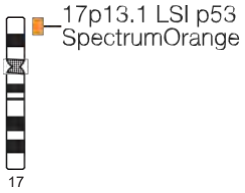
* premixed with Hybridization Buffer

References

1. Sandberg A., et al. Cancer Genetics and Cytogenetics 133 (2002): 1-23.
2. Dos Santos N., et al.Genes, Chromosomes and Cancer 30 (2001): 1-14.
3. Terry J., et al. Diagnostic Molecular Pathology 2005;14(2):77-82.
4. Ten Heuvel SE, et al. Applied Immunohistochemistry & Molecular Morphology 2008;16(3):246-250.
5. Laza A, et al. Archives of Pathology and Laboratory Medicine 2006;130:1199-1207.
6. Subramaniam MM., et al. Cancer Genetics and Cytogenetics 2007;172:23-28.
7. Amary MFC, et al. Modern Pathology 2007;20:482-496.

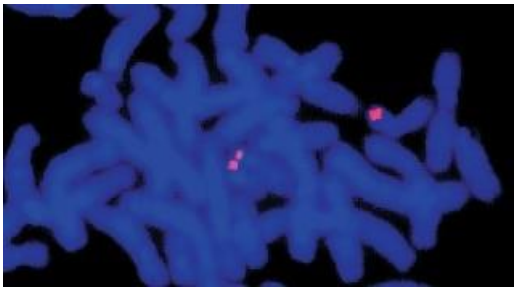
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe





The LSI TP53 probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene (HUGO name TP53). The ability to use FISH probes such as the LSI TP53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the TP53 locus.

The LSI TP53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.



LSI TP53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

Results of Hybridization

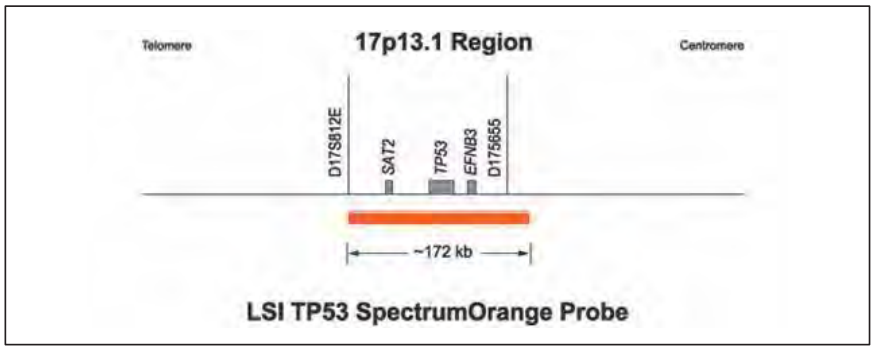
In a normal cell the two orange (2O) signal pattern is observed. In a cell containing a deletion of the LSI TP53 locus, one orange LSI TP53 signal will be observed (1O signal pattern). In a cell harboring amplification of the TP53 locus multiple copies of the orange signal will be observed.

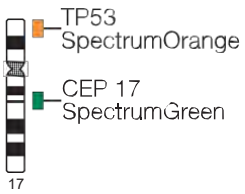
Ordering Information	Quantity	Order No.
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020

References

1. Döhner H, Fischer K, Bentz M, et al. p53 gene deletion predicts for poor survival and non-response to therapy with purine analogs in chronic B-cell leukemias. Blood 1995;85(6):1580-89.
2. Döhner H, Stilgenbauer S, Benner A, et al. Genomic aberrations and survival in chronic lymphocytic leukemia., N Eng J Med 2000;343:1910-16.
3. Lozanski G, Heerema NA, Flinn IW, et al. Alemtuzumab is an effective therapy for chronic lymphocytic leukemia with p53 mutations and deletions. Blood 2004;103(9)3278-81.
4. Byrd JC, Gribben JG, Peterson BL, et al. Select high-risk genetic features predict earlier progression following chemoimunnotherapy with fludarabine and rituximab in chronic lymphocytic leukemia: justification for risk-adapted therapy. J Clin Oncol 2006;24:437-43.
5. Drach J, Ackermann J, Fritz E, et al. Presence of a p53 gene deletion in patients with multiple myeloma predicts for short survival after conventional-dose chemotherapy. Blood 1998;92(3):802-09.
   Fonseca R, Blood E, Rue M, et al. Clinical and biologic implications of recurrent genomic aberrations in myeloma. Blood 2003;101(11):4569-75.
6. Chang H, Qi C, Yi QL, et al. p53 gene deletion detected by fluorescence in situ hybridization is an adverse prognostic factor for patients with multiple myeloma following autologous stem cell transplantation. Blood 2005;105(1):358-360.
7. Fink SR, Smoley SA, Stockero KJ, et al. Loss of TP53 is due to rearrangements involving chromosome region 17p10-p12 in chronic lymphocytic leukemia. Cancer Genet Cytogenet 2006;167:177-81.
8. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med 2006;8:16-23.

Vysis LSI TP53/CEP 17 FISH Probe Kit



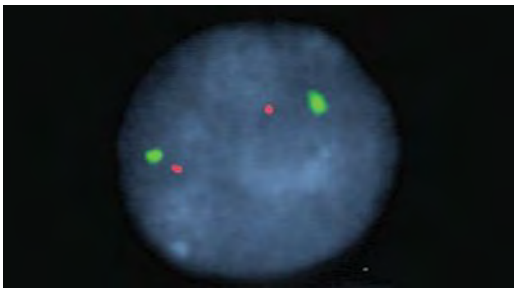


The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

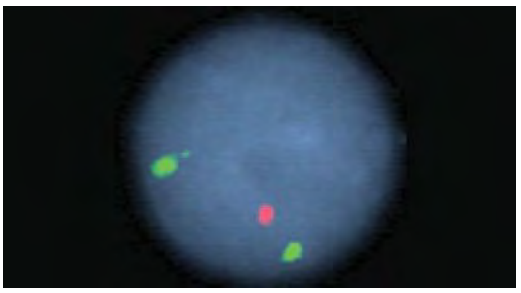
A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma.[1, 2] The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.[3, 4, 5]

Results of Hybridization

In a normal cell, the expected results for a nucleus hybridized with the LSI TP53 SpectrumOrange/CEP 17 SpectrumGreen Probe is a two orange and two green signal pattern.



Normal nucleus showing the two green and two orange signals.



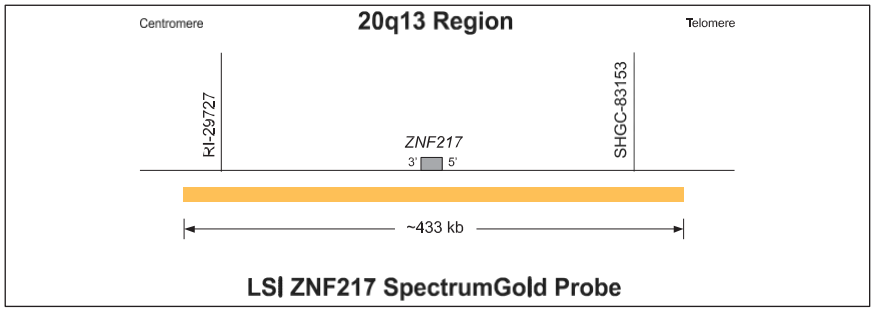
Abnormal nucleus showing the two green and one orange signal.

Ordering Information	Quantity	Order No.
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020

References

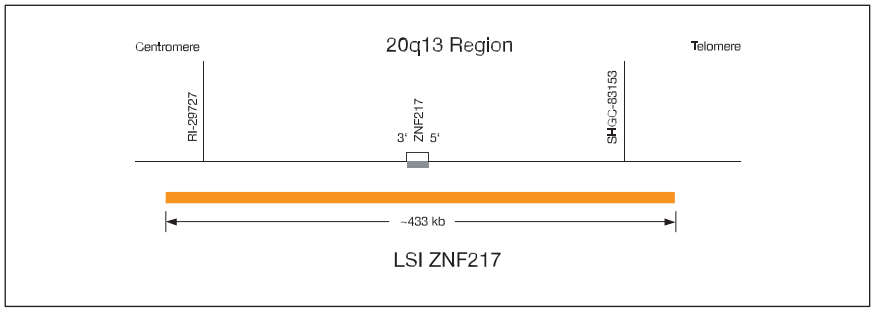
1. Shanafelt T, Geyer SM, and Kay NE. Blood. 2004;103(4):1202-10.
2. Avet-Loiseau H, Attal M, Moreau P, et al. Blood. 2007;109(8):3489-95.
3. Dewald GW, Brockman SR, Paternoster SF, et al. Br J Haematol. 2003;121:287-95.
4. Grever MR, Lucas DM, Dewald GW, et al. J Clin Oncol. 2007;25(7):799-804.
5. Fonseca R, Blood E, Rue M, et al. Blood. 2003;101(11):4569-75.

Vysis ZNF217 SpectrumGold FISH Probe Kit

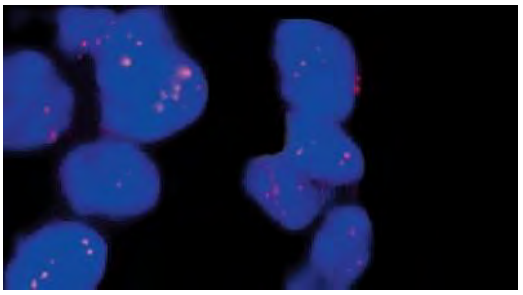


Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumGold FISH Probe Kit	20 µl	05N15-020

Vysis ZNF217 SpectrumOrange FISH Probe Kit

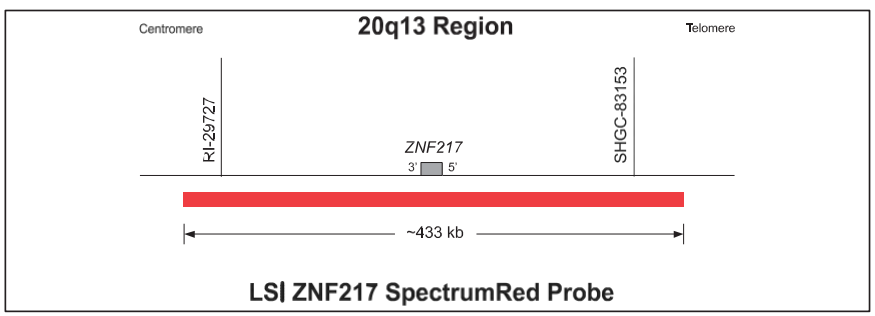


Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumOrange FISH Probe Kit	20 µl	03N91-020



LSI ZNF217 (20q13.2) SpectrumOrange hybridized to abnormal cells. Note multiple orange-pink signals contained within some cells indicate amplification of the ZNF217.

Vysis ZNF217 SpectrumRed FISH Probe Kit



Ordering Information	Quantity	Order No.
Vysis ZNF217 SpectrumRed FISH Probe Kit	10 µl	05N16-010

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Continuation:
Vysis ZNF217 SpectrumGold, SpectrumOrange & SpectrumRed FISH Probe Kit

The ZNF217 gene is a candidate oncogene suggested to play a key role during neoplastic transformation. ZNF217 is located at 20q13, a region that is frequently amplified in a variety of tumor types.[1–6] Amplification of ZNF217 in breast cancer is associated with aggressive tumor behaviour and poor clinical prognosis.[7]

The Vysis LSI ZNF217 (20q13.2) SpectrumOrange Probe was used in a study that indicated distinct differences in the role of genes known to be amplified in female breast cancer and their relevance for the pathogenesis of male breast cancer. In another study, fluorescence in situ hybridization was performed on 128 male breast tumors using the Vysis Spectrum- Orange LSI ZNF217 in addition to other Vysis probes including, LSI HER-2, LSI CCND1, LSI MYC, and the corresponding centromeric probes to
evaluate the frequencey of amplification of the genes in MBC.[8] A third study used the Vysis LSI ZNF217 SpectrumOrange** Probe to identify gain
of ZNF217 as an important abnormality and prognostic factor in larynx tumorigenesis. For this study a tissue microarray consisting of 863 larynx carcinomas was analysed.[9]

The Vysis LSI ZNF217 SpectrumRed Probe is a single approximately
433 kb unique sequence probe direct labeled in SpectrumRed,
that hybridizes to the 20q13.2 region of chromosome 20 and includes the 17.5 kb ZNF217 gene.

** Vysis LSI ZNF217 SpectrumOrange Probe was used in studies, which
are referenced here. Vysis LSI ZNF217 SpectrumRed Probe hybridizes to the same sequence as the Vysis LSI ZNF217 SpectrumOrange Probe, but labeled with SpectrumRed Fluorophore.

Results of Hybridization
When hybridized with the LSI ZNF217 Probe, a normal cell containing two copies of the 20q13.2 region will exhibit two signals. In a cell harboring amplification of the ZNF217 gene or 20q13.2 region, multiple copies of the gold, orange or red signal will be observed.

References
1. Collins C, Rommens JM, Kowbel D, et al. Proceedings of the National Academy of Sciences USA 1998;95:8703-8708.
2. Yang SH, Seo MY, Jeong HJ, et al. Clinical Cancer Research 2005;11:612-620.
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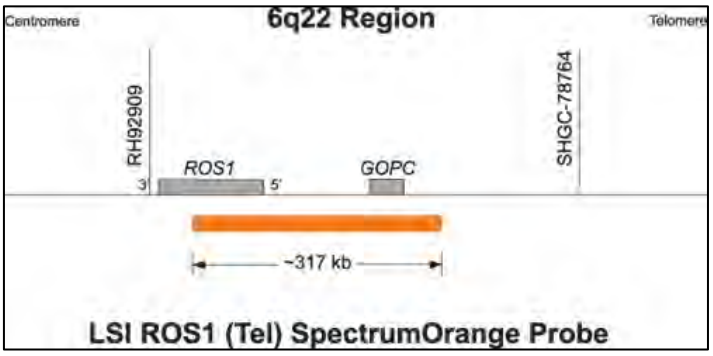
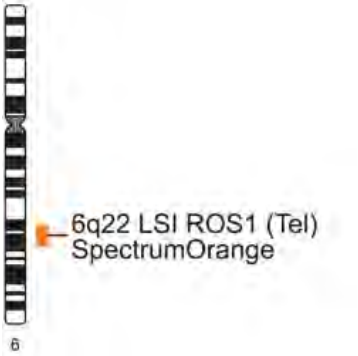
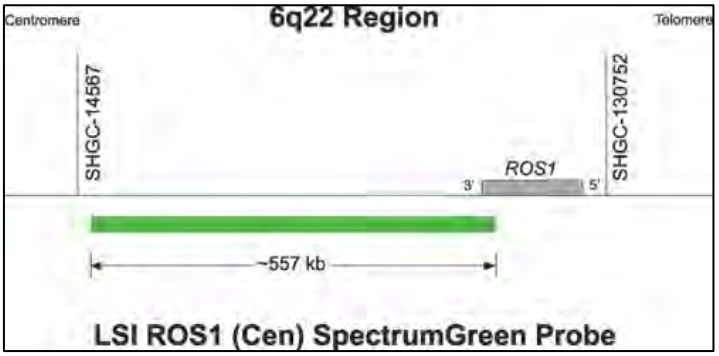
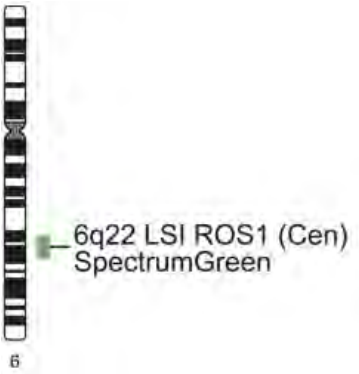
8. Bärlund M, Kuukasjärvi T, Syrjäkoski K, et al. International Journal of Cancer 2004;111:968-971.
9. Koynova D, Tsenova V, Kunev K, et al. Biotechnology & Biotechnological Equipment 2006;128-131.
10. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genetics in Medicine 2006;8(1):16-23.

LSI ROS1 (Tel) SpectrumOrange and LSI ROS1 (Cen) SpectrumGreen Probe







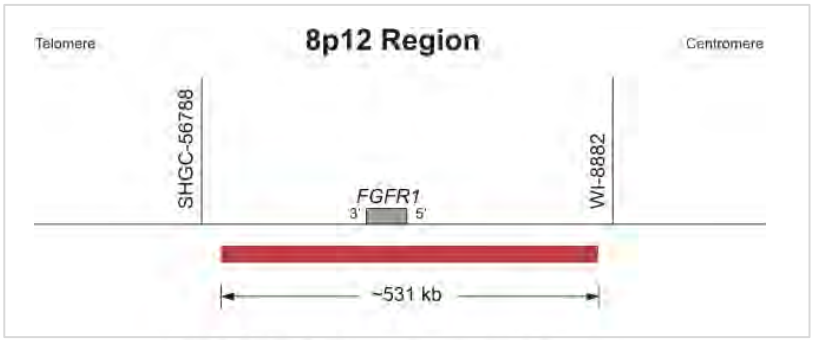


The SpectrumOrange Vysis LSI ROS1 (Tel) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 317 kb in size and positioned telomeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

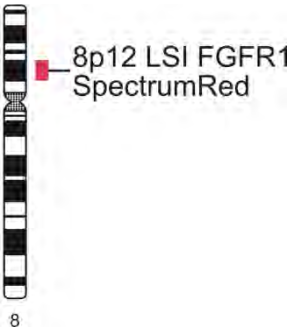
The SpectrumGreen Vysis LSI ROS1 (Cen) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 557 kb in size and positioned centromeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

Ordering Information	Quantity	Order No.
LSI ROS1 (Tel) SpectrumOrange Probe	20 uL	08N05-020
LSI ROS1 (Cen) SpectrumGreen Probe	20 uL	08N07-020

Vysis LSI FGFR1 SpectrumRed Probe



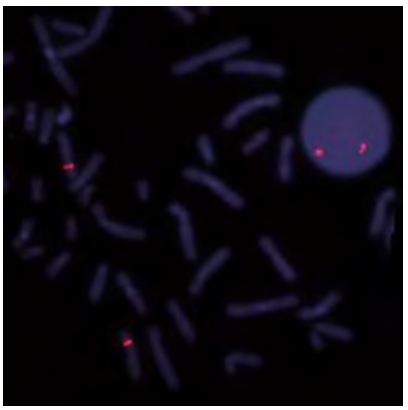
LSI FGFR1 SpectrumRed Probe



The FGFR1 gene encodes an FGFR tyrosine kinase that plays a crucial role in cell development and can be deregulated by the amplification of the FGFR1 gene. Amplification is seen in ~20% of Squamous Cell Carcinoma (SCC) of the lung, but is also seen in <2% of adenocarcinomas and 6% of Small Cell Lung Carcinoma (SCLC) (Dutt et al. 2011; Turner and Seckl 2010; Weiss et al. 2010).
The LSI FGFR1 SpectrumRed probe is ~531kb in length and spans the 8p12 region on chromosome 8.

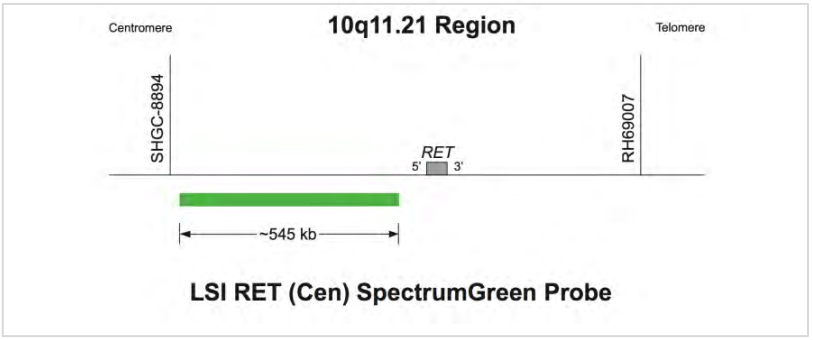
Results of Hybridization

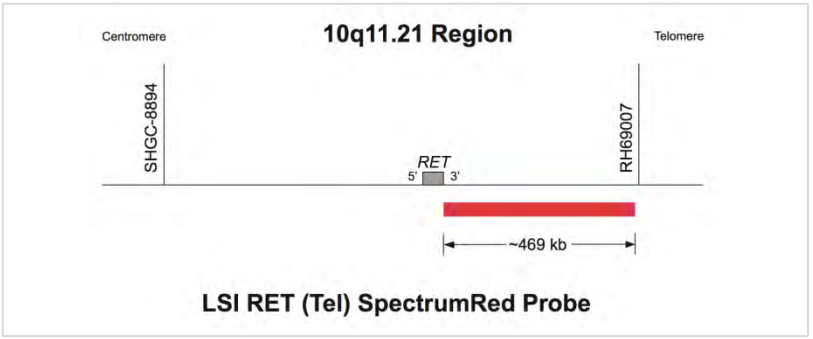
In a normal cell, the expected result is 2 red signals. In an abnormal cell the expected result is three or more red signals.

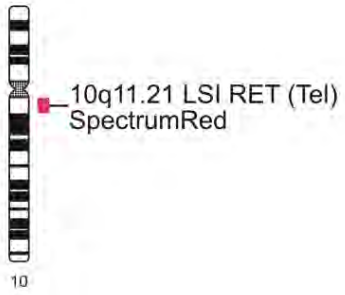


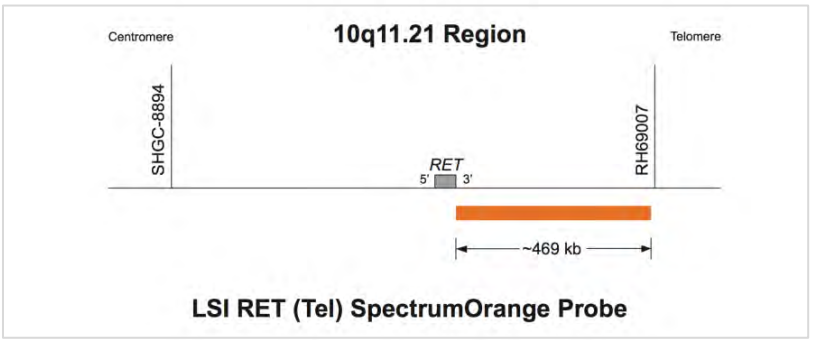
Ordering Information	Quantity	Order No.
Vysis LSI FGFR1 SpectrumRed Probe	20 test	08N21-020

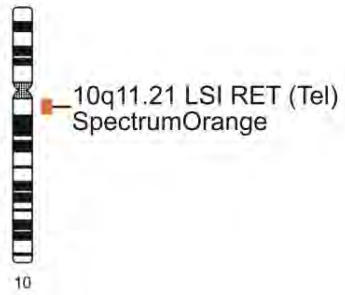
Vysis LSI RET Probes











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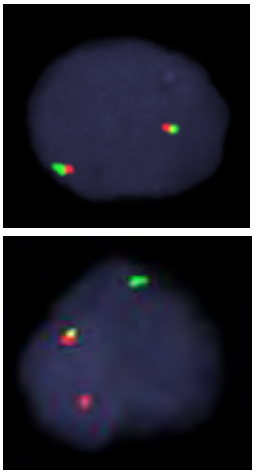
Continuation:
Vysis LSI RET Probes

The RET rearrangement encodes a receptor tyrosine kinase (RTK) belonging to the RET family of RTKs. Approximately 1-2% of lung tumours evaluated have chromosomal changes which lead to RET fusion genes (Ju et al. 2012; Kohno et al. 2012; Takeuchi et al. 2012; Lipson et al. 2012). These gene rearrangements appear to occur almost entirely in NSCLC, adenocarcinoma type histologic tumours. The RET fusion gene promotes increased cell growth and proliferation.
The LSI RET gene rearrangement probe is used in combination with either the LSI RET (Cen) SpectrumRed or the LSI RET (Cen) SpectrumOrange, targeted to the 10q11.21 region, with the LSI RET (Tel) SpectrumGreen probe targeted to the 10q11.21 region.

Results of Hybridization

In a normal cell, the expected result is 2 fusion signals when hybridized with a mixture of LSI RET SpectrumRed or LSI RET SpectrumOrange and LSI RET SpectrumGreen. In an abnormal cell the expected result is one fusion signal, one red (or Orange) signal and one green signal.



Result of the hybridization using the Vysis LSI RET SpectrumRed and the LSI RET SpectrumGreen Probe. Normal cells will have 2 fusion signals and an abnormal cell will have one fusion, one SR and one SG signal.

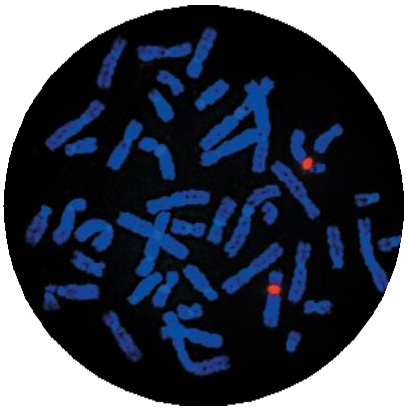
Ordering Information	Quantity	Order No.
Vysis LSI RET (Cen) SpectrumGreen Probe	20 uL	08N31-040
Vysis LSI RET (Tel) SpectrumRed Probe	20 uL	08N31-020
Vysis LSI RET (Tel) SpectrumOrange Probe	20 uL	08N31-030

Oncology

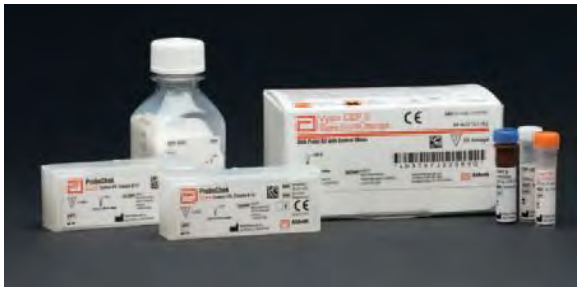
Hematology

Abbott Molecular offers a wide range of DNA Fluorescence *in situ* Hybridization (FISH) products for the effective and rapid identification of genetic aberrations associated with hematopoietic disorders. Used as single probes, or in multi-color probe sets, these products are designed to identify various chromosome translocations, deletions, chromosomal gains, as well as other rearrangements associated with specific hematopoietic disorders. These probes can be applied to a variety of sample types prepared for metaphase or interphase analysis.

Vysis FISH technology for hematological disorders provides the following advantages:



- Dual color, single fusion
  - Useful in detecting high percentages of cells possessing a specific chromosomal translocation.
  - The DNA probe hybridization targets are located on one side of each of the two genetic breakpoints.
- ES (Extra Signal)
  - Reduces the frequency of normal cells exhibiting an abnormal FISH pattern due to the random co-localization of probe signals in a normal nucleus.
  - One large probe spans one breakpoint, while the other probe flanks the breakpoint on the other gene.
- Dual color, break apart
  - Useful in cases where there may be multiple translocation partners associated with a known genetic breakpoint.
  - This labeling scheme features two differently colored probes that hybridize to targets on opposite sides of a breakpoint in one gene
- Dual color, dual fusion
  - Reduces the number of normal nuclei exhibiting abnormal signal patterns.
  - The probe offers advantages in detecting low levels of nuclei possessing a simple balanced translocation. Large probes span two breakpoints on different chromosomes



The CEP 8 DNA Probe Kit is FDA cleared for use as an adjunct to standard karyotyping to identify and enumerate chromosome 8 in interphase and metaphase cells obtained from bone marrow in three hours or less. The CEP 12 DNA Probe Kit is FDA cleared as an adjunct to standard karyotyping to identify and enumerate chromosome 12 in interphase nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (B-CLL) in 3 hours or less. The FDA Cleared CEP X/Y DNA Probe Kit may be used as an adjunct to standard karyotyping to evaluate engraftment success in recipients of sex mis-matched bone-marrow transplantation by determining the proportion of XX and XY donor cells. See the respective package insert for details on the use of these products.

Alphabetical Listing

Product description	Quantity	Order No.	Page Number
CEP 12 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-012	6-6
CEP 8 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-008	6-7
CEP X SpectrumOrange/CEP Y SpectrumGreen DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-050	6-8
Vysis 13q34 SpectrumGreen FISH Probe Kit previously: Vysis LSI (13q34) SpectrumGreen Probe	20 µl	05N34-020	6-9
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020	6-10
Vysis LSI 4q12 Tricolor Rearrangement Probe	20 µl	05N52-020	6-11
Vysis LSI 9q34 SpectrumAqua Probe	20 µl	05N53-020	6-12
Vysis LSI ATM (11q22) SpectrumOrange Probe	20 µl	01N33-020	6-13
Vysis LSI ATM/CEP 11 FISH Probe Kit previously: Vysis LSI ATM SpectrumOrange/CEP 11 SpectrumGreen Probe	20 µl	05N55-020	6-14
Vysis BCL2 Break Apart FISH Probe Kit previously: Vysis LSI BCL2 Dual Color, Break Apart Rearrangement Probe	20 µl	05N51-020	6-15
Vysis LSI BCL6 (ABR) Dual Color, Break Apart Rearrangement Probe	20 µl	01N23-020	6-16
Vysis BCR/ABL/ASS1 Tri-Color DF FISH Probe Kit previously: Vysis LSI BCR/ABL + 9q34 Tricolor, Dual Fusion Translocation Probe	20 µl	05N54-020	6-17
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	20 µl	08L10-001	6-19
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	50 µl	08L10-002	6-19
Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe	20 µl	08L56-050	6-20
Vysis LSI BCR/ABL ES Dual Color Translocation Probe	20 µl	08L55-020	6-21
Vysis BIRC3/MALT1 DF FISH Probe Kit previously: Vysis LSI API2/MALT1 t(11;18) (q21;q21) Dual Color, DF Translocation Probe	20 µl	05N50-020	6-22
Vysis CBFB Break Apart FISH Probe Kit previously: Vysis LSI CBFB Dual Color, Break Apart Rearrangement Probe	20 µl	05N44-020	6-24
Vysis CCND1 Break Apart FISH Probe Kit previously: Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe	20 µl	05N38-020	6-25
Vysis CCND1/CEP 11 FISH Probe Kit previously: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen	20 µl	03N88-020	6-26
Vysis CDKN2A /CEP 9 FISH Probe Kit previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe	20 µl	04N61-020	6-27
Vysis LSI CDKN2C SpectrumGreen/LSI CKS1B SpectrumOrange FISH Probe	20 µl	08N78-020	6-28
Vysis CSF1R/D5S23, D5S721 FISH Probe Kit previously: Vysis LSI CSF1R (5q33-q34) SpectrumOrange/D5S23, D5S721 SpectrumGreen Probe	20 µl	05N03-020	6-29
Vysis D13S25 (13q14.3) SpectrumOrange Probe	20 µl	01N37-020	6-30
Vysis D13S319/13q34 FISH Probe Kit	20 µl	05N37-020	6-31
Vysis D13S319 (13q314.3) SpectrumOrange Probe	20 µl	01N34-020	6-32
Vysis D20S108 FISH Probe Kit previously: Vysis LSI D20S108 (20q12) SpectrumOrange Probe	20 µl	05N02-020	6-33
Vysis LSI D5S23/D5S721, CEP9, CEP 15 Multi-color Probe	20 µl	05N35-020	6-34
Vysis D7S486/CEP 7 FISH Probe Kit previously: Vysis LSI D7S486 (7q31) SpectrumOrange / CEP 7 SpectrumGreen Probe	20 µl	05N07-020	6-35
Vysis D7S522/CEP 7 FISH Probe Kit previously: Vysis LSI D7S522 (7q31) SpectrumOrange / CEP 7 SpectrumGreen Probe	20 µl	05N08-020	6-36
Vysis LSI DEK/NUP214 Dual Color, Dual Fusion Translocation FISH Probe Kit	20 µl	09N24-060	6-37
Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Set	20 µl	08L68-020	6-38
Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe	20 µl	08L66-020	6-39
Vysis ETV6 Break Apart FISH Probe Kit previously: Vysis LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe	20 µl	04N09-020	6-40
Vysis LSI ETV6/RUNX1 DF FISH Probe Kit previously: VysisLSI TEL/AML1 ES Dual Color Translocation Probe	10 µl	05N96-010	6-41
Vysis IGH Dual Color, Break Apart Rearrangement Probe	20 µl	08L63-020	6-42

Quantities of 200 µl are prediluted with Hybridisation Buffer

Alphabetical Listing

Product description	Quantity	Order No.	Page Number
Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe	20 µl	08L60-020	6-43
Vysis IGH/CCND1 DF FISH Probe Kit previously: Vysis LSI IGH/CCND1 Dual Color, Dual Fusion Translocation Probe	20 µl	08L58-020	6-44
Vysis IGH/CCND1 XT DF FISH Probe Kit previously: Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probe	20 µl	05N33-020	6-45
Vysis IGH/FGFR3 DF FISH Probe Kit previously: Vysis LSI IGH/FGFR3 Dual Color, Dual Fusion Translocation Probe	20 µl	01N69-020	6-46
Vysis IGH/MAF DF FISH Probe Kit previously: Vysis LSI IGH/MAF Dual Color, Dual Fusion Probe	20 µl	05N32-020	6-47
Vysis IGH/MALT1 DF FISH Probe Kit	20 µl	05N47-020	6-48
Vysis IGH/MYC/CEP 8 Tri-Color FISH Probe Kit previously: Vysis LSI IGH/MYC, CEP 8 Tri-color, Dual fusion Translocation Probe	20 µl	04N10-020	6-49
Vysis MALT1 Break Apart FISH Probe Kit previously: Vysis LSI MALT1 (18q21) Dual Color, Break Apart Rearrangement Probe	20 µl	05N48-020	6-50
Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe	20 µl	08L57-020	6-51
Vysis MYB SpectrumAqua FISH Probe Kit previously: Vysis LSI MYB (6q23) SpectrumAqua Probe	20 µl	05N40-020	6-52
Vysis MYC Break Apart FISH Probe Kit previously: Vysis LSI MYC Dual Color, Break Apart Rearrangement Probe	20 µl	01N63-020	6-53
Vysis LSI p53/LSI ATM and LSI D13S319/LSI 13q34/CEP 12 Multi-color Probe	200 µl	04N02-021	6-54
Vysis PML/RARA SF FISH Probe Kit previously: Vysis LSI PML/RARA Dual Color Translocation Probe	20 µl	05N45-020	6-56
Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe	20 µl	01N36-020	6-57
Vysis PDGFRB Break Apart FISH Probe Kit	10 µl	06N24-010	6-58
Vysis RARA Break Apart FISH Probe Kit previously: Vysis LSI RARA Dual Color, Break Apart Rearrangement Probe	20 µl	05N46-020	6-59
Vysis RPN1/MECOM FISH DF Probe Kit	10 µl	06N60-010	6-60
Vysis RUNX1/RUNX1T1 DF FISH Probe Kit previously: Vysis LSI AML1/ETO Dual Color, Dual Fusion Translocation Probe	20 µl	08L70-020	6-61
Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe	20 µl	01N24-020	6-62
Vysis TRA/D Break Apart FISH Probe Kit previously: Vysis LSI TCR alpha/delta Dual Color Break Apart Rearrangement Probe	20 µl	05N41-020	6-63
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	6-64
Vysis TP53/CEP 17 FISH Probe Kit previously: Vysis LSI TP53 SpectrumOrange / CEP 17 SpectrumGreen Probe	20 µl	05N56-020	6-65

Listing by Disease State

ACUTE LYMPHOCYTIC LEUKEMIA (ALL)

Vysis BCR/ABL/ASS1 Tri-Color DF FISH Probe Kit	20 µl	05N54-020	6-17
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	20 µl	08L10-001	6-19
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	50 µl	08L10-002	6-19
Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe	20 µl	08L56-050	6-20
Vysis LSI BCR/ABL ES Dual Color Translocation Probe	20 µl	08L55-020	6-21
Vysis CDKN2A/CEP 9 FISH Probe Kit	20 µl	04N61-020	6-27
Vysis ETV6 Break Apart FISH Probe Kit	20 µl	04N09-020	6-40
Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe	20 µl	08L66-020	6-39
Vysis ETV6/RUNX1 DF FISH Probe Kit	10 µl	05N96-010	6-41
Vysis IGH/MYC/CEP 8 Tri-Color FISH Probe Kit	20 µl	04N10-020	6-49
Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe	20 µl	08L57-020	6-51
Vysis MYB SpectrumAqua FISH Probe Kit	20 µl	05N40-020	6-52
Vysis MYC Break Apart FISH Probe Kit	20 µl	01N63-020	6-53
Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe	20 µl	01N24-020	6-62
Vysis TRA/D Break Apart FISH Probe Kit	20 µl	05N41-020	6-63

Quantities of 200 µl are prediluted with Hybridisation Buffer

Listing by Disease State

Product description	Quantity	Order No.	Page Number
ACUTE MYELOID LEUKEMIA (AML)			
CEP 8 SpectrumOrange DNA Probe Kit without control slides, FDA Cleared	20 Assays	07J20-008	6-7
Vysis BCR/ABL/ASS1 Tri-color DF FISH Probe Kit	20 µl	05N54-020	6-17
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	20 µl	08L10-001	6-19
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	50 µl	08L10-002	6-19
Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe	20 µl	08L56-050	6-20
Vysis LSI BCR/ABL ES Dual Color Translocation Probe	20 µl	08L55-020	6-21
Vysis CBFB Break Apart FISH Probe Kit	20 µl	05N44-020	6-24
Vysis CSF1R/D5S23, D5S721 FISH Probe Kit	20 µl	05N03-020	6-29
Vysis D20S108 FISH Probe Kit	20 µl	05N02-020	6-33
Vysis D7S486/CEP 7 FISH Probe Kit	20 µl	05N07-020	6-35
Vysis D7S522/CEP 7 FISH Probe Kit	20 µl	05N08-020	6-36
Vysis LSI DEK/NUP214 Dual Color, Dual Fusion Translocation FISH Probe Kit	20 µl	09N24-060	6-37
Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Set	20 µl	08L68-020	6-38
Vsis ETV6 Break Apart FISH Probe Kit	20 µl	04N09-020	6-39
Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe	20 µl	08L57-020	6-51
Vysis PML/RARA SF FISH Probe Kit	20 µl	05N45-020	6-56
Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe	20 µl	01N36-020	6-57
Vysis RARA Break Apart FISH Probe Kit	20 µl	05N46-020	6-59
Vysis RUNX/RUNX1T1 DF FISH Probe Kit	20 µl	08L70-020	6-61
Vysis RPN1/MECOM FISH DF Probe Kit	10 µl	06N60-010	6-60
CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)			
CEP 12 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-012	6-6
Vysis LSI ATM (11q22) SpectrumOrange Probe	20 µl	01N33-020	6-13
Vysis ATM/CEP 11 FISH Probe Kit	20 µl	05N55-020	6-14
Vysis CCND1/CEP 11 FISH Probe Kit	20 µl	03N88-020	6-26
Vysis CCND1 Break Apart FISH Probe Kit	20 µl	05N38-020	6-25
Vysis LSI D13S25 (13q14.3) SprectrumOrange Probe	20 µl	01N37-020	6-30
Vysis LSI D13S319 (13q14) SpectrumOrange Probe	20 µl	01N34-020	6-32
Vysis D13S319/13q14.3 FISH Probe Kit	20 µl	05N37-020	6-31
Vysis IGH/CCND1 DF FISH Probe Kit	20 µl	08L58-020	6-44
Vysis IGH/CCND1 XT DF FISH Probe Kits	20 µl	05N33-020	6-45
Vysis MYB SpectrumAqua FISH Probe Kit	20 µl	05N40-020	6-52
Vysis LSI p53/LSI ATM and LSI D13S319/LSI 13q34/CEP 12 Multi-color Probe	200 µl	04N02-021	6-54
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	6-64
VysisTP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	6-65
CHRONIC MYELOID LEUKEMIA (CML)			
CEP 8 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-008	6-6
Vysis LSI 4q12 Tricolor Rearrangement Probe	20 µl	05N52-020	6-11
Vysis LSI 9q34 SpectrumAqua Probe	20 µl	05N53-020	6-12
Vysis BCR/ABL/ASS1 Tri-Color DF FISH Probe Kit	20 µl	05N54-020	6-17
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	20 µl	08L10-001	6-19
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	50 µl	08L10-002	6-19
Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe	20 µl	08L56-050	6-20
Vysis LSI BCR/ABL ES Dual Color Translocation Probe	20 µl	08L55-020	6-21
MULTIPLE MYELOMA (MM)			
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020	6-10
Vysis 13q34 SpectrumGreen FISH Probe Kit	20 µl	05N34-020	6-9

Quantities of 200 µl are prediluted with Hybridisation Buffer

Listing by Disease State

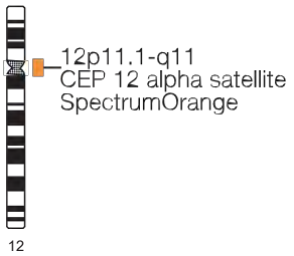
Product description	Quantity	Order No.	Page Number
MULTIPLE MYELOMA (MM)			
Vysis LSI CCND1 Break Apart FISH Probe Kit	20 µl	05N38-020	6-25
Vysis CCND1/CEP11 FISH Probe Kit	20 µl	03N88-020	6-26
Vysis LSI CDKN2C SpectrumGreen/LSI CKS1B SpectrumOrange FISH Probe	20 µl	08N78-020	6-28
Vysis LSI D13S25 (13q14) SpectrumOrange Probe	20 µl	01N37-020	6-30
Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe	20 µl	01N34-020	6-32
Vysis D13S319 /13q34 FISH Probe Kit	20 µl	05N37-020	6-31
Vysis LSI D5S23/D5S721, CEP 9, CEP 15 Multi-Color Probe	20 µl	05N35-020	6-34
Vysis IGH/CCND1 DF FISH Probe Kit	20 µl	08L58-020	6-44
Vysis IGH/CCND1 XT DF FISH Probe Kit	20 µl	05N33-020	6-45
Vysis LSI IGH Dual Color, Break Apart Rearragement Probe	20 µl	08L63-020	6-42
Vysis IGH/FGFR3 DF FISH Probe Kit	20 µl	01N69-020	6-46
Vysis IGH/MAF DF FISH Probe Kit	20 µl	05N32-020	6-47
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	6-64
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	6-65
MYELODYSPLASTIC SYNDROME (MDS)			
CEP 8 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-008	6-7
Vysis CSF1R/D5S23, D5S721 FISH Probe Kit	20 µl	05N03-020	6-29
Vysis D20S108 FISH Probe Kit	20 µl	05N02-020	6-33
Vysis D7S486/CEP 7 FISH Probe Kit	20 µl	05N07-020	6-35
Vysis D7S522/CEP 7 FISH Probe Kit	20 µl	05N08-020	6-36
Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Set	20 µl	08L68-020	6-38
Vysis ETV6 Break Apart FISH Probe Kit	20 µl	04N09-020	6-40
NON-HODGKINS LYMPOMA			
Vysis BCL2 Break Apart FISH Probe Kit	20 µl	05N51-020	6-15
Vysis LSI BCL 6 (ABR) Dual Color, Break Apart Rearrangement Probe	20 µl	01N23-020	6-16
Vysis BIRC3/MALT1 DF FISH Probe Kit	20 µl	05N50-020	6-22
Vysis CCND1 Break Apart FISH Probe Kit	20 µl	05N38-020	6-25
Vysis CCND1/CEP 11 FISH Probe Kit	20 µl	03N88-020	6-26
Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe	20 µl	08L63-020	6-42
Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe	20 µl	08L60-020	6-43
Vysis IGH/CCND1 DF FISH Probe Kit	20 µl	08L58-020	6-44
Vysis IGH/CCND1 XT DF FISH Probe Kit	20 µl	05N33-020	6-45
Vysis IGH/MALT1 DF FISH Probe Kit	20 µl	05N47-020	6-48
Vysis IGH/MYC/CEP 8 Tri-Color FISH Probe Kit	20 µl	04N10-020	6-49
Vysis MALT1 Break Apart FISH Probe Kit	20 µl	05N48-020	6-50
Vysis MYC Break Apart FISH Probe Kit	20 µl	01N63-020	6-53
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020	6-64
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020	6-65
SEX MISMATCHED BONE-MARROW TRANSPLANT MANAGEMENT (+BMT)			
CEP X SpectrumOrange/CEP Y SpectrumGreen DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-050	6-8

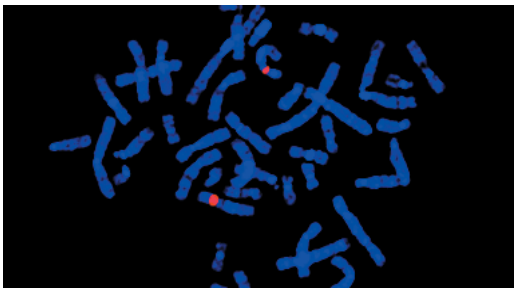
Quantities of 200 µl are prediluted with Hybridisation Buffer

CEP 12 SpectrumOrange DNA Probe Kit

FDA CLEARED

CEP 12 DNA Probe is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 12p11.1-q11.
The CEP 12 DNA Probe Kit which is FDA cleared may be used as an adjunct to standard karotyping to identify and enumerate chromosome 12 in nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (B-CLL). In multi-site clinical trials, the CEP 12 analysis of interphase nuclei was 100 % sensitive and 91 % specific as compared to traditional cytogenetic analysis when adequate metaphase preparations could be produced. Results are available within 3 hours or less. Trisomy 12 is the most commonly reported chromosome aberration in CLL. Chromosomal aberrations, determined by cytogenetic analysis are present in up to 55 % of all B-CLL cases. Trisomy 12 is present in 30 % of these cases, making it the most common cytogenetic abnormality in B-CLL. Trisomy 12 has been associated with decreased overall survival and the need for earlier treatment.





CEP 12 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 12.

Results of Hybridization

In a normal cell, the expected pattern for CEP 12 is the two orange (2O) signal pattern. In an abnormal cell containing trisomy 12, the expected pattern will be the three orange (3O) signal pattern.

Materials Provided

Materials provided with the CEP 12 DNA Probe Kit:

- CEP 12 DNA probe pre-denatured in hybridization buffer (200 µl)
- NP-40 (detergent for wash solution: 1000 µl)
- DAPI II counterstain (300 µl)
- 20X SSC (66 g)

Ordering Information	Quantity	Order No.
CEP 12 SpectrumOrange DNA Probe Kit without control slides FDA Cleared	20 Assays	07J20-012

References
1. Byrd, J., et al. Clin. Cancer Res 4 (1998): 1235-41.
2. Escudier, S., et al. Blood 81 (1993): 2702-7.
3. Heim, S., et al. Cancer Cytogenetics 2nd ed. (1995): 377.
4. Jenkins, R., et al. Blood 79 (1992): 3307-15.
5. Najfeld,V., et al. Bone Marrow Trans. 19 (1997): 829-34.

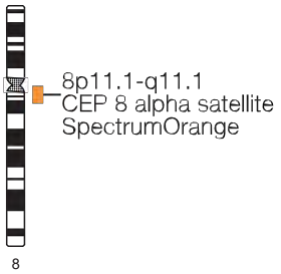
CEP 8 SpectrumOrange DNA Probe Kit

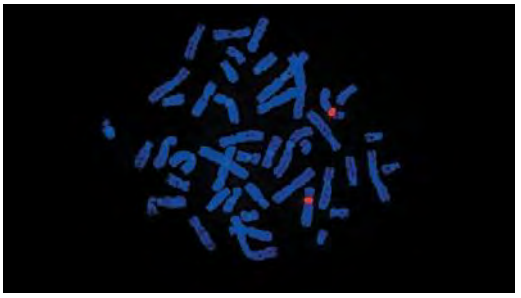
FDA CLEARED

CEP 8 is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 8p11.1-q11.1.

The CEP 8 DNA Probe Kit which is FDA cleared may be used as an adjunct to standard karotyping to identify and enumerate chromosome 8 in cells obtained from bone marrow. In multi-site clinical trials, the CEP 8 DNA Probe Kit for interphase analysis was 96 % sensitive and 98 % specific as compared to traditional cytogenetic analysis. A close association has been made between trisomy 8 and both myeloid blast crisis and basophilia. Trisomy 8 is a prevalent genetic aberration in several specific diseases:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Myeloproliferative disorders (MPD)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not specified (includes hyperproliferative states such as polycythemia vera, leukemoid reaction, lymphoproliferative disorders or chronic lymphocytic leukemia)





CEP 8 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 8.

Results of Hybridization

In a normal cell, the expected pattern for a nucleus hybridized with the CEP 8 probe is a two orange (2O) signal pattern. In an abnormal cell containing trisomy 8, the expected pattern will be the three orange (3O) signal pattern.

Components of the CEP 8 SpectrumOrange DNA Probe Kit include:

- CEP 8 SpectrumOrange alpha satellite DNA for centromere region 8p11.1-q11.1 predenatured in hybridization buffer (200 µl)
- NP-40 (detergent for wash solution: 1000 µl)
- DAPI II counterstain (300 µl)
- 20X SSC (66 g)

Ordering Information	Quantitiy	Order No.
CEP 8 SpectrumOrange DNA Probe Kit without control slides FDA Approved	20 Assays	07J20-008

References

1. Byrd, J., et al. (1998) Clin Cancer Res 4, 1235-41.
2. Escudier, S., et al. (1993) Blood 81, 2702-7.
3. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed. New York City, NY, John Wiley & Sons.
4. Jenkins, R., et al. (1992) Blood 79, 3307-15.
5. Najfeld, V., et al (1997) Bone Marrow Trans 19, 829-34.

CEP X SpectrumOrange/CEP Y SpectrumGreen DNA Probe Kit

FDA CLEARED

The CEP X/Y DNA Probe Kit, which is FDA approved, may be used as an adjunct to standard karotyping to evaluate engraftment success in recipients of sex mismatched bone-marrow transplantation by determining the proportion of XX and XY donor cells. Following transplantation, an assessment of the proportion of cells belonging to the donor and to the recipient can be used to evaluate engraftment, detect the presence of clonal neoplasms and determine disease recurrence. This probe kit offers a limit of detection of 1% through a combination of CEP X and CEP Y fluorescently labeled DNA probes for specific regions of chromosome X and chromosome Y, respectively. This probe provides rapid (results in 3 hours or less) and accurate identification of the genetic sex of the bone marrow cells. Bone-marrow transplantation is a critical therapeutic strategy in the management of hematologic malignancies, such as:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Acute Lymphocytic Leukemia (ALL)
- Myeloproliferative Disorder (MPD)
- Chronic Lymphocytic Leukemia (CLL)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not otherwise specified (including hyper-proliferative states such as polycythemia vera, leukemoid reaction, and lymphoproliferative disorders)

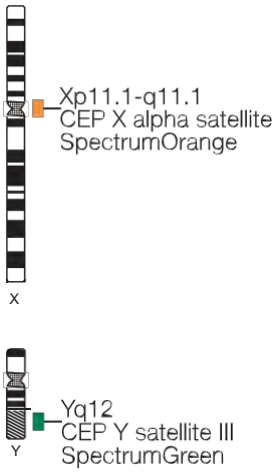
The CEP X/Y probe is a mixture of a SpectrumOrange labeled CEP X probe and a SpectrumGreen labeled CEP Y probe specific for the alpha satellite centromeric region of chromosome X and the satellite III (Yq12) region of chromosome Y.

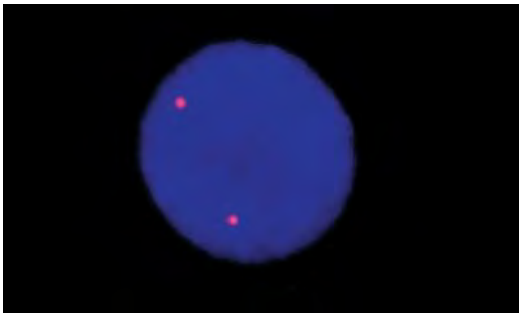
Materials Provided With the CEP X/Y DNA Probe Kit:

- CEP X/Y DNA probe pre-denatured in hybridization buffer (200 µl)
- NP-40 (detergent for wash solution 1000 µl)
- DAPI II counterstain (300 µl)
- 20X SSC (66 g)

Results of Hybridization

In a normal male cell, the expected pattern for a nucleus hybridized with the CEP X/Y DNA Probe is the one orange, one green (1O1G) signal pattern. In a normal female cell the two orange (2O) single pattern for female donor cells will be observed.





Normal female

Normal male

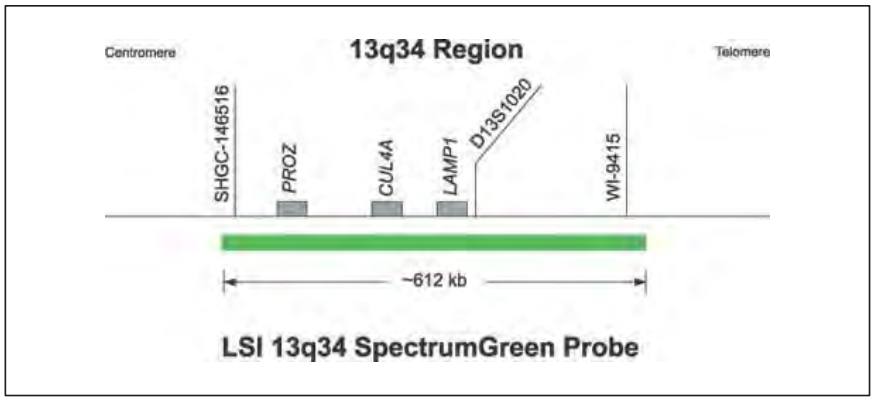
Ordering Information	Quantity	Order No.
CEP X SpectrumOrange/CEP Y SpectrumGreen DNA Probe Kit without control slides FDA Approved	20 Assays	07J20-050

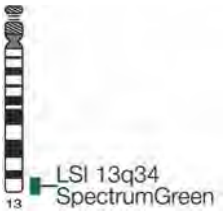
References

1. Byrd, J., et al. Clin. Cancer Res. 4 (1998): 1235-41.
2. Escudier, S., et al. Blood 81 (1993): 2702-7.
3. Heim, S., et al. Cancer Cytogenetics 2nd ed. (1995): 377.
4. Jenkins, R., et al. Blood 79 (1992): 3307-15.
5. Najfeld, V., et al. Bone Marrow Trans. 19 (1997): 829-34.

Vysis 13q34 SpectrumGreen FISH Probe Kit

previously: Vysis LSI (13q34) Spectrum Green Probe





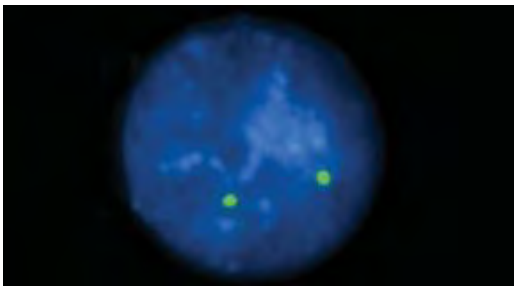
This fluorescence in situ hybridization (FISH) probe is intended to detect the copy number of the LSI 13q34 probe target located at chromosome 13q34.

Genetic aberrations of chromosome 13, especially 13q- and monosomy, are common in hematopoietic disorders. Deletions of 13q14 have been detected in 30 – 50 % of multiple myeloma patients. The differentiation of an interstitial deletion from loss of the entire q arm is made difficult for lack of a more telomeric marker. The LSI 13q34 probe is located near the telomere region of the q arm.[1, 2]

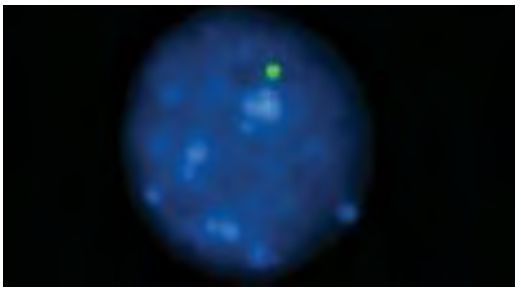
The Vysis LSI 13q34 SpectrumGreen Probe has been used to detect copy number abnormalities of the LSI 13q34 probe target in multiple myeloma samples.[3, 4]

Results of Hybridization

In a normal cell with two intact copies of chromosome 13, two green signals will be observed. In an abnormal cell that has lost the 13q34 region of chromosome 13, fewer than two green signals will be observed.



Result of the hybridization of the LSI 13q34 Probe as observed in a normal interphase cell.



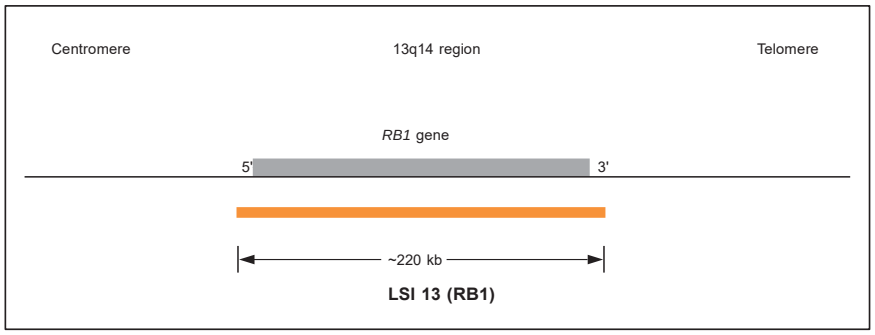
Abnormal cell hybridized with the LSI 13q34 Probe. The cell in this image shows deletion of one copy of the 13q34 region of chromosome 13 as indicated by the single green signal.

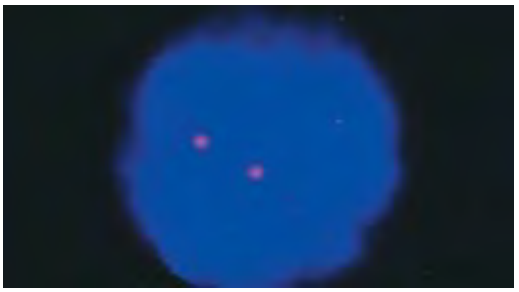
Ordering Information	Quantity	Order No.
Vysis 13q34 SpectrumGreen FISH Probe Kit	20 µl	05N34-020

References

1. Fonseca R, Oken MM, Harrington D,et al. Leukemia 2001;15:981?986.
2. Fonseca R, Harrington D, Oken MM, et al. Cancer Research 2002;62:715-720.
3. Takimoto M, Ogawa K, Kato Y, et al. International Journal of Hematology 2008;87:260-265.
4. Slovak ML, Bedell V, Pagel K, et al. Cancer Genetics and Cytogenetics 2005;158:99-109.

Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe





LSI 13 (RB1) SpectrumOrange hybridized to a normal cultured amniocyte.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene

Results of Hybridization

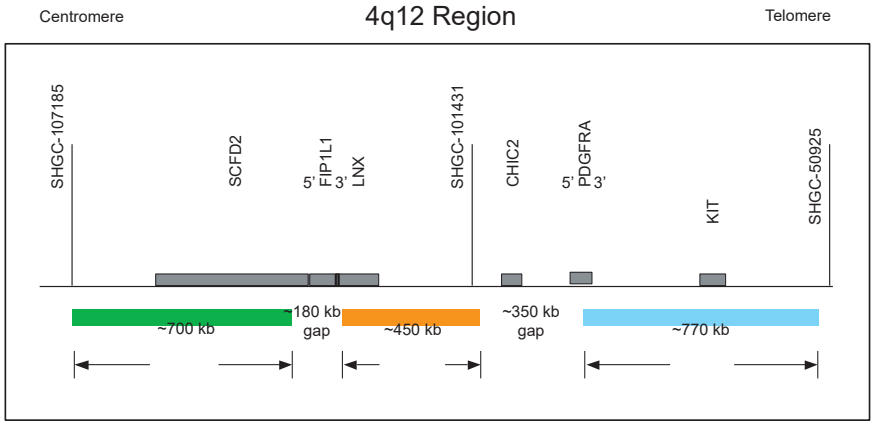
In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

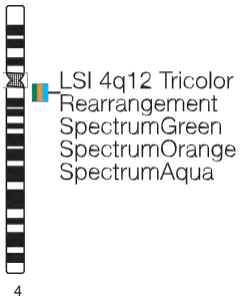
Ordering Information	Quantity	Order No.
Vysis LSI 13 (RB1) 13q14 SpectrumOrange Probe	20 µl	08L65-020

References

1. Amare PS, Ghule P, Jose J, et al. Constitutional genomic instability, chromosome aberrations in tumor cells an retinoblastoma. *Cancer Genet Cytogenet* 2004; 150: 33-43.
2. Elnenaei MO, Hamoudi RA, Swansbury J, et al. Delineation of the minimal region of loss at 13q14 in multiple myeloma. *Genes Chromosomes Cancer* 2003; 36: 99-106.
3. Fonseca R, Oken MM, Harrington D, et al. Deletions of chromosome 13 in multiple myeloma identified by interphase FISH usually denote large deletions of the q arm or monosomy. *Leukemia* 2001; 15: 981-86.
4. Kalachikov S, Migliazze A, Cayanis E, et al. Cloning and gene mapping of the chromosome 13q14 region deleted in chronic lymphocytic leukemia. *Genomics* 1997; 42: 369-77
5. Stilgenbauer S, Nickolenko J, Wilhelm J, et al. Expressed sequences as candidates for a novel tumor suppressor gene at band 13q14 in B-cell chronic lymphocytic leukemia and mantle cell lymphoma. *Oncogene* 1998; 16: 1891-97.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med* 2006; 8: 16-23.

Vysis LSI 4q12 Tricolor Rearrangement Probe





The Vysis LSI 4q12 Tri-Color Rearrangement Probe consists of three differently colored probes all located in the FIP1L1-PDGFRA region of chromosome 4q12. The SpectrumGreen probe begins approximately 75 kb centromeric to the FIP1L1 gene and extends toward the centromere for approximately 700 kb. The SpectrumOrange probe starts about 25 kb telomeric of the FIP1L1 gene, extends toward the 4q telomere for about 450 kb, and contains the LNX gene. The SpectrumAqua probe begins between exons 15 and 16 of the PDGFRA gene, extends toward the 4q telomere for approximately 770 kb, and contains the KIT gene.

Results of Hybridization

In interphase nuclei of normal cells, the probe is expected to appear as two tri-color (green, orange, aqua) fusions. In these fusions,overlapping orange and green signals may be perceived as yellow fusion signals with appropriate filters. FISH signal patterns in nuclei having interstitial deletions of the orange probe target on one chromosome 4 homolog should be observed as one tri-color fusion and one green/aqua fusion lacking an orange signal. If the intervening orange probe target is not deleted, but relocated to another separate chromosomal location, the expected pattern would be one tri-color fusion, one green/aqua fusion and one lone orange signal. In instances of translocations involving the PDGFRA gene with loci on other chromosomes, the expected signal pattern would be one tri-color fusion, one orange/green fusion, and one separate aqua signal.

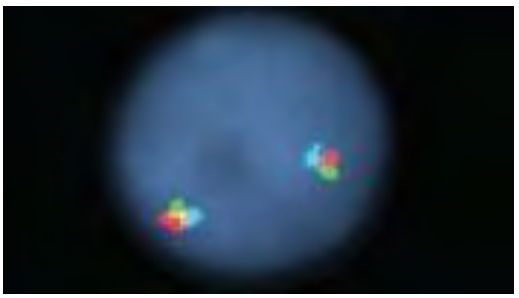


Figure 1. Normal nucleus showing the two tricolor green/orange/aqua fusion signals.

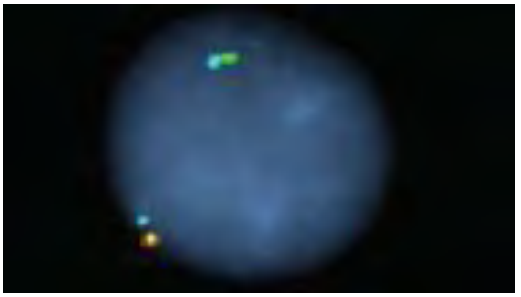
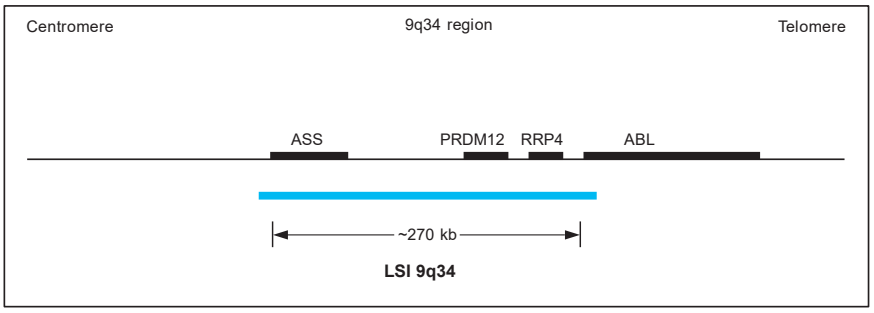
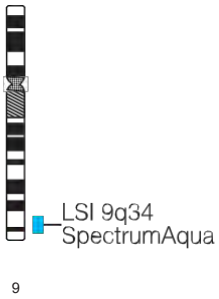


Figure 2. Abnormal nucleus showing the one tricolor green/orange/aqua fusion signal and one green/aqua fusion signal with the orange signal deleted.

Ordering Information	Quantity	Order No.
Vysis LSI 4q12 Tricolor Rearrangement Probe	20 µl	05N52-020

Vysis LSI 9q34 SpectrumAqua Probe



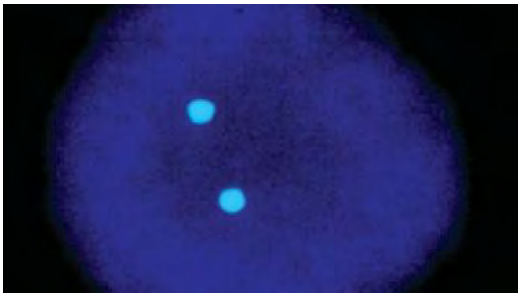


The t(9;22) translocation is a characteristic molecular feature of certain types of leukemia cells. Frequently, this translocation creates the BCR-ABL fusion gene, which encodes a functional, chimeric tyrosine kinase. Several studies have reported the detection of large chromosomal deletions on either side of the t(9:22) breakpoint that are believed to occur at the time of the initial translocation. The deletions can span several megabases but typically include the 9q34 region around the Argininosuccinate Synthetase (ASS) gene.

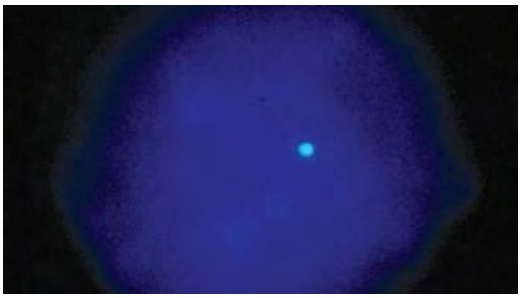
The LSI 9q34 probe is a single ~270 kb unique sequence probe that hybridizes to the 9q34 region containing the ASS gene. The probe is labeled with SpectrumAqua.

Results of Hybridization

This probe is provided for those interested in assessing the deletion status of the 9q34 region of chromosome 9. In a normal cell with two intact copies of chromosome 9, two aqua signals will be observed. In an abnormal cell that has lost the 9q34 region of chromosome 9, fewer than two aqua signals will be observed.



Result of the hybridization of the LSI 9q34 Probe as observed in a normal interphase cell.



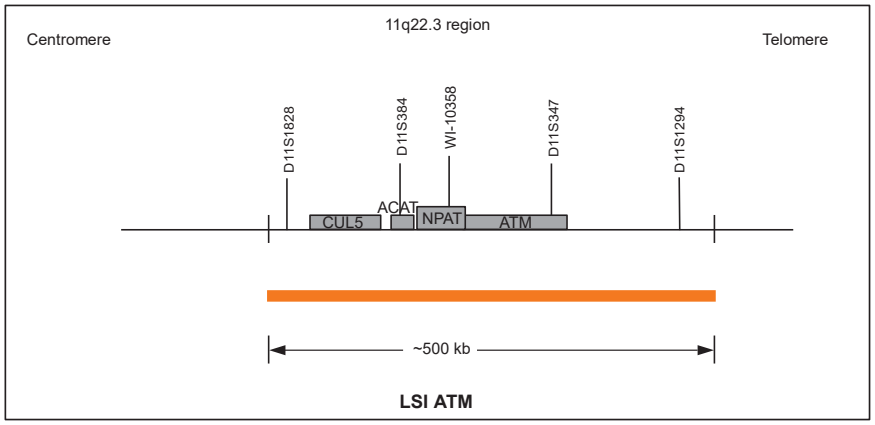
Abnormal cell hybridized with the LSI 9q34 Probe. The cell in this image shows deletion of one copy of the 9q34 region of chromosome 9 as indicated by the single aqua signal.

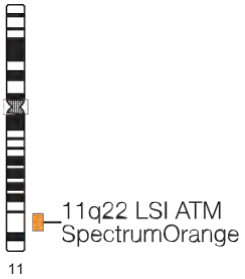
Ordering Information	Quantity	Order No.
Vysis LSI 9q34 SpectrumAqua Probe	20 µl	05N53-020

References

1. Faderl, S., et al. N. Eng. J.Med. 341 (1999): 167-172.
2. Deininger, M., et al. Blood 96 (2000): 3343-3356.
3. Sawyers, C. N. Eng. J.Med. 340 (1999): 1330-1340.
4. Heisterkamp, N., et al. Nature 344 (1990): 251-253.
5. Pear, W., et al. Blood 92 (1998): 3780-3792.
6. Honda, H., et al. Blood 91 (1998): 2067-2075.
7. Grand, F., et al. Cancer Res. 59 (1999): 3870-3874.
8. Dewald, G., et al. Leuk. Lymphoma 34 (1999): 481-491.
9. Herens, C., et al. Br. J. Haematol. 110 (2000): 214-216.
10. Sinclair, P.B., et al. Blood 95 (2000): 738-744.
11. Huntly, B.J.P., et al. Blood 98 (2001): 1732-1738.

Vysis LSI ATM (11q22) SpectrumOrange Probe





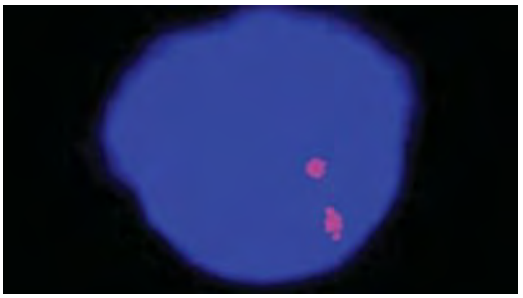
This fluorescence in situ hybridization (FISH) probe is intended to detect deletion of the LSI ATM probe target sequence containing the ATM gene at chromosomal location 11q22.3.

Loss of genetic information at chromosome band 11q22-q24 has been observed in a number of malignancies. Deletions in this region are commonly observed abnormalities in several types of lymphoproliferative diseases. In chronic lymphocytic leukemia (CLL), loss at 11q22.3-q23.1 is one of the most common chromosomal aberrations. Utilizing FISH, a commonly deleted 2-3 megabase region containing the ATM, RDX, and FDX genes has been characterized.[1] Loss of this region is associated with marked lymphadenopathy and unfavorable prognosis.[2,3] Due to its location and the role of its protein product in the regulation of p53, ATM is a candidate gene for the clinical effec of 11q deletions in CLL.[4, 5]

The approximately 500 kb SpectrumOrange LSI ATM probe contains the complete ATM gene and is located at 11q22.3.

Results of Hybridization

This probe set allows status assessment of the ATM gene region on chromosome 11q22.3. In a normal cell with two intact copies of the ATM gene region, a two orange signal pattern will be observed. In an abnormal cell with a deletion in the ATM gene region, fewer than two orange signals will be observed.



Result of the hybridization of the LSI ATM (11q22.3) Probe as observed in a normal interphase cell.

Abnormal cell hybridized with the LSI ATM (11q22.3) Probe. The cell in this image shows the one orange signal pattern indicative of a deletion of one copy of the ATM gene region on chromosome 11q22.3.

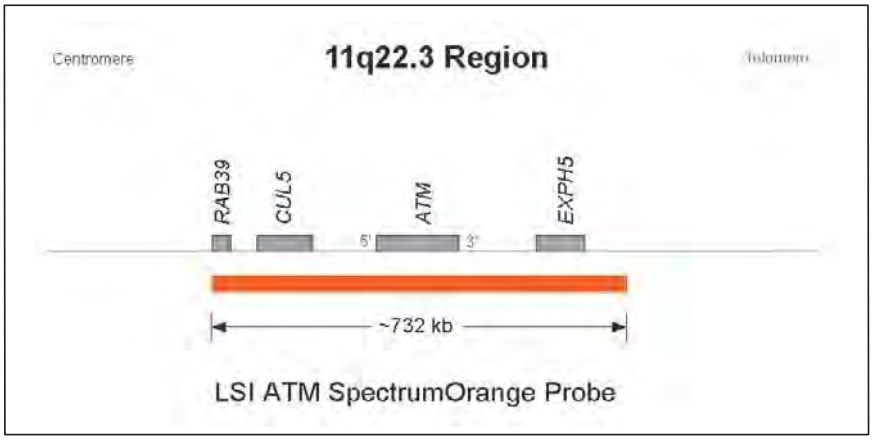
Ordering Information	Quantity	Order No.
Vysis LSI ATM (11q22.3) SpectrumOrange Probe	20 µl	01N33-020

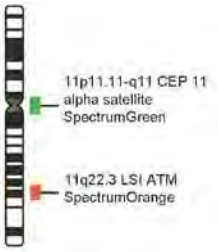
References

1. Stilgenbauer S, Liebisch P, James MR, et al. Molecular cytogenetic delineation of a novel critical genomic region in chromosome bands 11q22.3-q23.1 in lymphoproliferative disorders. Proc. Natl. Acad. Sci. USA 1996;93:11837-41.
2. Döhner H, Stilgenbauer S, James, MR, et.al. 11q deletions identify a new subset of B-cell chronic lymphocytic eukemia characterized by extensive nodal involvement and inferior prognosis. Blood 1997:89(7):2516-22.
3. Döhner H, Stilgenbauer S, Benner A, et al. Genomic aberrations and survival in chronic lymphocytic leukemia. N Eng J Med 2000;343:1910-16.
4. Byrd JC, Gribben JG, Peterson BL, et al. Select high-risk genetic features predict earlier progression following chemoimunnotherapy with fludarabine and rituximab in chronic lymphocytic leukemia: justification for riskadapted therapy. J Clin Oncol 2006;24:437-43.
5. Dewald GW, Brockman SR, Paternoster SF, et al. Chromosome anomalies detected by interphase fluorescence in situ hybridization: correlation with significant biological features of b-cell chronic lymphocytic leukaemia. Br J Haematol 2003;121:287-95.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med 2006;8:16-23..

Vysis LSI ATM/CEP 11 FISH Probe Kit

previously Vysis LSI ATM SpectrumOrange/CEP 11 SpectrumGreen Probe

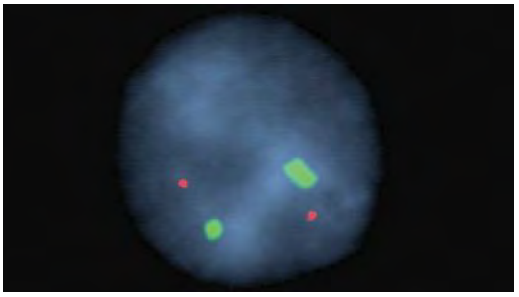




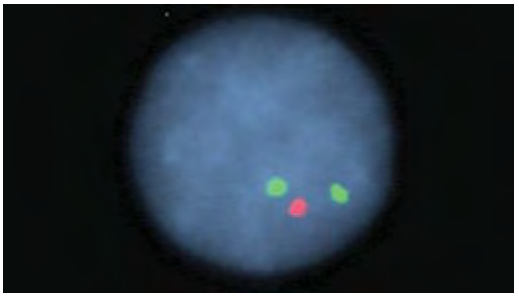
The Vysis ATM/CEP 11 FISH Probe Kit is intended to detect the copy number of the LSI ATM probe target located at chromosome 11q22.3.

A common deletion that occurs in chronic lymphocytic leukemia (CLL) is the loss of the 11q22 region.[1] Loss of ATM in CLL is associated with aggressive disease.[2] The LSI ATM/CEP 11 probe combination has been used to detect the loss of 11q in several CLL studies.[2,3]

The approximately 732 kb SpectrumOrange LSI ATM probe contains the complete ATM (ataxia telangiectasia mutated) gene and is located at chromosome 11q22.3 (chr11:107306249-108038407 March 2006 UCSC Browser). The SpectrumGreen CEP 11 probe is a control probe which hybridizes to the centromere region of chromosome 11p11.11-q11.



Normal nucleus showing the two green and two orange signals.



Abnormal nucleus showing the two green and one orange signal.

Results of Hybridization

In a cell with normal copy numbers of the LSI ATM/CEP 11 target, two orange and two green signals are expected. In a cell with an ATM deletion, a one orange and two green signal pattern is expected. Other abnormal FISH signal patterns may be observed and metaphase analysis may be useful in interpreting these results.

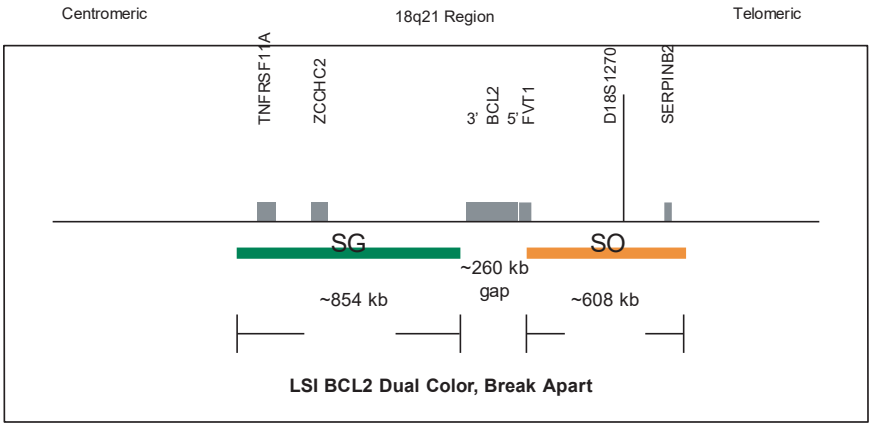
Ordering Information	Quantity	Order No.
Vysis LSI ATM/CEP 11 FISH Probe Kit	20 µl	05N55-020

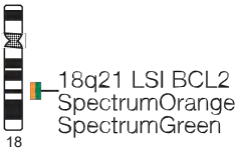
References

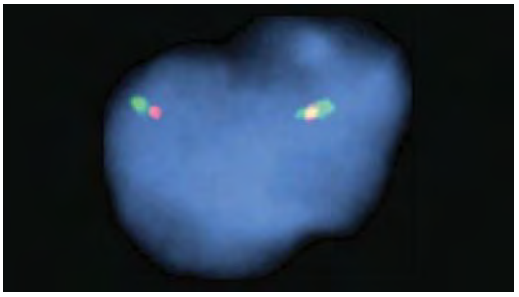
1. Shanafelt T, Geyer SM, and Kay NE. Prognosis at diagnosis: integrating molecular biologic insights into clinical practice for patients with CLL. Blood. 2004;103(4):1202-10.
2. Grever MR, Lucas DM, Dewald GW, et al. Comprehensive assessment of genetic and molecular features predicting outcome in patients with chronic lymphocytic leukemia: results from the US Intergroup Phase III Trial E2997. J Clin Oncol. 2007;25(7):799-804.
3. Dewald GW, Brockman SR, Paternoster SF, et al. Chromosome anomalies detected by interphase fluorescence in situ hybridization: correlation with significant biological features of B-cell chronic lymphocytic leukaemia. Br J Haematol. 2003;121:287-95.
4. Wiktor AE, Van DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

Vysis BCL2 Break Apart FISH Probe Kit

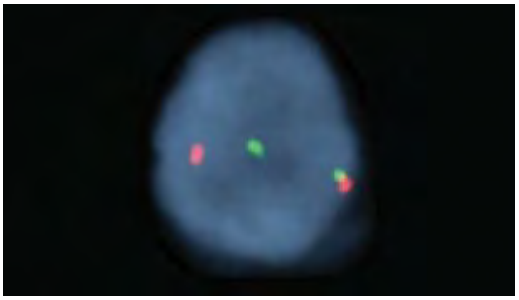
previously: Vysis LSI BCL2 Dual Color, Break Apart Rearrangement Probe







Normal cell hybridization using the Vysis BCL2 Break Apart FISH Probe.



Abnormal cell hybridization using the Vysis BCL2 Break Apart FISH Probe.

The Vysis BCL2 Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements at the BCL2 locus on chromosome 18q21 using the fluorescence in situ hybridization (FISH) technique.

The t(14;18)(q32;q21) translocation involving the IGH and BCL2 loci is observed in approximately 80% of follicular lymphoma and about 20% of diffuse large B-cell lymphoma (DLBCL).[1] BCL2 gene rearrangements have been shown to correlate with a significantly worse prognosis in DLBCL of non-germinal center phenotype (2). The Vysis LSI BCL2 Dual Color Break Apart Rearrangement Probe has been used to detect BCL2 gene rearrangements on tissue micro arrays of DLBCL specimens.[2,3] Primary mediastinal B-cell lymphoma (PMBCL) is a DLBCL with a clinically favorable outcome. In one study, 25 cases of PMBCL were analyzed by PCR and FISH for BCL2 gene rearrangements.[4] Three cases with BCL2 gene rearrangements were detected by the Vysis LSI BCL2 Dual Color Break Apart Rearrangement Probe.

The approximately 608 kb (chr18:59173695-59781804; March 2006 assembly, UCSC Genome Browser)[5] SpectrumOrange probe lies telomeric to the BCL2 breakpoint region. The approximately 854 kb (chr18:58058872-58913422; March 2006 assembly, UCSC Genome (Browser)[5] SpectrumGreen probe lies centromeric to the BCL2 breakpoint region.

Results of Hybridization

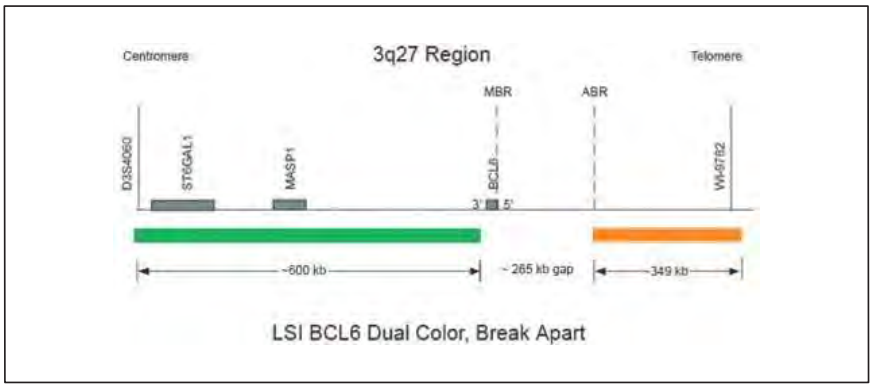
Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals. The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 18 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Ordering Information	Quantity	Order No.
Vysis BCL2 Break Apart FISH Probe Kit	20 µl	05N51-020

References

1. Akasaka T., et al. (1998) Genes, Chromosomes & Cancer 21: 17-29.
2. Buchonnet G., et al. (2000) Leukemia 14: 1563-1569.
3. Buchonnet G., et al. (2002) Leukemia 16: 1852-1856.
4. Heim S. (1995) Cancer Cytogenetics 2nd Edition.

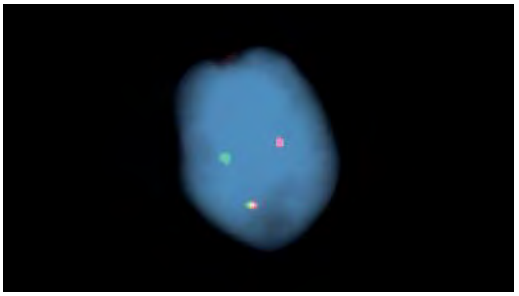
Vysis LSI BCL6 (ABR) Dual Color, Break Apart Rearrangement Probe



The LSI BCL6 (ABR)* Dual Color, Break Apart Rearrangement Probe targets chromosome breaks associated with a number of different translocations that involve the BCL6 gene located on chromosome 3.

The LSI BCL6 (ABR)* Dual Color, Break Apart Rearrangement Probe consists of a 5' BCL6 probe and 3' BCL6 probe. The 5' BCL6 SpectrumOrange probe is ~349 kb in size and flanks the ABR of BCL6. The 3' BCL6 SpectrumGreen probe is approximately 600 kb in size and flanks the 3' end of BCL6. There is an approximate 265 kb gap between the two probes.

Results of Hybridization
In a normal cell hybridized with the BCL6 probe, the expected signal pattern is two orange/green (2F) fusion signals.



LSI BCL6 (ABR) Dual Color, Break Apart Rearrangement Probe hybridized to a nucleus with a translocation breakpoint involving the BCL6 BCL6 gene showing a one orange, one green, one fusion (1O1G1F) pattern.

Ordering Information	Quantity	Order No.
Vysis LSI BCL6 (ABR) Dual Color, Break Apart Rearrangement Probe	20 µl	01N23-020

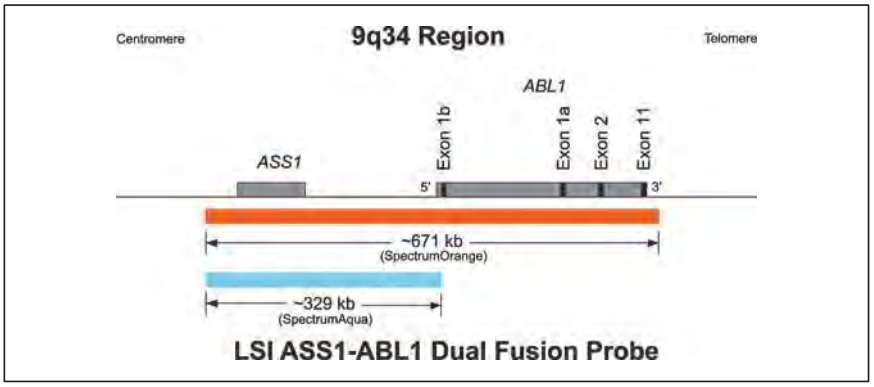
* ABR- Alternate Breakpoint Region

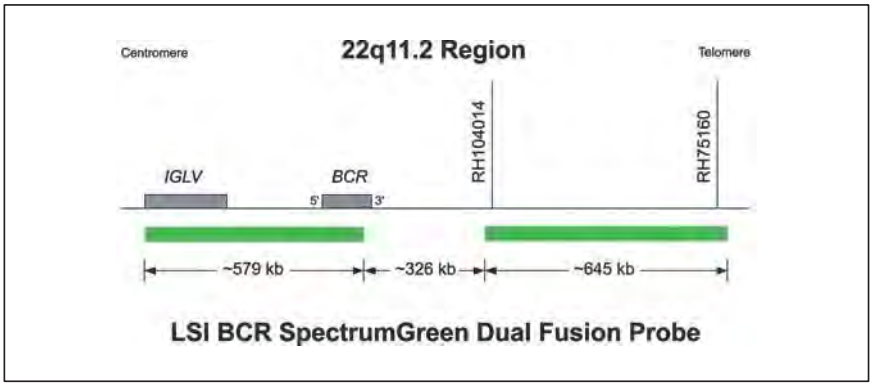
References

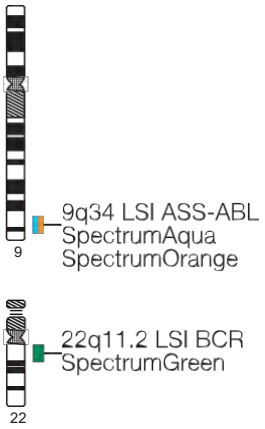
1. Iqbal J, et. al Leukemia. 2007 Nov;21(11):2332-43. Epub 2007 Jul 12.
2. Tapinassi C, et al, Cancer Genet Cytogenet. 2007 Jan 1;172(1):70-3.
3. Bosga-Bouwer AG, et al Chromosomes Cancer. 2005 Nov;44(3):301-4.
4. Chen W, et al; Oncogene. 1998 Oct 1;17(13):1717-22.

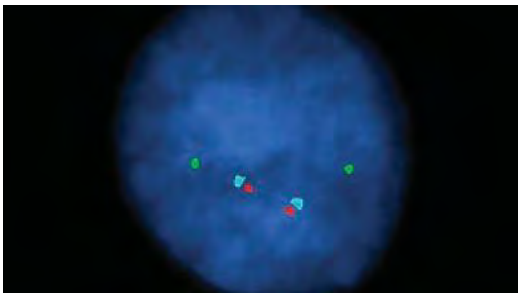
Vysis BCR/ABL/ASS1 Tri-Color DF FISH Probe Kit

previously: Vysis LSI BCR/ABL+ 9q34 Tricolor, Dual Fusion Translocation Probe

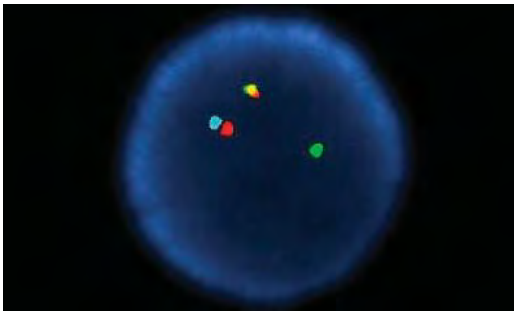








Nucleus showing the two aqua/orange and two green signal pattern.



Abnormal nucleus showing the one aqua/orange, one green, and one orange/green fusion (yellow) signal pattern.

The Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit is intended to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 gene regions using the fluorescence in situ hybridization technique.

The t(9;22) translocation which fuses the BCR gene on chromosome 22q11.2 and the ABL1 gene on chromosome 9q34 is observed by cytogenetics in greater than 80% of patients with chronic myelogenous leukemia (CML).[1] In CML cases lacking a cytogenetically detectable translocation, the BCR/ABL1 fusion can still almost always be detected by FISH or other molecular techniques. BCR/ABL1 fusions also occur in a portion of acute lymphocytic leukemia cases and more rarely in acute myeloid leukemia.[2] In about 15 to 20 percent of CML cases, the t(9;22) results in the loss of genetic material flanking the BCR and/or ABL1 breakpoints on the derivative 9 chromosome.[1,3] This loss can prevent the production of the highly specific two-fusion signal patterns expected of dual fusion probes and balanced translocations. If both BCR and ABL1 targets are deleted on the der(9) chromosome, low-level random overlap of orange and green signals within normal cells (producing a 1 orange, 1 green, 1 fusion pattern) cannot be discriminated from low-level true BCR/ABL1 fusions producing the same pattern. The Tri-Color design of this test uses a probe in a third color (aqua) on the centromeric side of the ABL1 breakpoint, which co-localizes with the orange signal in a random orange/green signal fusion, but is absent from a true BCR/ABL1 molecular fusion on the der(22) chromosome. The probes in this kit have been used in published papers to detect low levels of positive cells in CML patients who were undergoing therapy and had deletions of FISH signals on the derivative chromosome 9.[1,3]

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Continuation:
Vysis BCR/ABL/ASS1 Tri-Dolor DF FISH Probe Kit

The approximately 671 kb (chr9:132255025-132926107; March 2006 assembly, UCSC Genome Browser)[4] SpectrumOrange LSI ABL1 probe spans the ABL1 and ASS1 genes on chromosome 9q34. The approximately 329 kb (chr9:132255025-132584487; March 2006 assembly, UCSC Genome Browser)[4] SpectrumAqua LSI ASS1 probe overlays with part of the area covered by the SpectrumOrange probe, spans the ASS1 gene and lies centromeric to the ABL1 gene breakpoint regions.
The SpectrumGreen LSI BCR probe consists of two probes located at chromosome 22q11.2. The centromeric segment of the SpectrumGreen probe is approximately 579 kb (chr22:21382633-21962088 March 2006 assembly),[4] and contains the majority of the BCR gene. The telomeric segment of the SpectrumGreen probe is approximately 645 kb (chr22:22288218-22932815; March 2006 assembly),[4] and it lies telomeric to the BCR gene breakpoint region. There is an approximate 326 kb gap between the two green probes.

Results of Hybridization
The expected normal signal pattern of Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit is two orange, two aqua, and two green signals.
The expected abnormal pattern of the Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit will depend on deletion status of probe targets flanking the breakpoints that result in the derivative chromosome 9.

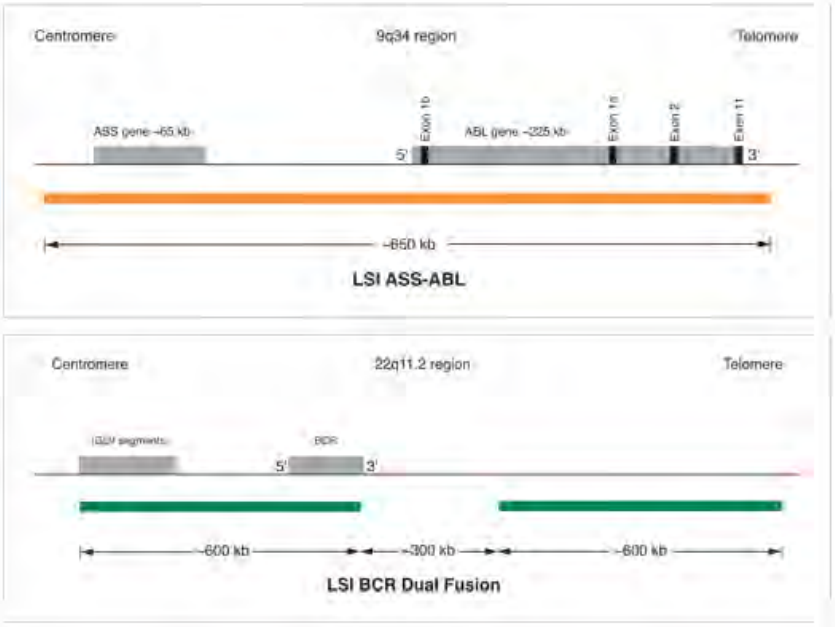
- In a balanced t(9;22) without any deletion of probe target on the der(9), a 1 orange 1 green 2 fusion pattern is expected. The 1 orange signal [normal 9] and one of the two fusions [der(9)] will each have associated aqua signals.
- If the ABL1 target on the der(9) is lost, a 1 orange 2 green 1 fusion pattern is expected. The orange signal [normal 9] will have an associated aqua signal.
- If the BCR target on the der(9) is deleted, a 2 orange 1 green 1 fusion pattern is expected. Both orange signals, normal chromosome 9 and der(9), will have an associated aqua signal.
- If both ABL1 and BCR targets are deleted on the der(9), a 1 orange 1green 1 fusion pattern will be expected. Again, the 1 orange signal [normal 9] will have an associated aqua signal.

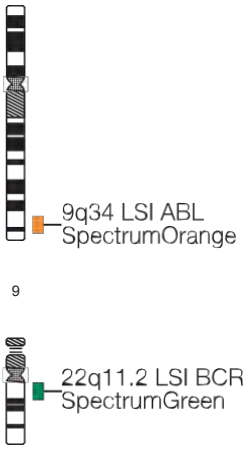
In all cases, a true BCR/ABL1 fusion signal will not have an associated aqua signal as the aqua probe lies centromeric to the ABL1 breakpoint and thus is not involved in the oncogenic gene fusion. This fact is the basis for discriminating a true 5' BCR/ 3' ABL1 molecular fusion from other orange/ green signal fusions whether they are the result of a der(9) or to random overlap of normal chromosome signals. Other abnormal signal patterns may occur, and metaphase analysis may be helpful in characterization of such patterns. The publications by Smoley et al[1] and Siu et al[3] used the probes contained in this kit and demonstrate the abnormal signal patterns observed in patients with der(9) deletions.

Ordering Information	Quantity	Order No.
Vysis LSI BCR/ABL/ASS1 Tri-Color DF FISH Probe Kit	20 µl	05N54-020

References:
1. Smoley SA, Brockman SR, Paternoster SF, et al. A novel tricolor, dual-fusion fluorescence in situ hybridization method to detect BCR/ABL fusion in cells with t(9;22)(q34;q11.2) associated with deletion of DNA on the derivative chromosome 9 in chronic myelocytic leukemia. Cancer Genet Cytogenet. 2004;148(1):1-6.
2. Primo D, Tabernero MD, Rasillo A, et al. Patterns of BCR/ABL gene rearrangements by interphase fluorescence in situ hybridization (FISH) in BCR/ABL leukemias: incidence and underlying genetic abnormalities. Leukemia. 2003;17(6):1124-9
3. Siu L, Ma E, Wong WS, et al. Application of tri-colour, dual fusion fluorescence in situ hybridization (FISH) system for the characterization of BCR-ABL1 fusion in chronic myelogenousleukaemia (CML) and residual disease monitoring. BMC Blood Disord. 2009;9:4.
4. Kent WJ, Sugnet CW, Furey TS, et al. The Human Genome Browser at UCSC. Genome Res. 2002;12(6):996-1006.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe





LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe hybridized to an abnormal nucleus containing a simple balanced t(9;22). One orange, one green and two orange/green fusion signals are observed (1O1G2F).

The LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI BCR probe labeled with SpectrumGreen and the LSI ABL probe labeled with SpectrumOrange. The spanning ABL probe has a genomic target of approximately 650 kb extending from an area centromeric of the argininosuccinate synthetase gene (ASS) to well telomeric of the last ABL exon. The BCR probe target spans a genomic distance of about 1.5 Mb. The BCR probe begins within the variable segments of the immunoglobulin lambda light chain locus (IGLV), extends along chromosome 22 through the BCR gene, and ends at a point approximately 900 kb telomeric of BCR. A region of about 300 kb containing low-copy number repeats has been eliminated from the probe which introduces a gap in the coverage of the probe target. Both probes span their respective breakpoints.

Results of Hybridization

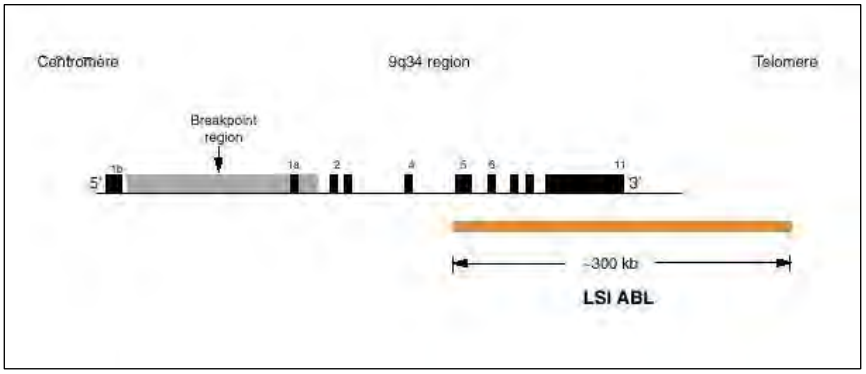
A nucleus lacking the t(9;22) translocation will exhibit the two orange, two green (2O2G) signal pattern. In a nucleus containing a simple balanced t(9;22), one orange and one green signal from the normal 9 and 22 chromosomes and two orange/green (yellow) fusion signals, one each from the derivative 9 and 22 chromosomes, will be observed (1O1G2F). In some instances, deletions may occur 3' of the BCR breakpoint and/or 5' of the ABL breakpoint resulting in either an ES (extra orange or green) signal pattern or a single fusion pattern.

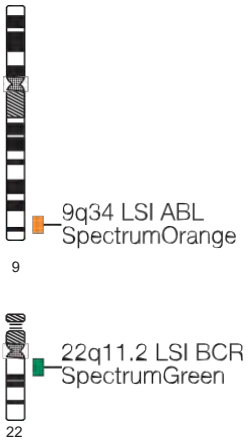
Ordering Information	Quantity	Order No.
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	20 µl	08L10-001
Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe	50 µl	08L10-002

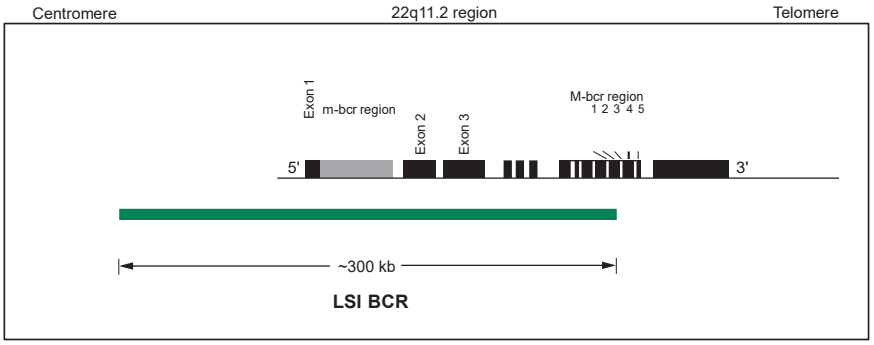
References

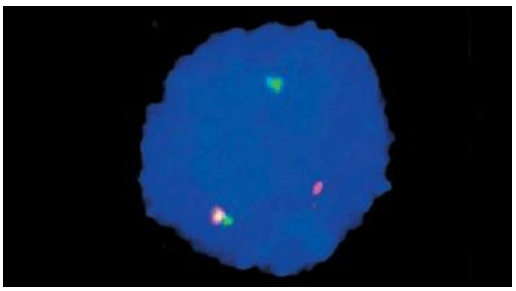
1. Bloomfield CD, Goldman AI, Alimena G, et al. Blood 1986;67:415-20.
2. Lugo TG, Pendergast AM, Muller AJ, et al. Science 1990; 247:1079-82.
3. Chase A, Huntley BJ, Cross NC. Best Prac Res Clin Haematol 2001;14(3):553-71.
4. Dewald GW.. In: Fan YS, ed. Methods in Molecular Biology, Vol 204: Molecular Cytogenetics: Protocols and Applications. Totowa, NJ: Humana Press Inc.;2002:311-42.
5. Primo D, Tabernero MD, Rasillo A, et al. Leukemia 2003;17:1124-29.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al.. Genet Med 2006;8:16-23.

Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe









LSI BCR/ABL Dual Color, Single Fusion Translocation Probe hybridized to an abnormal nucleus containing the t(9;22). One orange, one green and one fusion (IOIGIF) signal pattern is observed.

The LSI BCR/ABL Dual Color, Single Fusion Translocation Probeis a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The ABL probe begins between exons 4 and 5 and continues for about 300 kb toward the telomere of chromosome 9. The LSI BCR probe begins between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extends toward the centromere on chromosome 22 for approximately 300 kb, extending well beyond the m-bcr region.

Results of Hybridization

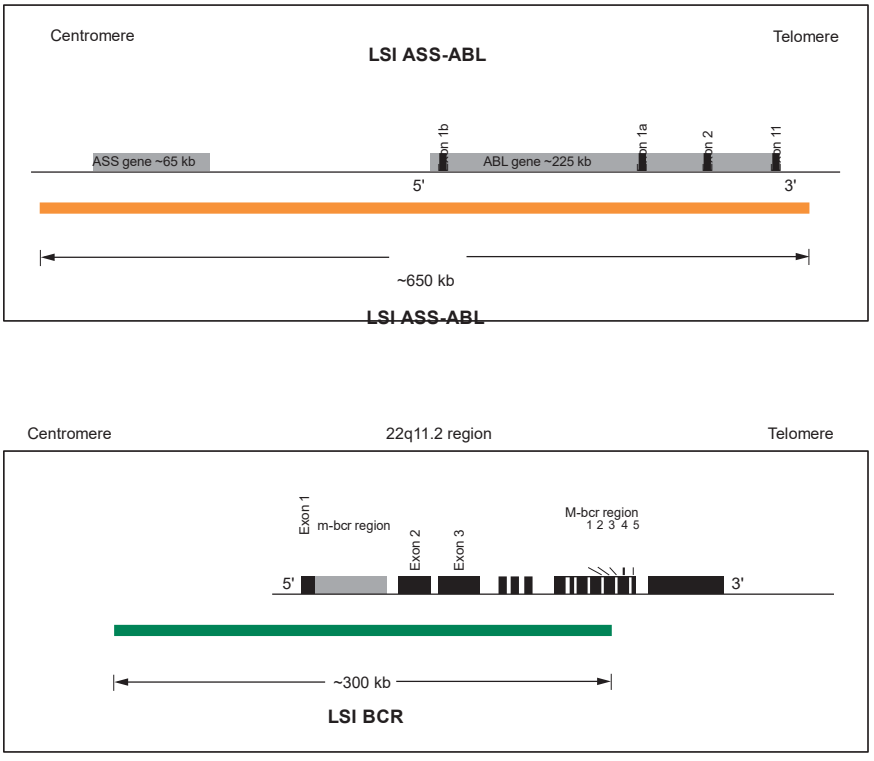
A nucleus lacking the t(9;22) will exhibit the two orange, two green (2O2G) signal pattern. In a cell harboring the t(9;22), one orange, one green, and one orange/green (yellow) fusion signal pattern (1O1G1F) will be observed. This simple probe design detects the 5' BCR/3' ABL gene fusion and is useful for detecting samples with a high percentage of cells possessing this translocation.

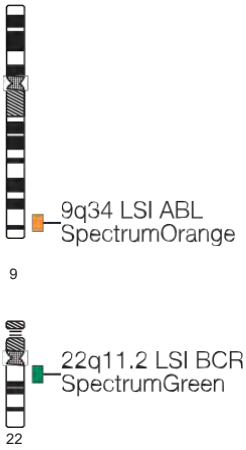
Ordering Information	Quantity	Order No.
Vysis LSI BCR/ABL Dual Color, Single Fusion Translocation Probe	20 µl	08L56-050

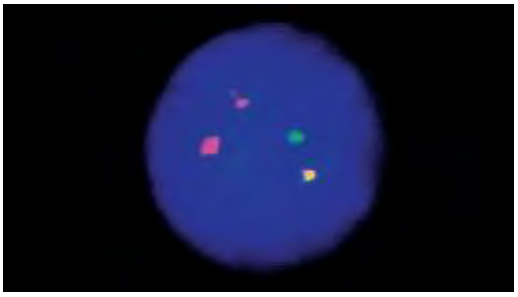
References

1. Bloomfield CD, Goldman AI, Alimena G, et al. Blood 1986;67:415-20.
2. Lugo TG, Pendergast AM, Muller AJ, et al. Science 1990; 247:1079-82.
3. Chase A, Huntley BJ, Cross NC. Best Prac Res Clin Haematol 2001;14(3):553-71.
4. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

Vysis LSI BCR/ABL ES Dual Color Translocation Probe







LSI BCR/ABL ES Dual Color Translocation Probe hybridized to an abnormal nucleus containing the t(9;22) showing one green (native BCR), one large orange (native ABL), one smaller orange (ES) and one fused orange/green (2OIGIF) signal pattern.

The BCR/ABL ES Dual Color Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The spanning ABL probe is approximately 650 kb extending from an area centromeric of the ASS gene to well telomeric of the last ABL exon. The SpectrumGreen BCR probe is approximately 300 kb beginning between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extending well beyond the m-bcr region.

Results of Hybridization

A nucleus lacking the t(9;22) will exhibit a two orange, two green (2O2G) signal pattern. In a nucleus possessing the t(9;22) involving the M-bcr, one green (native BCR), one large orange (native ABL), one smaller orange (ES), and one fused orange/green signal (5' BCR/3' ABL), (2O1G1F) will be observed. Minor breakpoint (m-bcr) signal patterns may appear as one orange, one green, and two fusion signals. In some cells a deletion may occur 5'; of the ABL breakpoint that may reduce the ES pattern to a single fusion pattern.

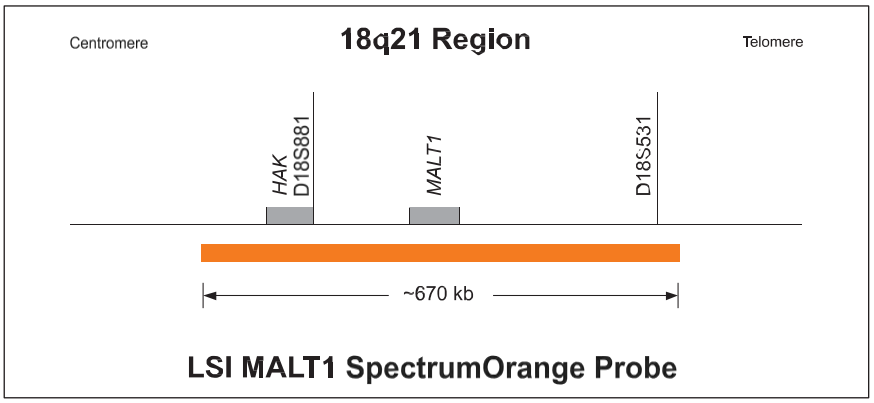
Ordering Information	Quantity	Order No.
Vysis LSI BCR/ABL ES Dual Color Translocation Probe	20 µl	08L55-020

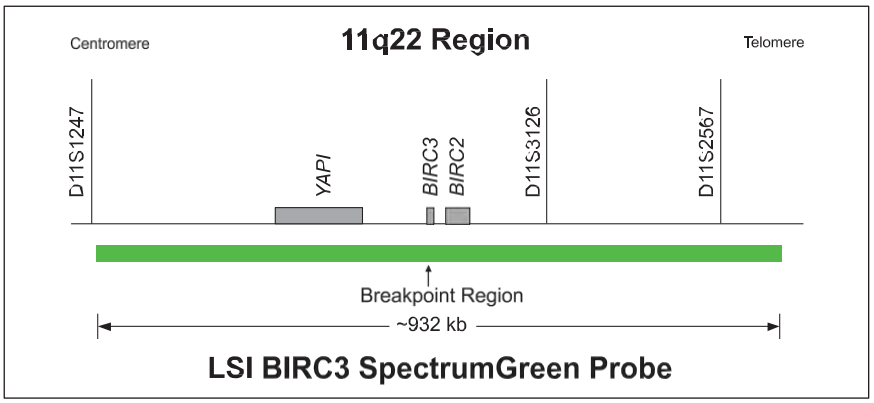
References

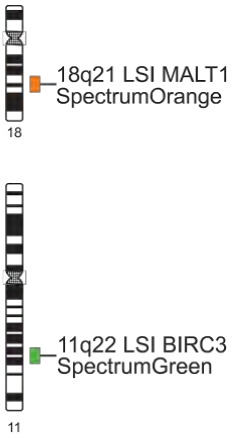
1. Bloomfield CD, Goldman AI, Alimena G, et al. Blood 1986;67:415-20.
2. Lugo TG, Pendergast AM, Muller AJ, et al Science 1990; 247:1079-82. Best Prac Res Clin Haematol 2001;14(3):553-71.
3. Dewald GW. Methods in Molecular Biology, Vol 204: Molecular Cytogenetics: Protocols and Applications. Totowa, NJ: Humana Press Inc.; 2002:311-42.
4. Primo D, Tabernero MD, Rasillo A, et al. Leukemia 2003;17:1124-29.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

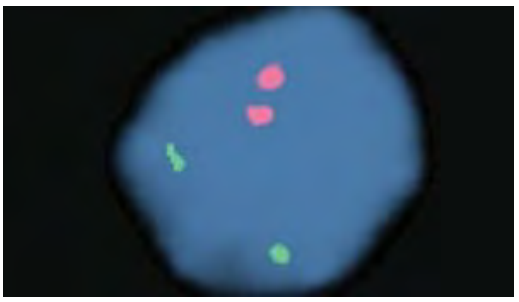
Vysis BIRC3/MALT1 DF FISH Probe Kit

previously Vysis LSI API2/MALT1 t(11;18) (q21;q22) Dual Color, Dual Fusion Translocation Probe







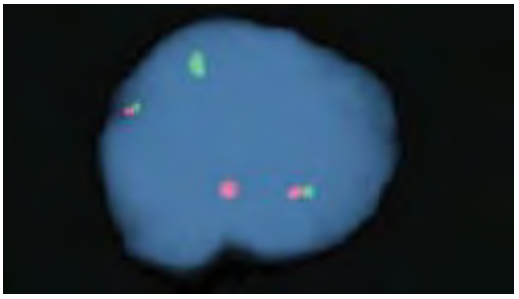


Result of the hybridization of the Vysis BIRC3/MALT1 DF FISH Probe as observed in normal interphase cells.

The Vysis BIRC3/MALT1 DF FISH Probe Kit is intended to detect the t(11;18)(q21;q21) reciprocal translocation involving the BIRC3 and MALT1 gene regions using the fluorescence in situ hybridization (FISH) technique.

The t(11;18)(q21;q21) translocation is the most common chromosomal translocation found in mucosa-associated lymphoid tissue (MALT) lymphoma[1] and is the most common in gastric MALT lymphoma.[2] The t(11;18)(q21;q21) translocation is associated with failure to respond to Helicobacter pylori eradication and an aggressive disease.[3,4] The Vysis LSI BIRC3/MALT1 Dual Color Dual Fusion probe has been used to identify the t(11;18)(q21;q21) translocation in published reports.[5]

The SpectrumOrange probe spans approximately 670 kb (chr18:54220804-54891192; March 2006 assembly)[6] and covers the MALT1 gene region. The approximately 932 kb (chr11:101247706-102179265; March 2006 assembly)[6] SpectrumGreen probe spans the BIRC3 gene region.



An abnormal cell hybridized with the LSI API2/MALT1 t(11;18)(q21;q22) Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one orange, one green and two fusion signal pattern indicative of the t(11;18)(q21;q22) translocation.

Continuation on the following page >

Continuation:
Vysis BIRC3/MALT1 DF FISH Probe Kit

Results of Hybridization

The expected normal signal pattern of the Vysis LSI BIRC3/MALT1 Dual-Color Dual Fusion Probes is two orange and two green signals. The expected abnormal pattern of the Vysis LSI BIRC3/MALT1 Dual Color Dual Fusion Probes is one orange, one green and two fusions. Other abnormal signal patterns may occur and metaphase analysis may be helpful in characterization of such patterns.

Ordering Information	Quantity	Order No.
Vysis BIRC3/MALT1 DF FISH Probe Kit	20 µl	05N50-020

References

1. Auer IA, Gascoyne RD, Connors JM, et al. Ann Oncol. 1997;8(10):979-85.
2. Raderer M, Wöhrer S, Streubel B, et al. J Clin Oncol. 2006;24(19):3136-41.
3. Ye H, Liu H, Raderer M, et al. Blood. 2003;101(7):2547-50.
4. Liu H, Ye H, Ruskone-Fourmestraux A, et al. Gastroenterology. 2002;122(5):1286-94.
5. Nakamura S, Ye H, Bacon CM, et al. Gut. 2007;56(10):1358-63.
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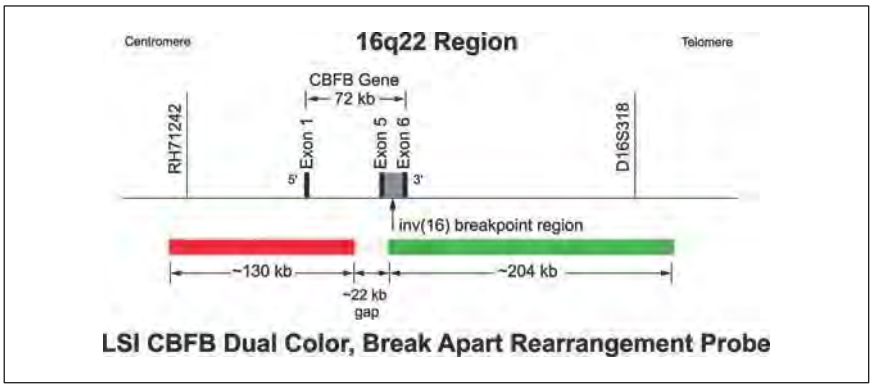
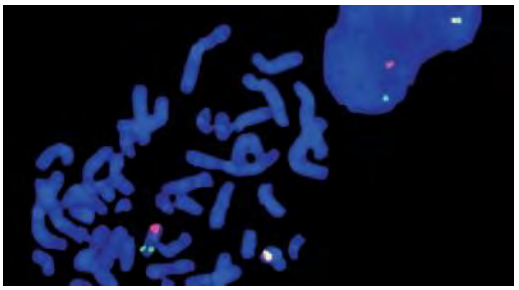
7. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Genet Med. 2006;8(1):16-23.

Vysis CBFB Break Apart FISH Probe Kit

previously Vysis LSI CBFB Dual Color, Break Apart Rearrangement Probe





LSI CBFB Dual Color Break Apart Rearrangement Probe hybridized to a cell exhibiting one red and one green signal. On the metaphase cell, contains the red signal on one arm and the green signal on the other arm

The Vysis CBFB Break Apart FISH Probe is intended to detect chromosomal rearrangements at the CBFB locus on chromosome 16q22.

Aberrations of chromosome 16q22 have been found to be associated with acute myeloid leukemia (AML).[1] A favorable outcome in AML has been associated with inv(16) and t(16;16).[2,3] The Vysis CBFB Break Apart FISH Probe has been used to detect inv(16)/t(16;16) in a study of 237 diagnostic specimens from AML patients enrolled in a clinical trial.[4]

The SpectrumRed probe is approximately 130 kb (chr16:65525674-65655811; March 2006 assembly)[5] and hybridizes centromeric to the inv(16) and t(16;16) breakpoint region.
The SpectrumGreen probe is approximately 204 kb (chr16:65677619-65881775; March 2006 assembly)[5] and hybridizes telomeric to the breakpoint.

Results of Hybridization

The expected pattern in a nucleus lacking inv(16) will be two fused red/green (yellow) signals (2F). The pattern in a nucleus containing an inv(16) results in separate red and green signals appearing on opposite arms of the inverted 16 chromosome. The pattern of t(16;16)(p13;q22) results in an adjacent or fused red/green signal on the q arm of one of the 16 chromosomes and a green signal on the other arm of 16, while the 16 chromosome homolog will only contain the red signal on one arm.

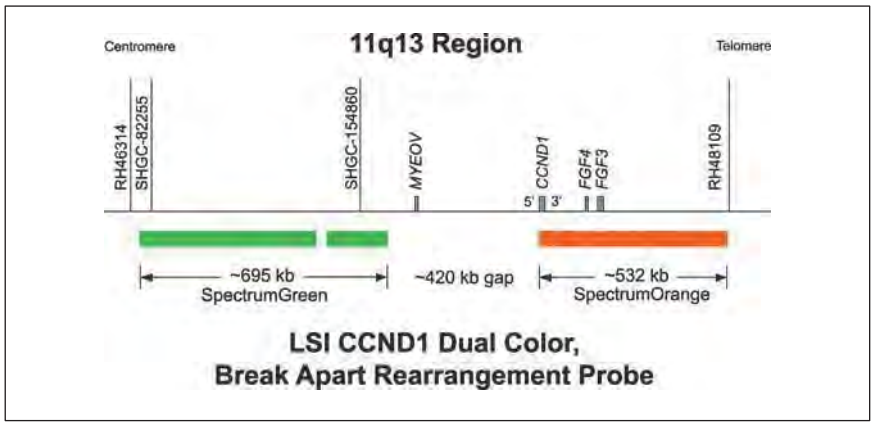
Ordering Information	Quantity	Order No.
Vysis CBFB Break Apart FISH Probe Kit	20 µl	05N44-020

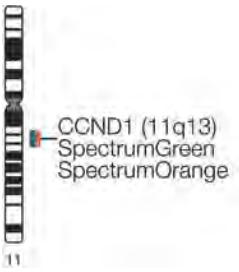
References

1. Le Beau MM, Larson RA, Bitter MA, et al. Association of an inversion of chromosome 16 with abnormal marrow eosinophils in acute myelomonocytic leukemia. A unique cytogenetic clinicopathological association. N Engl J Med. 1983;309(11):630-6.
2. Larson RA, Williams SF, Le Beau MM, et al. Acute myelomonocytic leukemia with abnormal eosinophils and inv(16) or t(16;16) has a favorable prognosis. Blood. 1986;68(6):1242-9.
3. Grimwade D, Walker H, Oliver F, et al. The importance of diagnostic cytogenetics on outcome in AML: analysis of 1,612 patients entered into the MRC AML 10 trial. The Medical Research Council Adult and Children's Leukaemia Working Parties. Blood. 1998;92(7):2322-33.
4. Vance GH, Kim H, Hicks GA, et al. Utility of interphase FISH to stratify patients into cytogenetic risk categories at diagnosis of AML in an Eastern Cooperative Oncology Group (ECOG) clinical trial (E1900). Leuk Res. 2007;31(5):605-9.
5. Kent WJ, Sugnet CW, Furey TS, et al. The Human Genome Browser at UCSC. Genome Res. 2002:12(6):996-1006.

Vysis CCND1 Break Apart FISH Probe Kit

previously: Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe

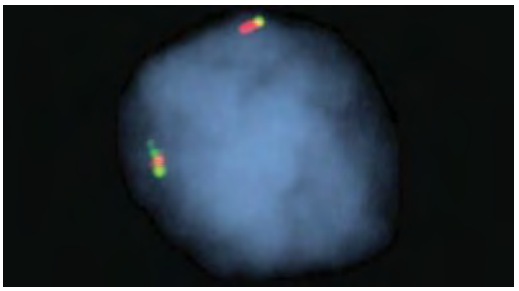




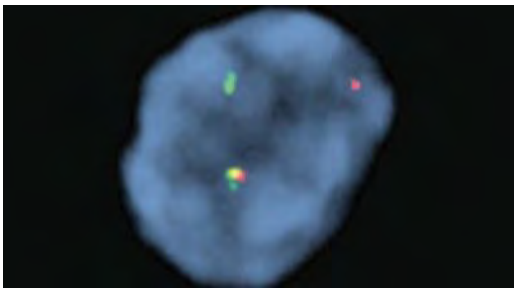
The CCND1 Dual Color Break Apart Rearrangement FISH probe is intended to detect chromosomal rearrangements involving the Cyclin D1 (CCND1) gene region at chromosome 11q13.

Mantle cell lymphoma (MCL) is an aggressive B-cell lymphoma and is commonly characterized by over-expression of CCND1 resulting from the t(11;14)(q13;q32) translocation.[1] Over-expression of CCND1, which can result from chromosomal anomalies such as translocations or gain of the involved area, have been found to occur in multiple myeloma (MM) and MCL.[2] The CCND1 Dual Color Break Apart Rearrangement Probe has been used to help identify rearrangement in the CCND1 breakpoint region in MCL.[3]

The SpectrumGreen probe is located centromeric to CCND1 and spans approximately 695 kb (chr11:68042961-68737635; March 2006 assembly)4 with an approximately 30 kb gap (chr11:68539031-68568590; March 2006 assembly)[4].The SpectrumOrange probe spans approximately 532 kb (chr11:69162485-69694376; March 2006 assembly)[4] and covers CCND1



Normal cell hybridization using the Vysis CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe.



Abnormal cell hybridization using the LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe.

Results of Hybridization

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals. The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 11 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

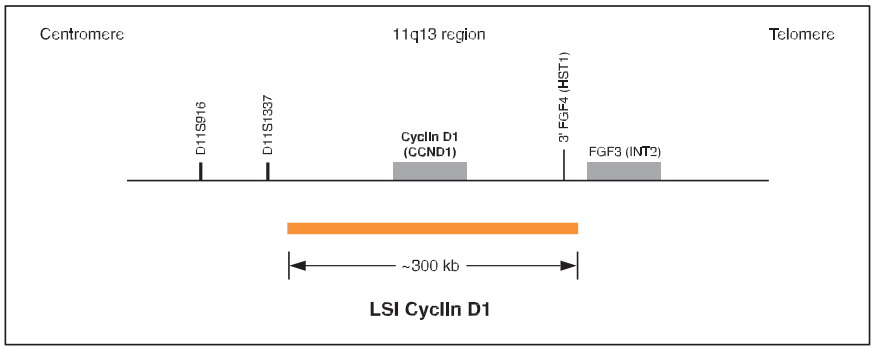
Ordering Information	Quantity	Order No.
Vysis CCND1 Break Apart FISH Probe Kit	20 µl	05N38-020

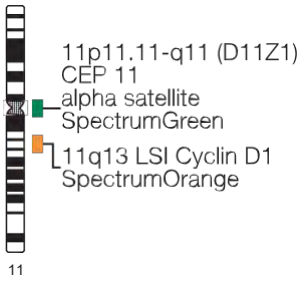
References

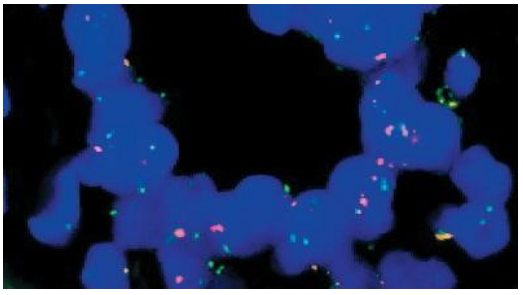
1. Williams ME, Dreyling MH, Kahl BS, et al. Leukemia & Lymphoma. 2010;51(3):390-8.
2. Liebisch P, Döhner H. Eur J Cancer. 2006;42(11):1520-9.
3. Bzorek M Sr, Petersen BL, Hansen L. Appl Immunohistochem Mol Morphol. 2008;16(3):279-86.
4. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002:12(6):996-1006.
5. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Genet Med. 2006;8(1):16-23.

Vysis CCND1/CEP 11 FISH Probe Kit

previoulsy: Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen







Vysis CCND1/CEP 11 FISH Probe hybridized to abnormal tissue.

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.[1,2,3]

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases.[4] CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen.[5] The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al.[6] found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb, contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

Results of Hybridization

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange signals. Other patterns may be observed if additional genetic alterations are present.

Ordering Information	Quantity	Order No.
Vysis CCND1/CEP 11 FISH Probe Kit	20 µl	03N88-020

Bibliography

1. Schuuring E, Verhoeven E, Tinteren Hv, et al. Amplification of genes within the chromosome 11q13 region is indicative of poor prognosis in patients with operable breast cancer. *Cancer Research* 1992; 52: 5229-5234.
2. Bieche I, Olivi M, Nogues C et al. Prognostic value of CCND1 gene status in sporadic breast tumors, as determined by real-time quantitative PCR assays. British Journal of Cancer 2002; 86: 580-586.
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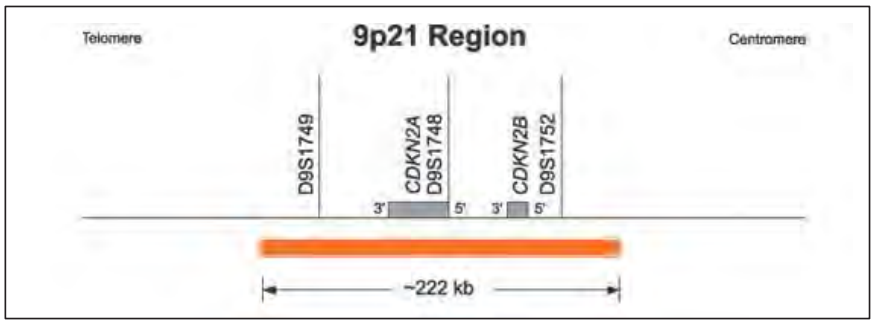
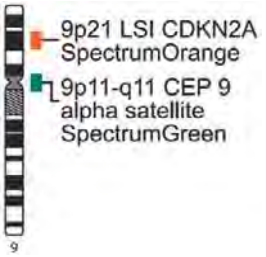
6. Katz RL, Caraway NP, Gu J, et al. Detection of chromosome 11q13 breakpoints by interphase fluorescence in situ hybridization. *American Journal of Clinical Pathology* 2000; 114: 248-257.
7. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med.* 2006; 8(1): 16-23.

Vysis CDKN2A/CEP 9 FISH Probe Kit

previously: Vysis LSI p16 (9p21) SpectrumOrange/CEP 9 SpectrumGreen Probe

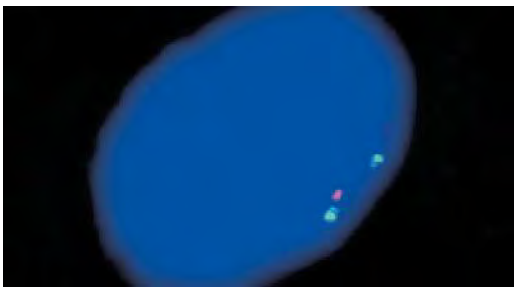




Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A(p16) are implicated in different Meningiomas and Gliomas[1–4]. Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that is is a marker of worse prognosis in anaplastic oligodendroglimas.[5–6]

The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in serval cytogenetic studies to detect losses of the CDKN2A gene.[2,7–9] Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histologically confirmed glial tumors.[7] In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.[9]

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN 2A probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately 222 kb and contains a number of genetic loci including D9S1749, D9S1747, p16 (INK4B), p14 (ARF), D9S1748, p15 (INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9.



Vysis LSI CDKN2A/CEP 9 Dual Color Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively.

Results of Hybridization

In a normal sample, the expected pattern for a nucleus hybridized with the Vysis LSI CDKN2A / CEP 9 Probe is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orange, two green (1O2G) signal pattern is expected. Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.

Ordering Information	Quantity	Order No.
Vysis CDKN2A/CEP 9 FISH Probe Kit	20 µl	04N61-020

References

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2. Perry A, Banerjee R, Lohse CM, et al. A. Brain Pathol. 2002;12(2):183-190.
3. Boström J, Meyer-Puttlitz B, Wolter M, et al. Am J Pathol. 2001;159(2):661-669.
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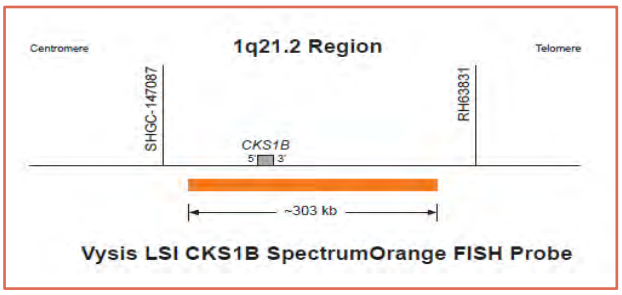
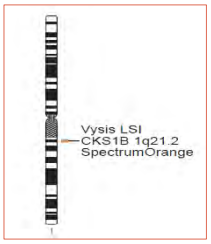
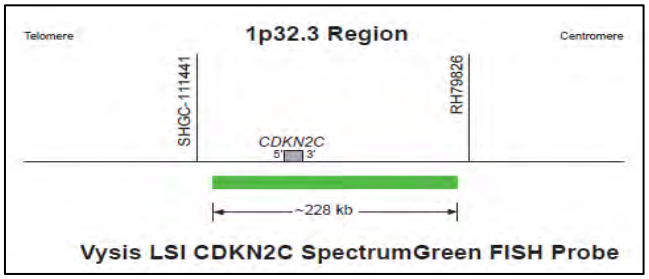
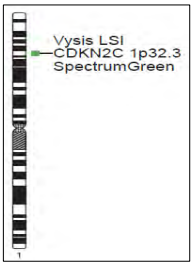
9. Korshunov A, Sycheva R, Golanov A. Cancer. 2005;104(4):825-832.

Vysis LSI CDKN2C SpectrumGreen/LSI CKS1B SpectrumOrange FISH Probe









PRODUCT DESCRIPTION

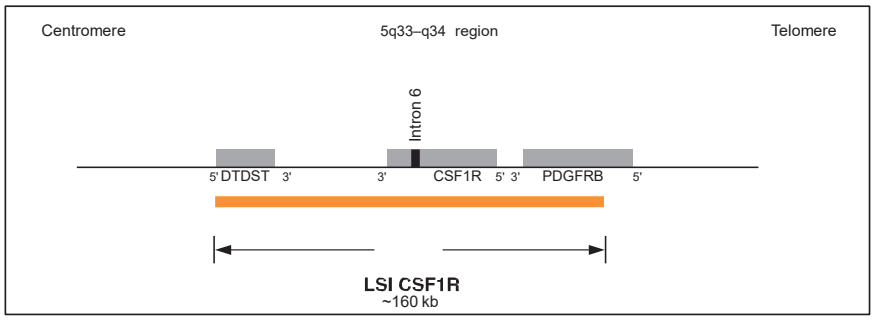
The Vysis LSI CDKN2C SpectrumGreen FISH Probe is a fluorescence in situ hybridization (FISH) probe for the detection of copy number changes involving the CDKN2C (Cyclin-dependent kinase 4 inhibitor C) gene locus at chromosome 1p32.3. The LSI CDKN2C probe is about 228 Kb in size and spans the CDKN2C gene at chromosome 1p32.3 and is labeled in SpectrumGreen.

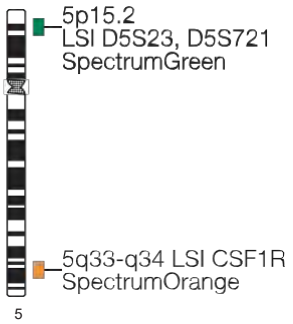
The Vysis LSI CKS1B SpectrumOrange FISH Probe is a fluorescence in situ hybridization (FISH) probe for the detection of chromosomal rearrangements on CKS1B (CDC28 protein kinase regulatory subunit 1B) locus at chromosome 1q21.2. The LSI CKS1B probe is approximately 303 Kb in size and covers the entire CKS1B locus on chromosome 1q21.2 and is labeled in SpectrumOrange.

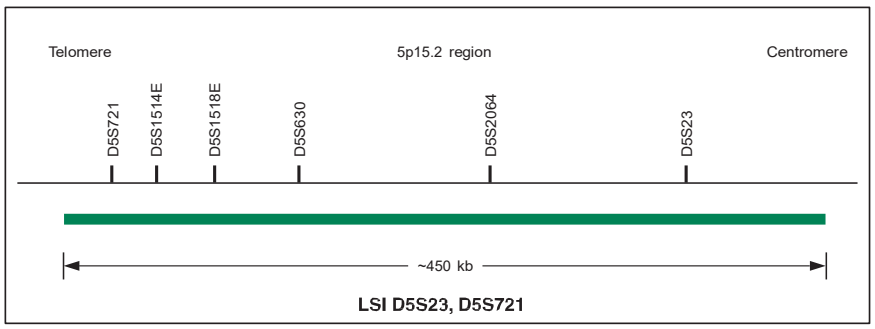
Ordering Information	Quantity	Order No.	GTIN
LSI CDKN2C SpectrumGreen/LSI CKS1B SpectrumOrange FISH Probe **(RUO)**	20 µL	08N78-020	00884999043206

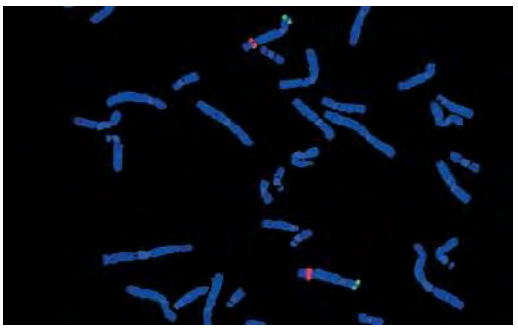
Vysis CSF1R/D5S23, D5S721 FISH Probe Kit

previously: Vysis LSI CSF1R (5q33-q34) SpectrumOrange/D5S23, D5S721 SpectrumGreen Probe









LSI CSF1R/D5S23, D5S721 Dual Color Probe hybridized to a normal metaphase cell showing the two orange, two green (2O2G) signal pattern.

The LSI CSF1R/D5S23, D5S721 FISH Probe may be used to identify deletions of the region 5q33-q34. The CSF1R gene is located in the 5q33-q34 region on chromosome 5 and is telomeric to the EGR1 locus. The D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.

The LSI CSF1R/D5S23, D5S721 FISH Probe is a mixture of the approximately 160 kb SpectrumOrange labeled LSI CSF1R probe and the approximately 450 kb SpectrumGreen labeled D5S23, D5S721 probe.

Results of Hybridization

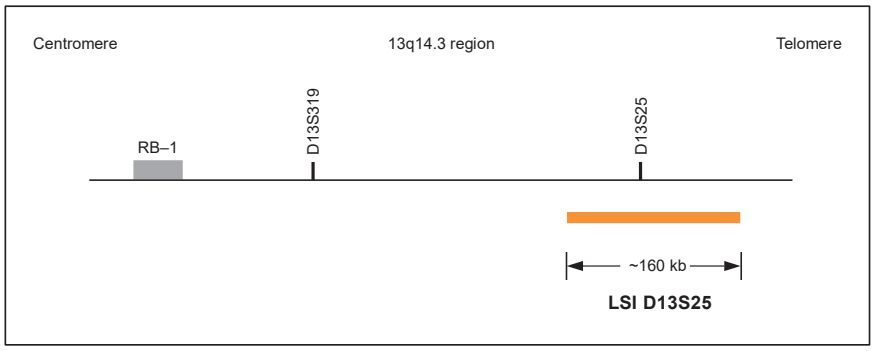
In a normal cell, the expected pattern for FISH Probe LSI CSF1R/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the 5q33-q34 deletion, the one orange, two green (1O2G) signal pattern will be observed.

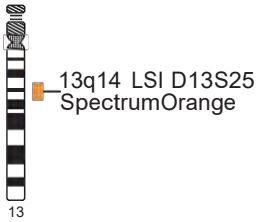
Ordering Information	Quantity	Order No.
Vysis CSF1R/D5S23, D5S721 FISH Probe Kit	20 µl	05N03-020

References

1. Kelaidi C, Eclache V, Fenaux P. The role of lenalidomide in the management of myelodysplasia with del 5q. *Br J Haematol*. 2008; 140(3): 267-278.
2. Boultwood J, Fidler C, Strickson AJ, et al. Narrowing and genomic annotation of the commonly deleted region of the 5q-syndrome. *Blood*. 2002; 99(12): 4638-4641.
3. Bram S, Swolin B, Rödjer S, et al. Is monosomy 5 an uncommon aberration? *Cancer Genet Cytogenet.* 2003; 142(2): 107-114.
4. Herry A, Douet-Guilbert N, Morel F, et al. Redefining monosomy 5 by molecular cytogenetics in 23 patients with MDS/AML. *Eur J Haematol.* 2007; 78(6): 457-467.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med*. 2006; 8(1): 16-23.

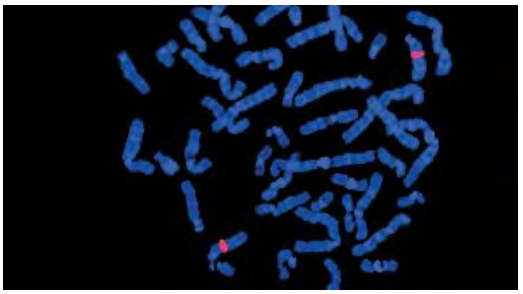
Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe





The LSI D13S25 Probe may be used to identify deletions in the 13q14.3 region. A candidate tumor suppressor gene may reside telomeric of the RB1 gene at 13q14. Deletion of the locus D13S25 at 13q14.3 occurs in a substantial number of cases without deletion of the RB1 gene.

The LSI D13S25 Probe is an approximately 160 kb SpectrumOrange labeled probe.



LSI D13S25 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

Results of Hybridization

In a normal cell, the expected pattern for a nucleus hybridized with the LSI D13S25 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

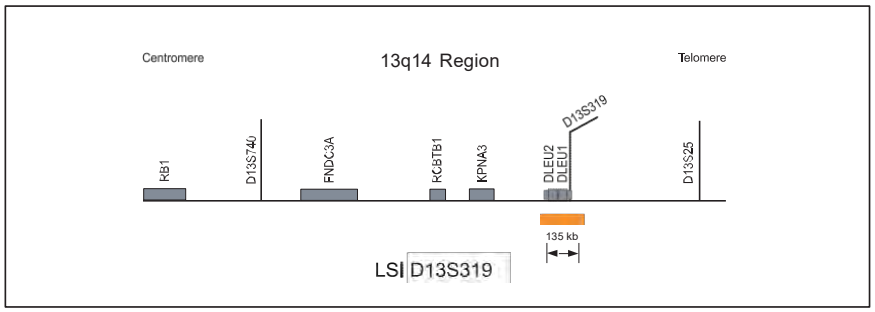
Ordering Information	Quantity	Order No.
Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe	20 µl	01N37-020

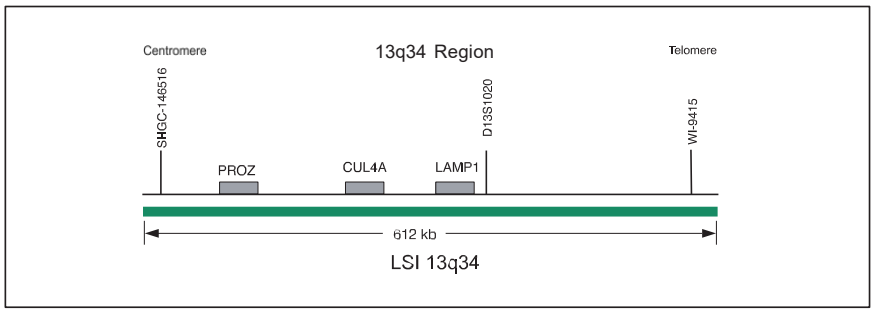
References

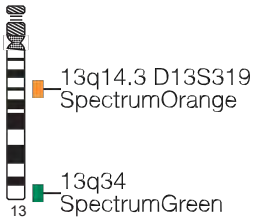
1. Corcoran MM, Hammersund M, Zhu C, et al. DLEU2 Encodes an Antisense RNA for the Putative Bicistronic RFP2/LEU5 Gene in Humans and Mouse. *Genes Chromosomes Cancer* 2004; 40: 285-97.
2. Calin GA, Dumitru CD, Shimizu M, et al. Frequent deletions and down-regulation of micro-RNA genes miR15 and miR16 at 13q14 in chronic lymphocytic leukemia. *Proc Natl Acad Sci USA* 2002; 99(24): 15524-29.
3. Mertens D, Wolf S, Tschuch C, et al. Allelic silencing at the tumor-suppressor locus 13q14.3 suggests an epigenetic tumor-suppressor mechanism. *Proc Natl Acad Sci USA* 2006; 103(20): 7741-46.
4. Navarro B, Garcia-Marco JA, Jones D, et al. Association and clonal distribution of trisomy 12 and 13q14 deletions in chronic lymphotic leukaemia. *Br J Haematol* 1998; 102: 1330-34.
5. Königsberg R, Ackermann J, Kaufmann H, et al. Deletions of chromosome 13q in monoclonal gammopathy of undetermined significance. *Leukemia* 2000; 14: 1975-79.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med*. 2006; 8(1): 16-23.

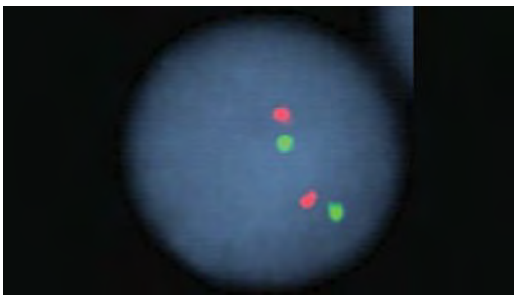
Vysis D13S319/13q34 FISH Probe Kit

previously Vysis LSI D13S319 (13q14.3) SpectrumOrange/Vysis LSI 13q34 SpectrumGreen Probe

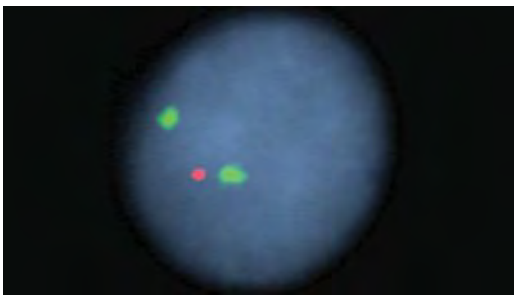








Normal nucleus showing the two green and two orange signals.



Abnormal nucleus showing the two green and one orange signal.

The Vysis D13S319/LSI13q34 FISH Probe Kit is intended to detect the copy number of the LSI D13S319 probe target located at chromosome 13q14 and the copy number of the LSI13q34 probe target located at chromosome 13q34.

Loss 13q or all of chromosome 13 occurs commonly in multiple myeloma.[1] Avet-Loiseau et al[2] utilized the Vysis D13S319 probe in alarge study to demonstrate the negative effects of the loss of 13q on event-free survival and overall survival in myeloma patients.

The approximately 135 kb SpectrumOrange D13S319 probe contains the D13S319 marker and is located at chromosome 13q14 (chr13:49500369-49635302 March 2006 UCSC Browser).

Results of Hybridization:

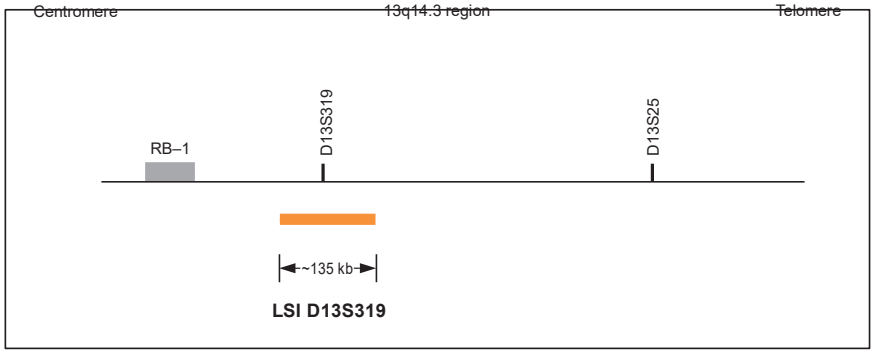
In a cell with normal copy numbers of the LSI D13S319/LSI13q34 Probe targets, two orange signals and two green signals will be expected. The expected abnormal pattern is one orange and two green signals (deletion pattern) or one orange and one green signal (monosomy pattern). Other abnormal FISH signal patterns may be observed and metaphase analysis may be useful in interpreting these results.

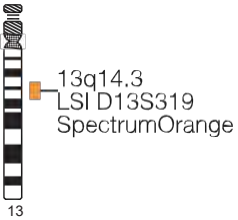
Ordering Information	Quantity	Order No.
Vysis D13S319/13q34 FISH Probe Kit	20 µl	05N37-020

References

1. Fonseca R, Blood E, Rue M, et al. Clinical and biologic implications of recurrent genomic aberrations in myeloma. Blood. 2003;101(11):4569-75.
2. Avet-Loiseau H, Attal M, Moreau P, et al. Genetic abnormalities and survival in multiple myeloma: the experience of the Intergroup Francophone du Myélome. Blood. 2007;109(8):3489-95.
3. Wiktor AE, Van DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

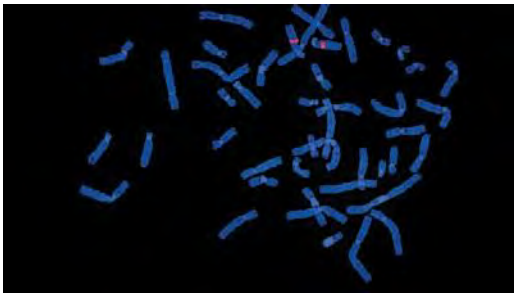
Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe





The LSI D13S319 Probe may be used to identify deletions of the LSI D13S319 locus at 13q14.3. D13S319 located between RB1 and the D13S25 loci is a commonly deleted marker. A candidate tumor suppressor gene resides telomeric of the RB1 gene at 13q14.

LSI D13S319 Probe is an approximately 135 kb SpectrumOrange labeled probe.



LSI D13S319 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

Results of Hybridization

In a normal cell, the expected pattern for the LSI D13S319 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

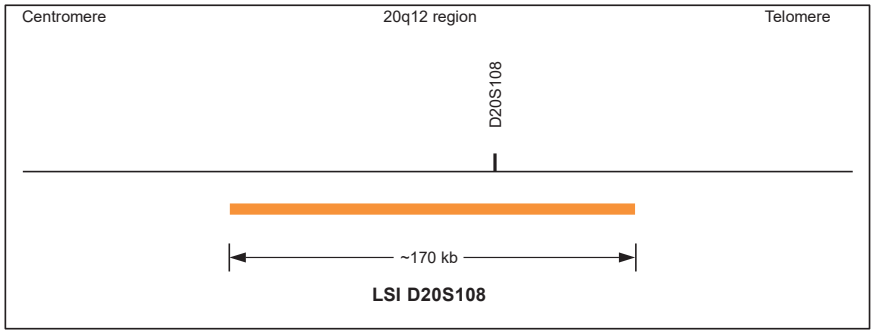
Ordering Information	Quantity	Order No.
Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe	20 µl	01N34-020

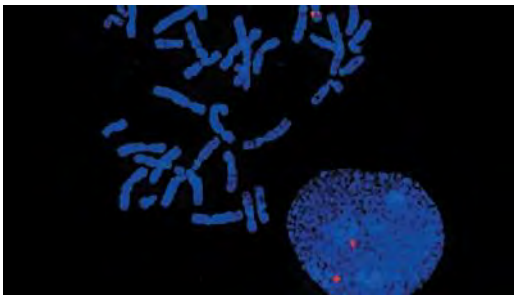
References

1. Corcoran MM, Hammersund M, Zhu C, et al. DLEU2 Encodes an Antisense RNA for the Putative Bicistronic RFP2/LEU5 Gene in Humans and Mouse. *Genes Chromosomes Cancer* 2004; 40: 285-97.
2. Kalaschikov S, Migliazza A, Cayanis E, et al. Cloning and gene mapping of the chromosome 13q14 region deleted in chronic lymphocytic leukemia. *Genomics* 1997; 42: 369-77.
3. Stilgenbauer S, Nickolenko J, Wilhelm J, et al. Expressed sequences as candidates for a novel tumor suppressor gene at bend 13q14 in B-cell chronic lymphocytic leukemia and mantle cell lymphoma. *Oncogene* 1998; 16: 1891-97.
4. Reddy KS. Chronic lymphocytic leukaemia profiled for prognosis using a fluorescence in situ hybridisation panel. *Br J of Haematol* 2006; 132: 105-22.
5. Döhner H, Stilgenbauer S, Benner A, et al. Genomic aberrations and survival in chronic lymphocytic leukemia. *N Eng J Med* 2000; 343: 1910-16.
6. Elnenaei MO, Hamoudi RA, Swansbury J, et al. Delineation of the minimal region of loss at 13q14 in multiple myeloma. *Genes Chromosomes Cancer* 2003; 36: 99-106.
7. Fonseca R, Oken MM, Harrington D, et al. Deletions of chromosome 13 in multiple myeloma identified by interphase FISH usually denote large deletions of the q arm or monosomy. *Leukemia* 2001; 15: 981-86.
8. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med* 2006; 8: 16-23.

Vysis D20S108 FISH Probe Kit

previously: Vysis LSI D20S108 (20q12) SpectrumOrange Probe





LSI D20S108 Single Color Probe hybridized to normal cells showing the two orange (2O) signal pattern.

The Vysis LSI D20S108 fluorescence in situ hybridization (FISH) probe is intended to detect deletions of Vysis LSI D20S108 probe target locus on 20q12.

Acquired deletions of the long arm of chromosome 20 are found in ~4 % of patients with a myelodysplastic syndrome (MDS) and in 1 to 2% of patients with acute myeloid leukemia (AML) and myeloproliferative disorders (MPD).[1] Cytogenetic analysis of del(20q) revealed that the deletion is variable in size, with a commonly deleted region (CDR) spanning 20q11.[2] to q12. Within the commonly deleted segment lies the SRC oncogene and possibly other tumor suppressor genes.[2, 3] The CDR is defined as a 2.7 Mb segment in MPD and a 2.6 Mb segment in AML/MDS, with an overlapping region of 1.7 Mb.[3, 4] In a study of 36 MPD, MDS, and AML patients with del(20q), statistical analyses showed that patients with del(20q) as a sole cytogenetic aberration (favorable subgroup) live longer than patients with del(20q) and other chromosomal changes (poor prognosis subgroup).[1] Among patients from MDS, MPD and MDS/MPD groups, Douet-Guilbert et al[4] identified one commonly deleted region in all 38 investigated samples using FISH, including the Vysis LSI D20S108 FISH Probe.

The Vysis LSI D20S108 Probe is an approximately 201 kb Spectrum-Orange labeled probe and contains the D20S108 locus located on chromosome 20q12.

Results of Hybridization

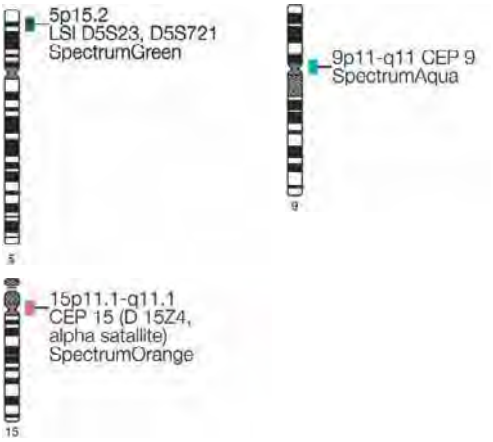
In a normal cell hybridized with the LSI D20S108 probe, the expected pattern is the two orange (2O) signal pattern. In an abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

Ordering Information	Quantity	Order No.
Vysis D20S108 FISH Probe Kit	20 µl	05N02-020

References

1. Bfezinová J, Zemanová Z, Ransdorfová Š, et al. Prognostic significance of del(20q) in patients with hematological malignancies. Cancer Genet Cytogenet. 2005;160(2):188-192.
2. Roulston D, Espinosa R 3rd, Stoffel M, et al 1993. Molecular genetics of myeloid leukemia: identification of the commonly deleted segment of chromosome 20. Blood. 1993;82(11):3424-3429.
3. Bench AJ, Nacheva EP, Hood TL, et al. Chromosome 20 deletions in myeloid malignancies: reduction of the common deleted region, generation of a PAC/BAC contig and identification of candidate genes. UK Cancer Cytogenetics Group (UKCCG) Oncogene. 2000; 19(34):3902-3913.
4. Douet-Guilbert N, Basinko F, Morel F, et al. Chromosome 20 deletions in myelodysplastic syndromes and Philadelphia-chromosome-negative myeloproliferative disorders: characterization by molecular cytogenetics of commonly deleted and retained regions. Ann Hematol. 2008;87(7):537-544.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

Vysis LSI D5S23/D5S721, CEP9, CEP 15 Multi-Color Probe

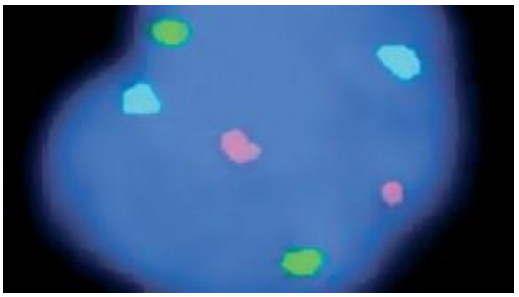


The LSI D5S23/D5S721, CEP 9, CEP 15 Multi-color Probe Set is comprised of a mixture of an approximately 450 kb SpectrumGreen labeled D5S23/D5S721 probe, a SpectrumAqua labeled CEP 9 probe and a SpectrumOrange labeled CEP 15 probe. The LSI D5S23/D5S721 probe is specific for the 5p15.2 region. The CEP 9 probe is specific for the alpha satellite (centromeric) region, 9p11-q11. The CEP 15 probe is specific for the alpha satellite (D15Z4 centromeric) region, 15p11.1-q11.1.

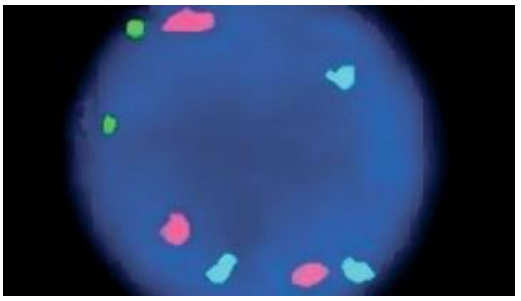
Results of Hybridization

In a normal cell that lacks hyperdiploidy of chromosome 5, chromosome 9 and chromosome 15, a two green, two aqua and two orange signal pattern will be observed reflecting the two copies of each chromosome. In an abnormal cell containing hyperdiploidy of either chromosome 5, chromosome 9 or chromosome 15, greater than two signals will be observed for the respective chromosomes.

Ordering Information	Quantity	Order No.
Vysis LSI D5S23/D5S721, CEP 9, CEP 15 Multi-Color Probe	20 µl	05N35-020



An interphase cell hybridized with the LSI D5S23/D5S721, CEP 9, CEP 15 Probe. The cell shows the two green (LSI D5S23/D5S721), two aqua (CEP 9) and two orange (CEP 15) signal patterns.



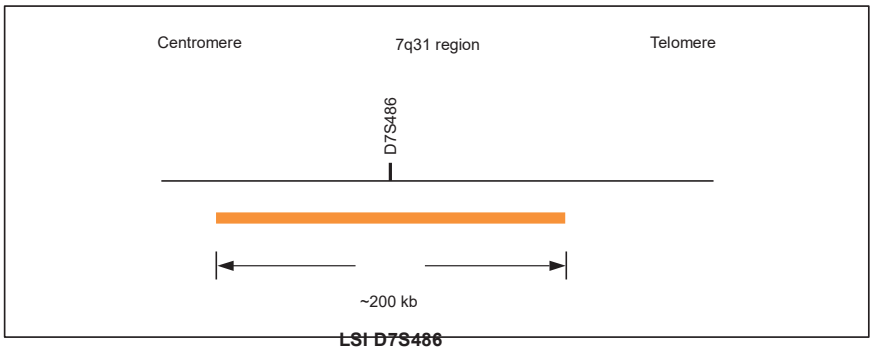
An interphase cell hybridized with the LSI D5S23/D5S721, CEP 9, CEP 15 Probe. The cell in this image shows a two green (LSI D5S23/D5S721), three aqua (CEP 9) and three orange (CEP 15) signal patterns.

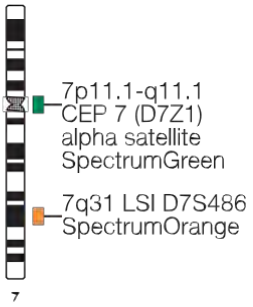
References

1. Fonseca, R., et al. Cancer Research 64 (2004): 1546-1558.
2. Fonseca, R., et al. Blood 102 (7) (2003): 2562-2567.
3. Debes-Marun, C., et al. Leukemia 17 (2003): 427-436.
4. Fonseca, R., et al. Blood 101 (11) (2003): 4569-4575.
5. Perez-Simon, J., et al. Blood 91 (1998): 3366-3371.

Vysis D7S486/CEP 7 FISH Probe Kit

previously: Vysis LSI D7S486 (7q31) SpectrumOrange/CEP 7 SpectrumGreen Probe

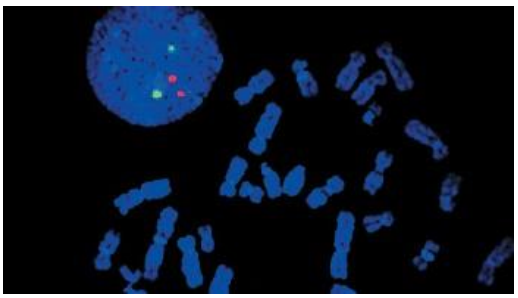




The Vysis D7S486/CEP7 FISH Probe Kit is intended to detect the copy number of the LSI D7S486 and CEP 7 probe targets located at chromosome 7q31 and 7p11.1-q11.1, respectively.

Monosomy 7 and loss of chromosome 7q are observed in a variety of myeloid malignancies such as myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). In some instances, these abnormalities are associated with patient outcome.1,2 The Vysis LSI D7S486 SpectrumOrange/CEP 7 SpectrumGreen Probes have been used to detect copy number abnormalities of the LSI D7S486 and CEP7 probe targets in both AML and MDS.3,4

The Vysis LSI D7S486 SpectrumOrange/CEP 7 SpectrumGreen Probes are a mixture of a SpectrumOrange D7S486 probe (7q31) and a SpectrumGreen CEP 7 probe (7p11.1-q11.1). The LSI D7S486 probe target is approximately 308 kb in length.The CEP 7 probe targets the D7Z1 alpha satellite sequence at the centromere of chromosome 7.



LSI D7S486/CEP 7 Dual Color Probe hybridized to a normal nucleus showing the two orange, two green (2O2G) signal pattern.

Results of Hybridization

In a normal cell, the expected pattern when hybridized with the LSI D7S486/CEP 7 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.

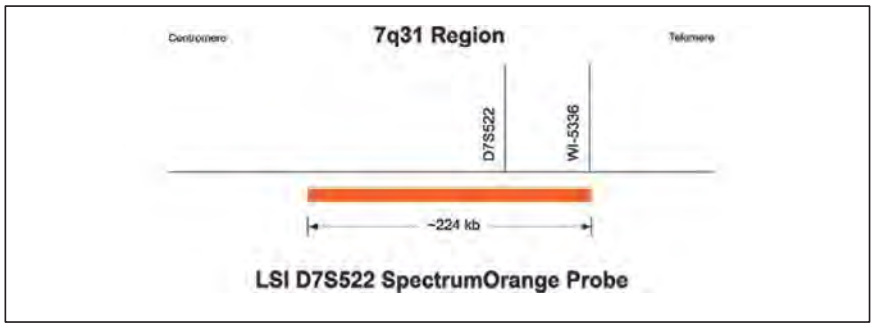
Ordering Information	Quantity	Order No.
Vysis D7S486/CEP 7 FISH Probe Kit	20 µl	05N07-020

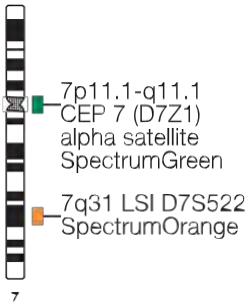
References

1. Bernasconi P, Klersy C, Boni M, et al. Br J Haematol. 2007;137(3):193-205.
2. Byrd JC, Mrózek K, Dodge RK, et al. Blood. 2002;100(13):4325-4336.
3. Cherry AM, Brockman SR, Paternoster SF, et al. Leuk Res. 2003;27(12):1085-1090.
4. Vance GH, Kim H, Hicks GA, et al. Leuk Res. 2007;31(5):605-609.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al.Genet Med. 2006;8(1):16-23.

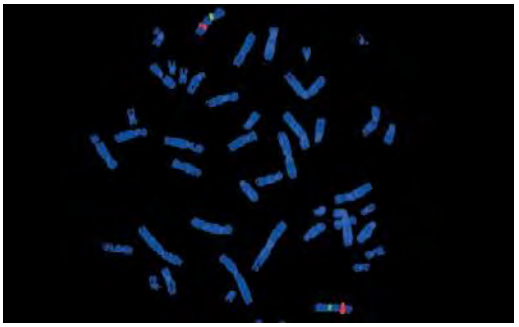
Vysis D7S522 / CEP 7 FISH Probe Kit

previously: Vysis LSI D7S522 (7q31) SpectrumOrange/CEP 7 SpectrumGreen Probe





The Vysis D7S522/CEP7 FISH Probe Kit is intended to detect the copy number of the LSI D7S522 and CEP 7 probe targets located at chromosome 7q31 and 7p11.1-q11.1, respectively. Monosomy 7 and loss of chromosome 7q are observed in a variety of myeloid malignancies such as myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). In some instances, these abnormalities are associated with patient outcome.1,2 The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes have been used to detect copy number abnormalities of the LSI D7522 and CEP7 probe targets in both AML and MDS.3,4 The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes are a mixture of a SpectrumOrange D7S522 probe (7q31) and a SpectrumGreen CEP 7 probe (7p11.1-q11.1). The LSI D7S522 probe target is approximately 224 Kb in length. The CEP 7 probe targets the D7Z1 alpha satellite sequence at the centromere of chromosome 7.



LSI D7S522/CEP 7 Dual Color Probe hybridized to a normal metaphase cell showing the two orange, two green (2O2G) signal pattern.

Results of Hybridization

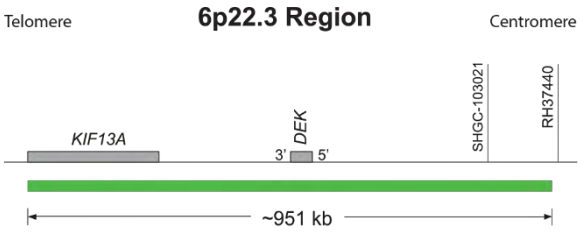
In a normal cell hybridized with the LSI D7S522/CEP 7 Probe, the expected pattern is the two orange, two green (2O2G) signal pattern. In an abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.

Ordering Information	Quantity	Order No.
Vysis D7S522/CEP 7 FISH Probe Kit	20 µl	05N08-020

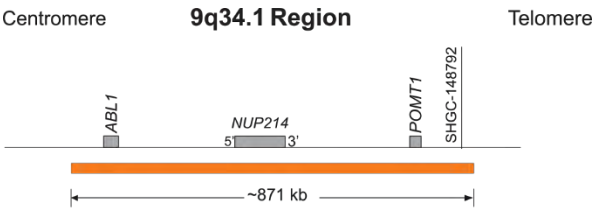
References

1. Bernasconi P, Klersy C, Boni M, et al. World Health Organization classification in combination with cytogenetic markers improves the prognostic stratification of patients with de novo primary myelodysplastic syndromes. Br J Haematol. 2007;137(3):193-205.
2. Byrd JC, Mrózek K, Dodge RK, et al. Pretreatment cytogenetic abnormalities are predictive of induction success, cumulative incidence of relapse, and overall survival in adult patients with de novo acute myeloid leukemia: results from Cancer and Leukemia Group B (CALGB 8461). Blood. 2002;100(13):4325-4336.
3. Li X, Wu L, Ying S, et al. Differentiation and hematopoietic-support of clonal cells in myelodysplastic syndromes Leuk Lymphoma. 2007; 48(7):1353-1371.
4. Abdelrazik HN, Farawila HM, Sherif MA, et al. Molecular characterization of chromosome 7 in AML and MDS patients. Afr J Health Sci. 2006;13(3-4):33-42.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

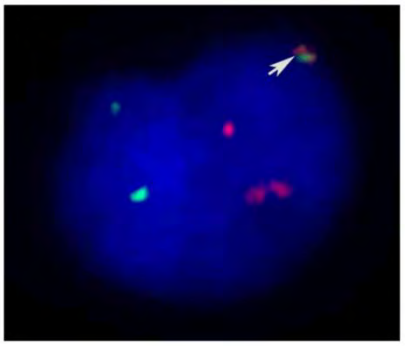
Vysis LSI DEK/NUP214 Dual Color, Dual Fusion Translocation FISH Probe Kit



Vysis LSI DEK SpectrumGreen Probe



Vysis LSI NUP214 SpectrumOrange Probe



Fluorescence in situ hybridization detection of the DEK/NUP214 fusion gene. Arrow indicates the fusion probe signal, where red indicates the NUP214 probe and green indicates the DEK probe.

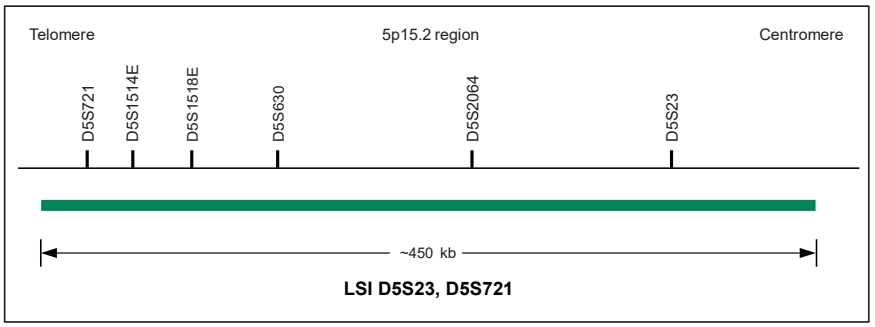
PRODUCT DESCRIPTION

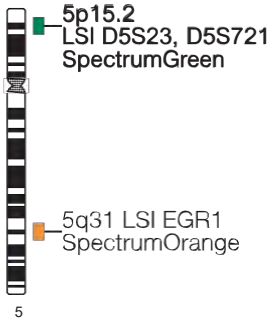
The Vysis LSI DEK SpectrumGreen probe is targeted to the 6p22.3 region spanning the DEK gene. The probe is approximately 951 kb in size spanning the entire region.

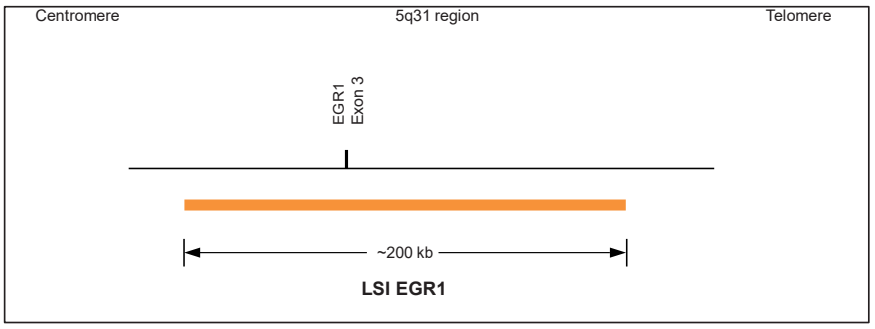
The Vysis LSI NUP214 SpectrumOrange probe is targeted to the 9q34.1 region spanning the NUP214 gene. The probe is approximately 871 kb in size spanning the entire region.

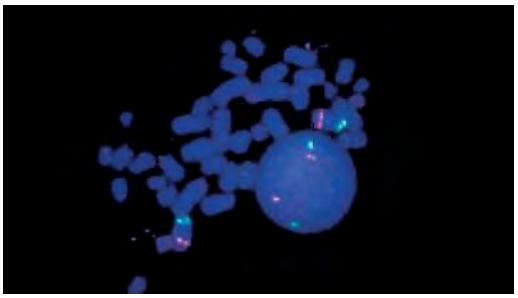
Ordering Information	Quantity	Order No.
LSI DEK/NUP214 Dual Colour, Dual Fusion Probe	20 uL	09N24-060

Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Set









LSI EGR1/D5S721, D5S23 Dual Color Probe hybridized to normal cells showing the two orange, two green (2O2G) signal pattern.

The LSI EGR1/D5S23, D5S721 Dual Color Probe may be used to detect deletions of 5q31 containing the EGR1 locus. The LSI D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.

The LSI EGR1/D5S23, D5S721 Probe is a mixture of the approximately 200 kb SpectrumOrange labeled LSI EGR1 probe and the approximately 450 kb SpectrumGreen labeled LSI D5S28, D5S721 probe.

Results of Hybridization

In a normal cell, the expected pattern for a nucleus hybridized with the LSI EGR1/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.

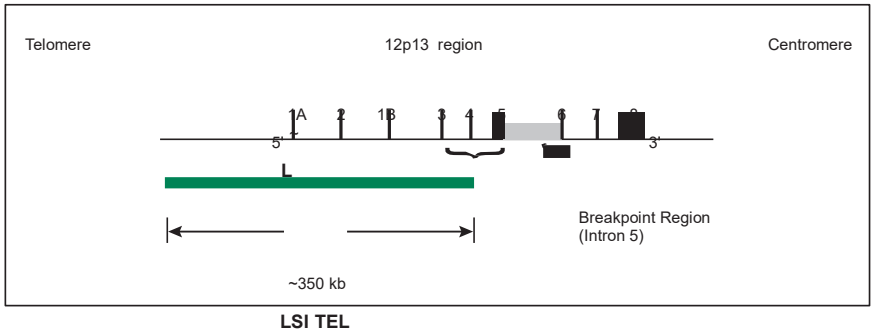
Ordering Information	Quantity	Order No.
Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Set	20 µl	08L68-020

References

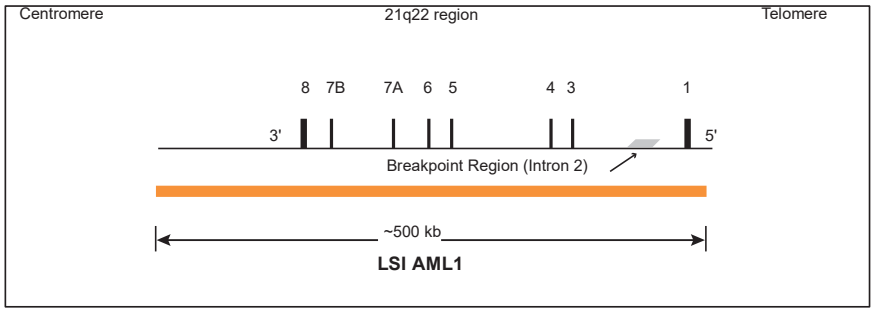
1. Lai F, Godley LA, Joslin J, et al. *Genomics* 2001; 71: 235-45.
2. Joslin JM, Femald AA, Tennant TR, et al. *Blood* 2007; 110(2): 719-726.
3. Zou YS, Fink SR, Stockero KJ, et al. *Leuk Res* 2007; 31: 1185-89.
4. Vance GH, Kim H, Hicks GA, et al. *Leuk Res* 2007; 31: 605-09.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. *Genet Med* 2006; 8: 16-23.

Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe

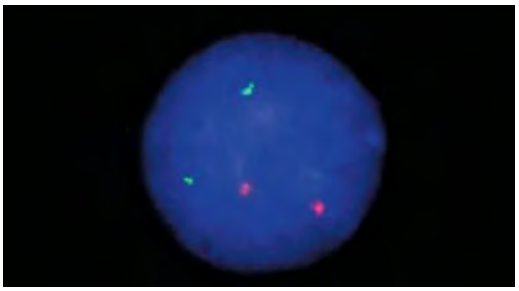
previously: Vysis LSI TEL/AML1 ES Dual Color Translocation Probe



LSI TEL



LSI AML1



Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe hybridized to a normal nucleus lacking the TEL/AML1 fusion gene showing the two orange and two green (2O2G) signal pattern.

The Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe is designed to detect the TEL (ETV6)/AML1 (RUNX1) gene fusion that occurs as a result of a translocation between chromosomes 12p13 and 21q22. Cytogenetically, the t(12;21) is a subtle abnormality and thus not easily detectable with standard cytogenetic banding techniques.

The Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe is a mixture of the LSI TEL probe labeled with SpectrumGreen and the LSI AML1 probe labeled with SpectrumOrange. The LSI TEL probe begins between exons 3-5 and extends approximately 350 kb toward the telomere on chromosome 12. The approximately 500 kb AML1 probe spans the entire gene.

Results of Hybridization

In a normal nucleus, the expected pattern for a cell hybridized with the LSI TEL/AML1 ES Dual Color Translocation probe is the two orange (AML1), two green (TEL) (2O2G) signal pattern. In an abnormal cell containing the TEL/AML1 fusion, the expected signal pattern is one green (native TEL), one large orange (native AML1), one smaller orange signal (residual AML1) and one fused orange/green (yellow) signal. The green native signal may be absent in some instances due to the deletion of the non-translocated TEL allele.

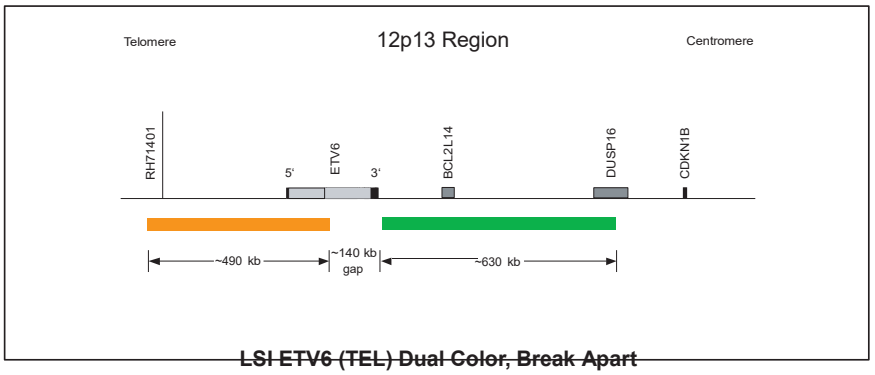
Ordering Information	Quantity	Order No.
Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe	20 µl	08L66-020

References

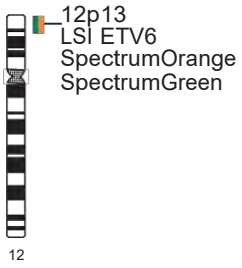
1. Golub, TR. et. al.1995. Proc. Natl. Acad. Sci. USA, 92: 4917-4921;
2. Romona, SP. et. al.1995. Blood, 86(110): 4264-4269;
3. Shurtleff, SA. et. al. 1995. Leukemia 9: 1985-1989;
4. Cayuela, JM, et. al. 1996. Blood, 88(1): 302-308;
5. Raynaud, S. et. al. 1996. Blood, 87(7): 2891-2899.

Vysis ETV6 Break Apart FISH Probe Kit

previously Vysis LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe



LSI ETV6 (TEL) Dual Color, Break Apart

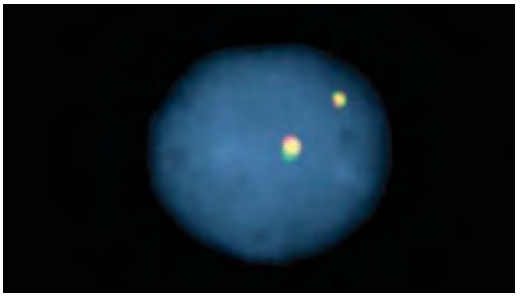


Hybridization with the Vysis ETV6 Break Apart FISH Probe Kit will identify rearrangements at the ETV6 gene region, regardless of what other chromosomal regions are involved. For example, this will allow detection of a chromosomal break caused by a translocation in the ETV6 gene region even when the translocation partner is unknown.

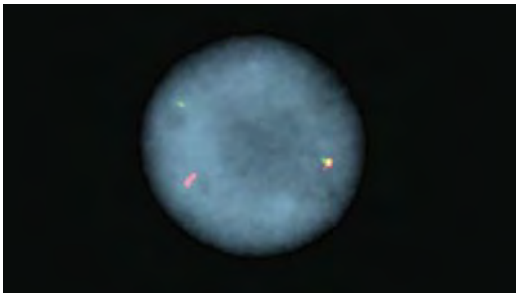
The Vysis ETV6 Break Apart FISH Probe Kit is a mixture of two probes. The first probe, a 630 kb probe labeled in SpectrumGreen begins about 6 kb proximal to the ETV6 (TEL) gene and extends to toward the centromere. The second probe, labeled in SpectrumOrange, begins within ETV6 intron 2 and extends toward the 12p telomere for approximately 490 kb. There is a gap between the two probes of about 140 kb.

Results of Hybridization

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals. The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 12 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.



Normal cell hybridization using the Vysis ETV6 Break Apart FISH Probe Kit.



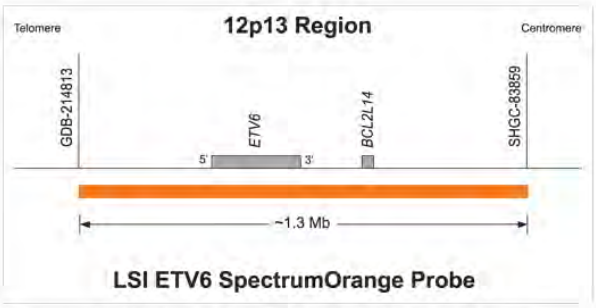
Abnormal cell hybridization using the Vysis ETV6 Break Apart FISH Probe Kit.

Ordering Information	Quantity	Order No.
Vysis ETV6 Break Apart FISH Probe Kit	20 µl	04N09-020

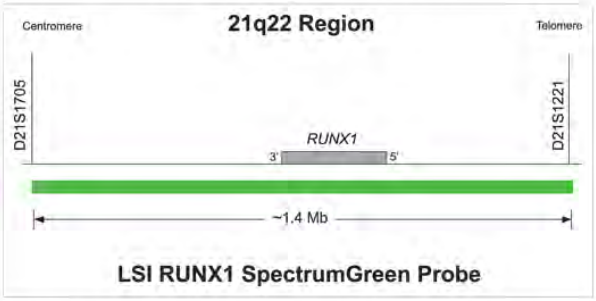
References

1. Bohlander SK. Semin Cancer Biol. 2005;15(3):162-174.
2. Odero MD, Carlson K, Calasanz MJ, et al. Genes Chromosomes Cancer. 2001;31(2):134-142.
3. Schwindt H, Vater I, Kreuz M, et al. Leukemia. 2009. [Epub ahead of print]
4. Park J, Kim M, Lim J, et al. Cancer Genet Cytogenet. 2009;191(2):102-105.
5. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med. 2006;8(1):16-23.

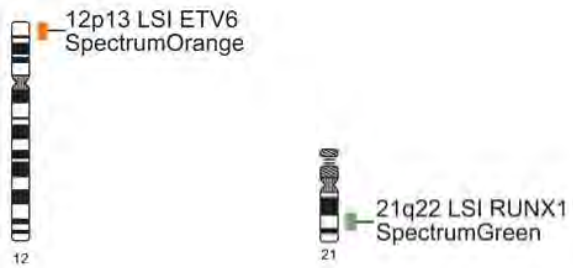
Vysis ETV6/RUNX1 DF FISH Probe Kit

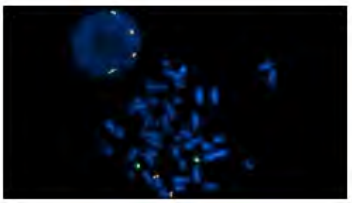


The approximately 1.3 Mb SpectrumOrange probe spans the ETV6 breakpoint region.

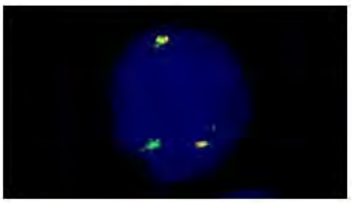


The approximately 1.4 Mb SpectrumGreen probe spans the RUNX1 breakpoint region.





Two lymphocyte cells, one in interphase (upper left) next to chromosomes from a metaphase cell (lower right), that have been hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. Both cells show the two orange (RUNX1), two green (ETV6) signal pattern.



A bone marrow cell in interphase hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. The cell in this image shows the one orange (RUNX1), one green (ETV6), two fusion (der (12) and der (21)) signal pattern.

The Vysis ETV6/RUNX1 DF FISH Probe Kit is intended to detect the t(12;21)(p13;q22) translocation between the ETV6 gene and the RUNX1 gene using the fluorescence in situ hybridization (FISH) technique.

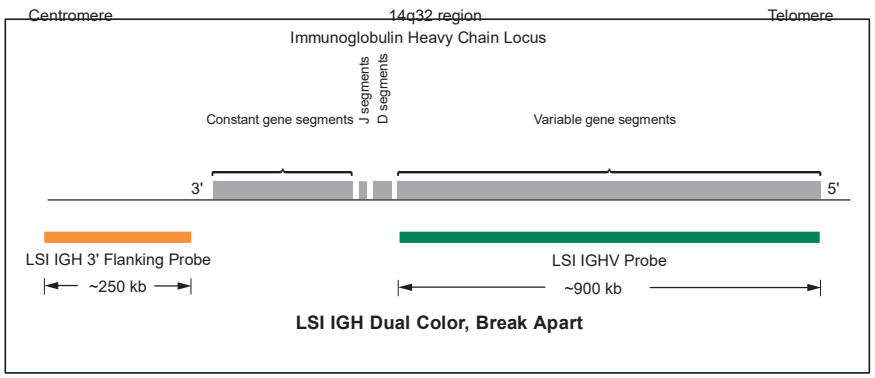
The t(12;21)(p13;q22) chromosomal translocation is the most common chromosomal rearrangement in childhood acute lymphocytic leukemia (ALL). Although not detectable by classical cytogenetics,[1] the t(12;21) resulting in the fusion of the 5' section of the ETV6 (TEL) gene on chromosome 12p13 to almost the entire RUNX1 (AML1) gene located on chromosome 21q22 occurs in about 25% of childhood ALL.[2] The Vysis ETV6/RUNX1 DF FISH Probe Kit uses a dual-color, dual-fusion probe design to detect the t(12;21) by fluorescence in situ hybridization.

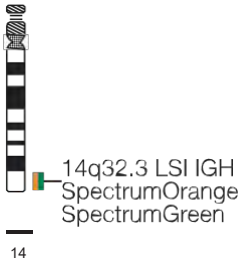
Ordering Information	Quantity	Order No.
Vysis ETV6/RUNX1 DF FISH Probe Kit	10 µl	05N96-010

Reference:

1. Romana SP, Poirel H, Leconiat M, et al. High frequency of t(12;21) in childhood B-lineage acute lymphoblastic leukemia. Blood. 1995;86(11):4263-4269.
2. Harrison CJ, Haas O, Harbott J, et al. Detection of prognostically relevant genetic abnormalities in childhood B-cell precursor acute lymphoblastic leukaemia: recommendations from the Biology and Diagnosis Committee of the International Berlin-Frankfürt-Münster study group. Br J Haematol. 1995;151(2):132-142.

Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe



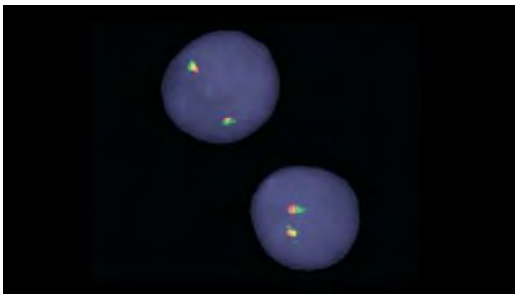


The LSI IGH Dual Color, Break Apart Rearrangement Probe is designed to detect chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is associated with 14q32 translocations involving a variety of other loci. Breakpoints within the IGH locus may occur at either the J segments [e.g., breakpoints commonly observed with t(14;18)] or within switch sequences located within the constant gene segments.

The LSI IGH Dual Color, Break Apart Rearrangement Probe is a mixture of two probes that hybridize to opposite sides of the J through constant regions of the IGH locus. The approximately 900 kb SpectrumGreen labeled LSI IGHV probe covers essentially the entire IGH variable region. The hybridization target of the approximately 250 kb SpectrumOrange labeled LSI IGH 3' flanking probe lies completely 3' to the IGH locus. As a result of this probe design, any translocation with a breakpoint at the J segments or within switch sequences should produce separate orange and green signals.

Results of Hybridization

When hybridized to a normal nucleus, the LSI IGH Dual Color, Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) signal pattern. As there is no probe targeted to the J or constant regions, a slight gap between the two differently colored probe signals may sometimes be observed in nuclei from normal cells. When the IGH Dual Color, Break Apart Translocation Probe is hybridized to a nucleus containing an IGH translocation, one orange, one green, and one orange/green fusion signal pattern is observed (1O1G1F). This signal pattern indicates that the genomic targets for the LSI IGHV and LSI IGH 3' flanking probes have been physically separated as a result of the translocation. As V(D)J rearrangements may occur on either, or both, of the translocated and non-translocated IGH alleles, the green LSI IGHV probe signal intensity on either, or both, of the alleles may be diminished as a result of probe target deletion in some samples.

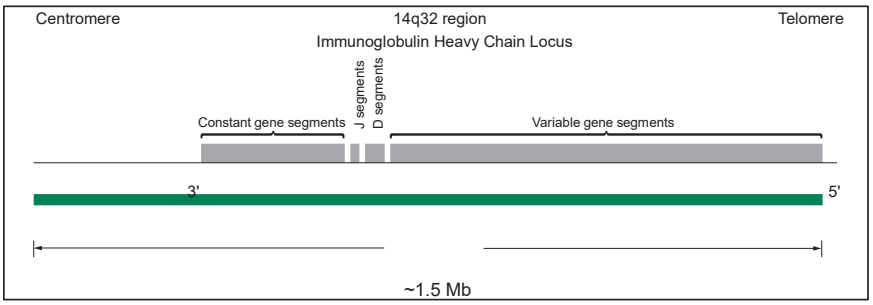


LSI IGH Dual Color, Break Apart Rearrangement Probe hybridized to normal nuclei exhibiting the expected two fusion (2F) signal pattern.

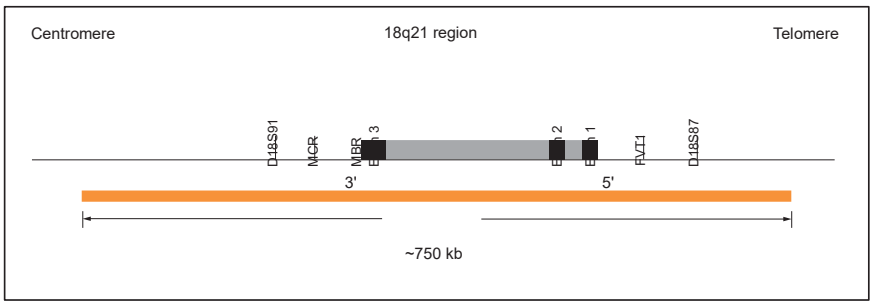
Ordering Information	Quantity	Order No.
Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe	20 µl	08L63-020

References
1.Chesi, M., et al. Ann. Oncol. 11 (2000): S131-5.
2.DeVita,V.T. Cancer: Principles Practices of Oncology 5th ed. (1997).

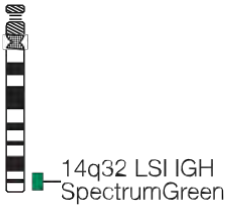
Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe

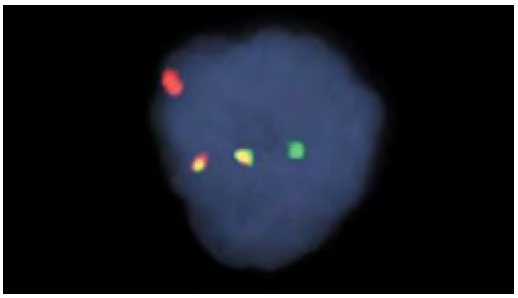


LSI IGH



LSI BCL2





LSI IGH/BCL2 Dual Color, Dual Fusion Translocation the t(14;18) (q32;q21) showing the 1O1G2F signal pattern.

The LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is designed to detect the juxtaposition of immunoglobulin heavy chain (IGH) locus and BCL gene sequences. The translocation involving IGH at 14q32 and BCL2 at 18q21, t(14;18)(q32;q21) is common. Relocation of an IGH transcriptional enhancer next to the BCL2 gene as a result of the t(14;18) translocation is thought to cause constitutive over-expression of the anti-apoptotic BCL2 protein. The breakpoints at 14q32 occur at the IGH J segments and about 75% of the breaks at 18q21 occur in either the 2.8 kb major breakpoint region (MBR) 3' of BCL2 exon 3 or in the minor cluster region (MCR) located about 30 kb 3' to the MBR. The remaining BCL2 breakpoints are thought to lie between the MBR and MCR regions, or 5' of the BCL2 gene.

The LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI IGH probe labeled with SpectrumGreen spanning approximately 1.5 Mb and containing sequences homologous to essentially the entire IGH locus, as well as sequences extending about 300 kb beyond the 3' end of the IGH locus. The LSI BCL2 probe labeled with SpectrumOrange covers an approximate 750 kb region, including the entire BCL2 gene with additional sequences extending approximately 250 kb both distal and proximal to the gene.

Results of Hybridization

The expected pattern in a normal nucleus hybridized with the LSI IGH/ BCL2 probe is the two orange, two green signal pattern (2O2G). In a nucleus harboring a t(14;18), the most common pattern is one orange signal, one green signal (representing the normal homolog) and two orange/ green (yellow) fusion signals representing the two derivative chromosomes resulting from the reciprocal translocation (1O1G2F pattern). Patterns other than 1O1G2F may be observed in some abnormal cells including instances of nuclei containing more than two fusion signals.

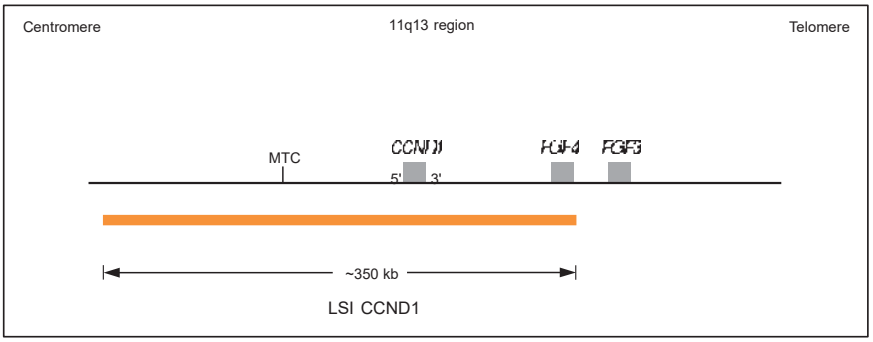
Ordering Information	Quantity	Order No.
Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe	20 µl	08L60-020

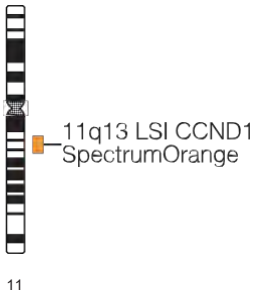
References

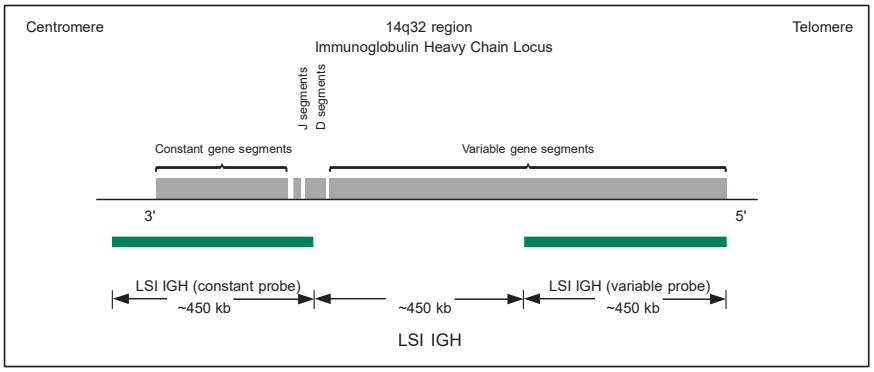
1. Rowely J. J Clin Oncol 1988;6:919-925.
2. Horsman D, Gascoyne R, Coupland R, et al. AM J Clin Pathol 1995;103:472-478.
3. Jacobson J, Wilkes B, Kwiatkowski D, et al. Cancer 1993;72:231-6.
4. Weiss L, Warnke R, Sklar J, et al. N Engl J Med 1987;317(19):1185-89.
5. Nowakowski GS, Dewald GW, Hoyer JD, et al. Br J Haematol 2005;130:36-42.
6. Streubel B, Scheucher B, Valencak J, et al. AM J Surg Pathol 2006;20(4):529-36.
7. Paternoster SF, Brockman SR, McClure RF, et al. Am J Pathol 2002;160(6):1967-72.
8. Einerson RR, Kurtin PJ, Dayharsh GA, et al. Am J Clin Pathol 2005;124:421-29.
9. Barrans SL, Evans P, O'Connor S, et al. J Mol Diagn 2003;5:168-75.
10. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

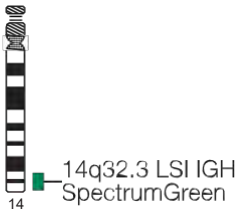
Vysis IGH/CCND1 DF FISH Probe Kit

previously Vysis LSI IGH/CCND1 Dual Color, Dual Fusion Translocation Probe

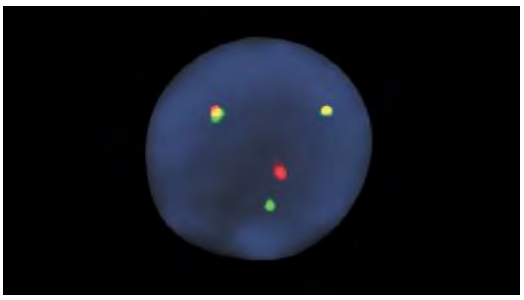








These fluorescence in situ hybridization (FISH) probes are intended to detect the t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.Mantle cell lymphoma is commonly associated with the balanced translocation t(11;14)(q13;q32).[1] Mantle cell lymphoma has the most aggressive clinical course among the small cell lymphomas. FISH has emerged as an important aid in the diagnosis of mantle cell lymphoma.[1, 2, 3] The Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes have been used in publications to detect t(11;14) in Mantle Cell Lymphoma.[3, 4]



Vysis IGH/CCND1 DF FISH Probe hybridized to an abnormal nucleus showing the common 1O1G2F signal pattern.

Results of Hybridization

LSI IGH/CCND1 hybridized to a cell containing t(11;14) with breakpoints at the MTC on 11q13 and at the IGH J region on 14q32 is expected to result in a signal pattern of two orange/green (yellow) fusions, one on each of the abnormal chromosomes 11 and 14 and single orange and green signals from the normal chromosomes.

Due to the gap between the two probes in the IGH probe set, the normal IGH loci may sometimes appear as two slightly separated green signals. This gap may also cause a slight separation of the orange and green signals on the der(11) chromosome, in some instances. Analysis of t(11;14) samples suggests that due to variation in breakpoint location on 11q13 and loss of V segments within the LSI IGH probe target, some samples containing t(11;14) might display signal patterns different than 1O1G2F.

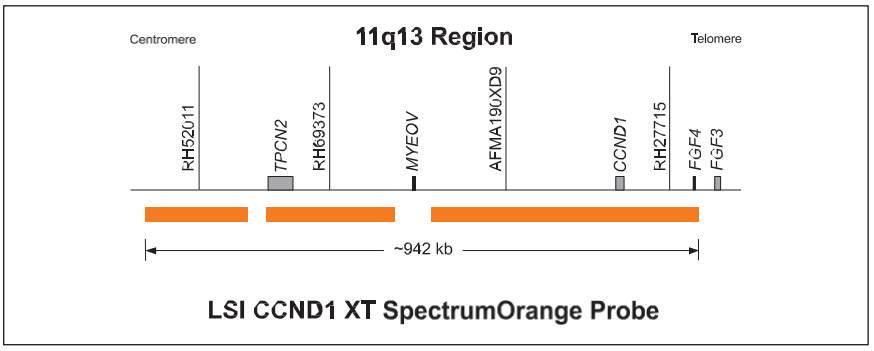
Ordering Information	Quantity	Order No.
Vysis IGH/CCND1 DF FISH Probe Kit	20 µl	08L58-020

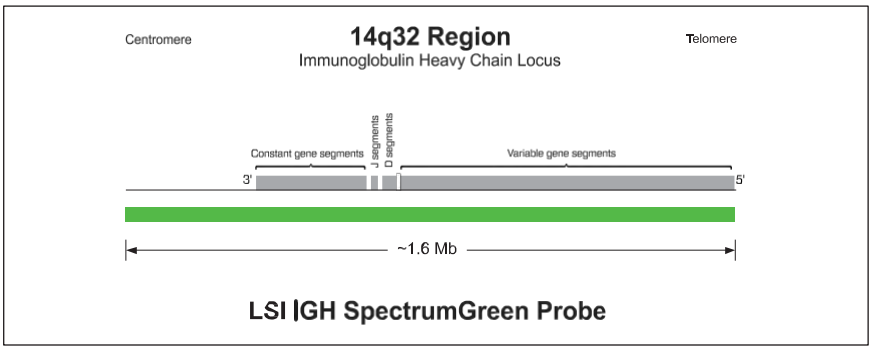
References

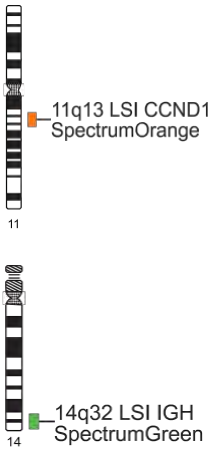
1. Cook JR. Diagn Mol Pathol. 2004;13(4):197-206.
2. Zelenetz AD, Abramson JS, Advani RH, et al. National Comprehensive Cancer Network. 2009;3:1-156. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf. Accessed November 16, 2009.
3. Sun T, Nordberg ML, Cotelingam JD, et al. Am J Hematol. 2003;74(1):78-84.
4. Remstein ED, Kurtin PJ, Buño I, et al. Br J Haematol. 2000;110(4):856-62.

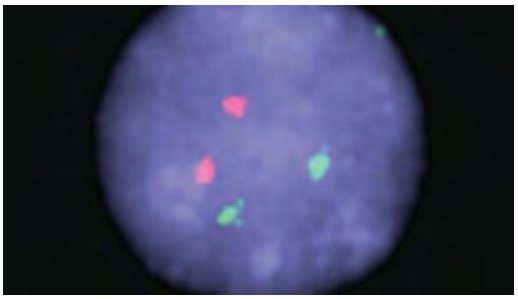
Vysis IGH/CCND1 XT DF FISH Probe Kit

previously Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probe

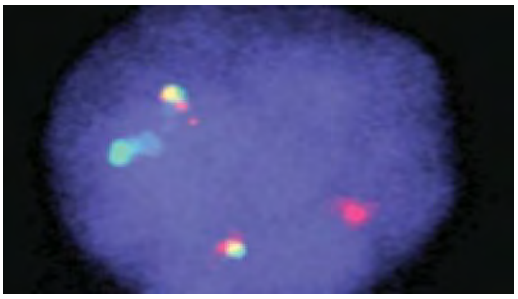








A normal interphase cell hybridized with the Vysis IGH/CCND1 XT DF FISH Probe. The cell shows the expected two orange (CCND1 XT), two green (IGH) signal pattern.



An abnormal interphase cell hybridized with the Vysis IGH/CCND1 XT DF FISH Probe. The cell in this image shows the one orange (CCND1 XT), one green (IGH), two fusion (der (11) and der (14)) signal pattern indicative of a t(11;14).

These fluorescence in situ hybridization (FISH) probes are intended to detect t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

The t(11;14)(q13;q32) is the most common translocation detected in myeloma.[1,2,3] Patients with t(11;14) have been reported to have a better survival and response to treatment particularly high dose therapy and stem cell support.[1,4] The Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes have been used in publications to detect t(11;14).[5]

The approximately 942 kb SpectrumOrange probe spans the CCND1 breakpoint region with gaps of 30 kb and 62 kb. the contig is composed of three segments of approximately 176 kb (chr11:68363475-68539031; UCSC March 2006), 219 kb (chr11:68568591-68787877; UCSC March 2006) and 455 kb (chr11:68850088-69305335; UCSC March 2006). Th approximately 1.6 Mb SpectrumGreen probe spans the IGH region. (chr14:104736507-106339460; UCSC March 2006).

Results of Hybridization

The expected normal signal pattern of the Vysis LSI IGH / CCND1 XT Dual Color Dual Fusion Probes are two orange signals and two green signals. The expected abnormal pattern of the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes are one orange, one green, and two fusions. Other abnormal signal patterns may occur and metaphase analysis may be helpful in characterization of such patterns.

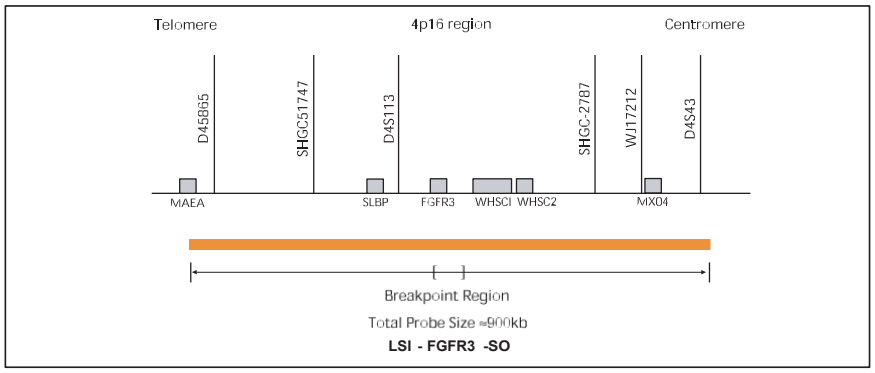
Ordering Information	Quantity	Order No.
Vysis IGH/CCND1 XT DF FISH Probe Kit	20 µl	05N33-020

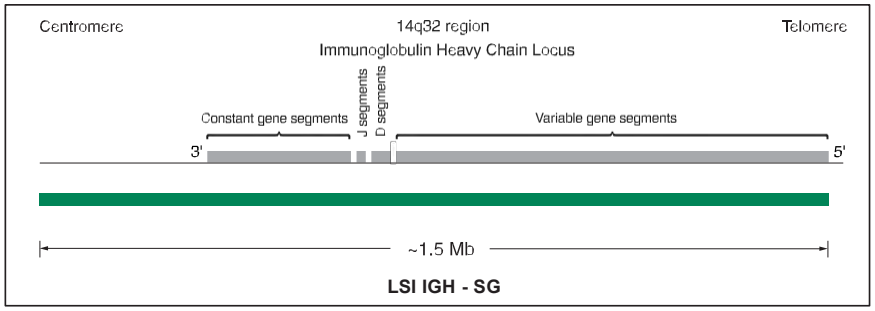
References

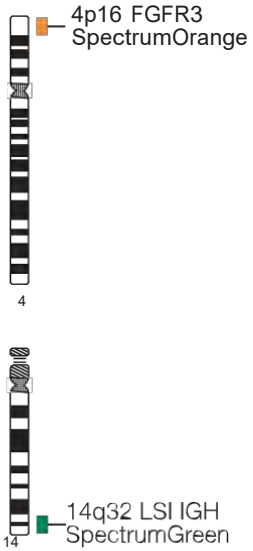
1. Gertz MA, Lacy MQ, Dispenzieri A, et al. Clinical implications of t(11;14)(q13;q32), t(4;14)(p16.3;q32), and -17p13 in myeloma patients treated with high-dose therapy. Blood. 2005;106(8):2837-40.
2. Zelenetz AD, Abramson JS, Advani RH, et al. NCCN clinical practice guidelines in oncology: non-Hodgkin's lymphomas. J Natl Compr Canc Netw.2009;3:1-156. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf. Accessed 2009.
3. Soverini S, Cavo M, Cellini C, et al. Cyclin D1 overexpression is a favorable prognostic variable for newly diagnosed multiple myeloma patients treated with high-dose chemotherapy and single or double autologous transplantation. Blood. 2003;102(5):1588-94.
4. Moreau P, Facon T, Leleu X, et al. Recurrent 14q32 translocations determine the prognosis of multiple myeloma, especially in patients receiving intensive chemotherapy. Blood. 2002;100(5):1579-83.
5. Bang SM, Kim YR, Cho HI, et al. Cancer Genet Cytogenet. 2006;168(2):124-32.
6. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

Vysis IGH/FGFR3 DF FISH Probe Kit

previously Vysis LSI IGH/FGFR3 Dual Color, Dual Fusion Translocation Probe







Translocations of the immunoglobulin heavy chain locus (IGH) located at 14q32 are frequently observed in patients with various hematological disorders. These IGH translocations result in the upregulation of oncogenes due to the juxtaposition of IGH enhancers with these oncogenes.

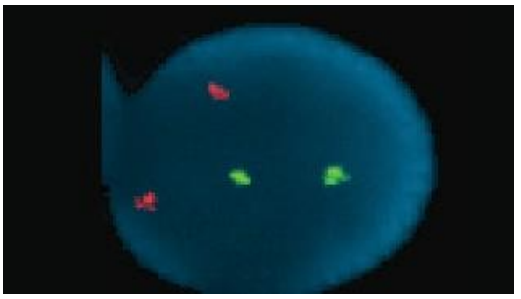
Vysis IGH/FGFR3 DF FISH Probe is comprised of a mixture of a 1.5 Mb SpectrumGreen labeled IGH probe and an ~900 Kb SpectrumOrange labeled FGFR3 probe.

The IGH probe contains sequences homologous to the entire IGH locus, as well as sequences extending about 300 kb beyond the 3' end of the IGH locus.

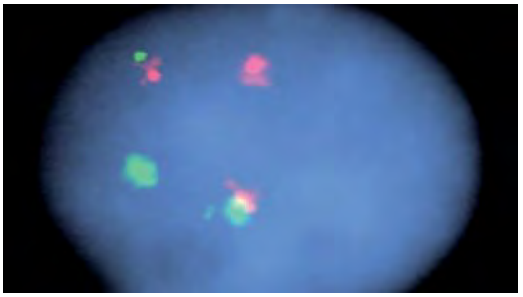
The FGFR3 probe contains sequences that extend from a point 460 Kb telomeric to FGFR3, through the FGFR3 and WHSC1 (Wolf-Hirschhorn Syndrome Candidate 1) genes and ends proximally at a locus ~360 Kb centromeric to FGFR3.

Results of Hybridization

In a normal cell that lacks the t(4;14), a two orange and two green signal pattern will be observed reflecting the two intact copies of the FGFR3 and IGH regions respectively. In an abnormal cell containing the t(4;14), one orange (FGFR3), one green (IGH), and two fusion signal pattern (der (4) and der (14)) may be observed. Some samples containing the t(4;14) may display signal patterns differently than one orange, one green, and two fusions.



A normal interphase cell hybridized with the Vysis IGH/FGFR3 DF FISH Probe. The cell shows the expected two orange (FGFR3), two green (IGH) signal pattern.



An abnormal interphase cell hybridized with the Vysis IGH/FGFR3 DF FISH Probe. The cell in this image shows the one orange (FGFR3), one green (IGH), two fusion (der (4) and der (14)) signal pattern indicative of a t(4;14).

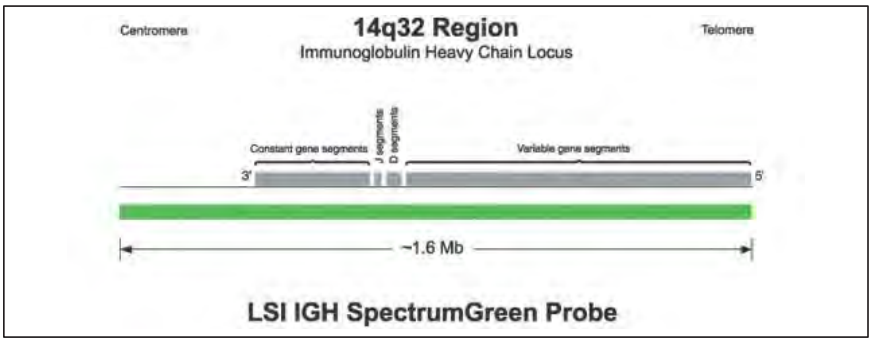
Ordering Information	Quantity	Order No.
Vysis IGH/FGFR3 DF FISH Probe Kit	20 µl	01N69-020

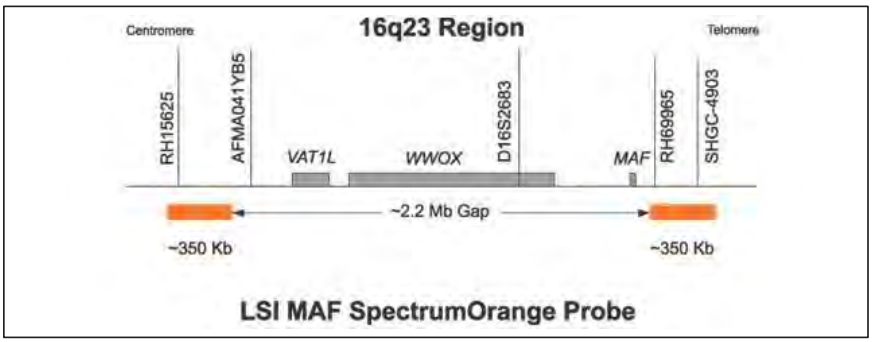
References

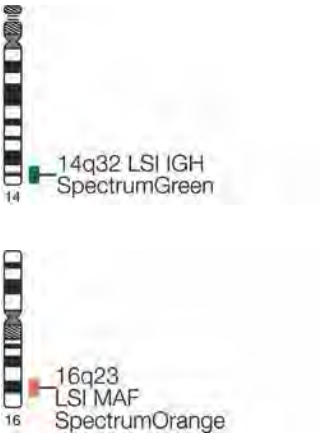
1. Fonseca, R., et al. Blood 101 (11) 2003: 4569-4575.
2. Keats, J., et al. Blood 101 (4) 2003: 1520-1529.
3. Chesi, M., et al. Blood 92 (1) 1998: 3025-3034.

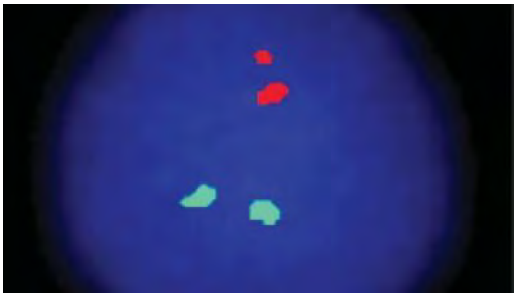
Vysis IGH/MAF DF FISH Probe Kit

previously Vysis LSI IGH/MAF Dual Color, Dual Fusion Probe

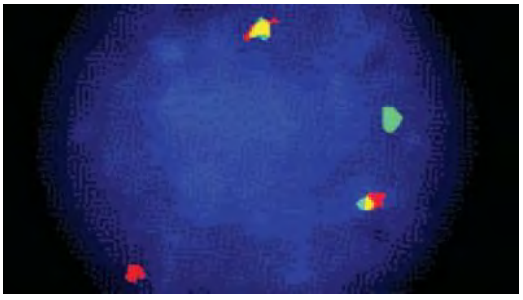








A normal interphase cell hybridized with the Vysis IGH/MAF DF FISH Probe. The cell shows the expected two green (IGH), two orange (MAF) signal pattern.



An abnormal interphase cell hybridized with the Vysis IGH/MAF DF FISH Probe. The cell in this image shows the one green (IGH), one orange (MAF), two fusion (der (14) and der (16)) signal pattern indicative of a t(14;16).

The Vysis IGH/MAF DF FISH Probe Kit is intended to detect the t(14;16)(q32;q23) reciprocal translocation involving the IGH and MAF gene regions.

MAF is an oncogene that has been found to be over-expressed in multiple myeloma (MM).[1] Recent studies have analyzed the effect of del(16q), perhaps due to loss of the WWOX gene, on prognosis in newly diagnosed MM and found an association with worse overall survival.[2] Both MAF and WWOX genes are found in tandem on chromosome 16q23. t(14;16)(q32;q23) has been associated with more aggressive forms of MM.[3] Thus, FISH testing for t(14;16)(q32;q23) has been indicated as one of the minimum clinical tests during MM diagnosis and treatment determination.[4, 5]

Results of Hybridization

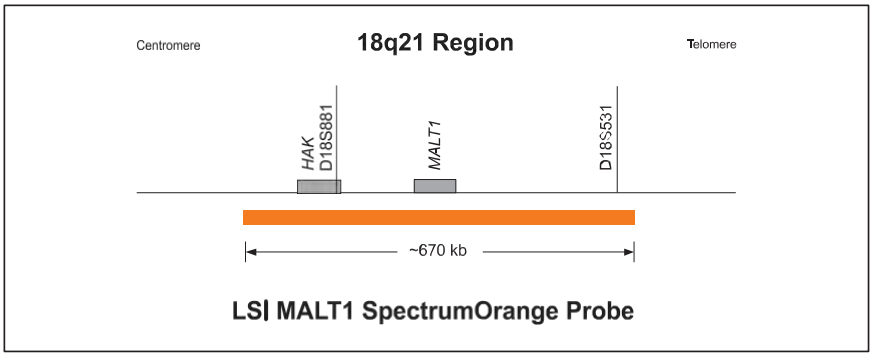
In a normal cell that lacks the t(14;16), a two green and two orange signal pattern will be observed reflecting the two intact copies of IGH and the MAF region respectively. Due to the presence of the ~2.2 Mb gap between the two SpectrumOrange labeled MAF probes, signal splitting of the orange probe may be observed in both normal and abnormal cells. In an abnormal cell containing the t(14;16), one green (IGH), one orange (MAF) and two fusion signal pattern (der (14) and der (16)) may be observed. Some samples containing the t(14;16) may display signal patterns different than one orange, one green and two fusions.

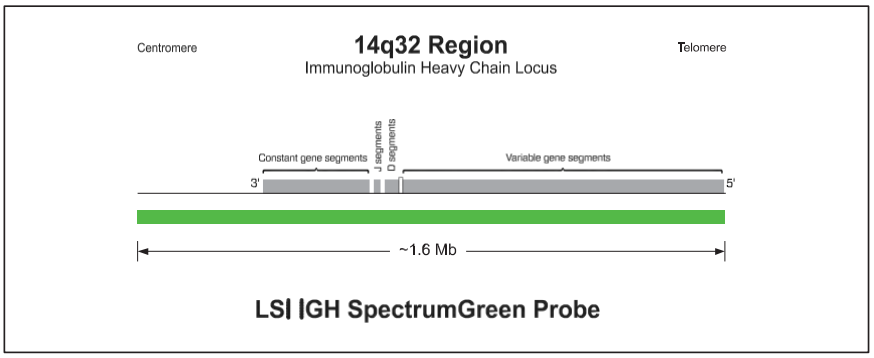
Ordering Information	Quantity	Order No.
Vysis IGH/MAF DF FISH Probe Kit	20 µl	05N32-020

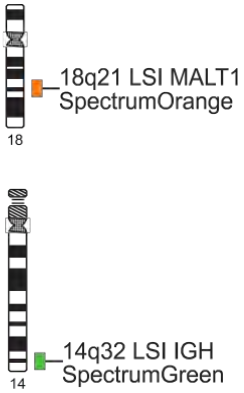
References

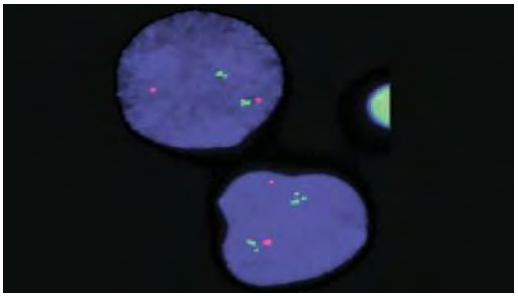
1. Chesi M, Bersagel PL, Shonukan O, et al. Blood. 1998;91(12):4457-63.
2. Jenner MW, Leone PE, Walker BA, et al. Blood. 2007;110(9):3291-300.
3. Fonseca R, Blood E, Rue M, et al. Blood. 2003;101(11):4569-75.
4. Fonseca R, Bergsagel PL, Drach J, et al. Leukemia. 2009;23(12):2210-21.
5. Anderson KC, Alsina M, Bensinger W, et al. NCCN clinical practice guidelines in oncology: multiple myeloma. Natl Compr Canc Netw. 2009;7(9):908-42.

Vysis IGH/MALT1 DF FISH Probe Kit

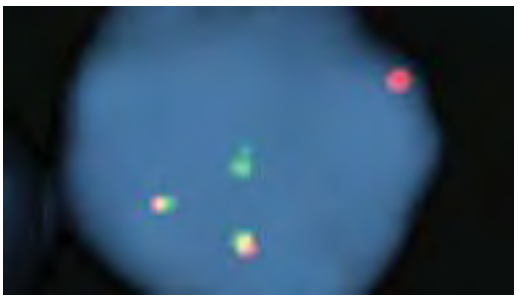








Result of the hybridization of the LSI IGH/MALT1 t(14;18)(q32;q21) Dual Color, Dual Fusion Translocation Probe as observed in normal interphase cells.



An abnormal cell hybridized with the LSI IGH/MALT1 t(14;18)(q32;q21) Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one orange, one green and two fusion signal pattern indicative of the t(14;18)(q32;q21) translocation.

The Vysis IGH/MALT1 DF FISH Probe Kit is intended to detect the t(14;18)(q32;q21) reciprocal translocation involving the IGH and MALT1 gene regions using the fluorescence in situ hybridization (FISH) technique. The t(14;18)(q32;q21) translocation is the second most common chromosomal translocation found in mucosa-associated lymphoid tissue (MALT) lymphoma[1] and is the most common in non-gastric MALT lymphoma.[1,2] The t(14;18)(q32;q21) translocation has been used to aid in the diagnosis of MALT lymphomas.[3,4] The Vysis LSI IGH/MALT1 Dual Color Dual Fusion Probes have been used to identify the t(14;18) (q32;q21) translocation in published reports.[5]

The SpectrumOrange probe spans approximately 670 kb (chr18:54220804-54891192; March 2006 assembly)[6] and covers theMALT1 gene region. The approximately 1.6 Mb SpectrumGreen probe spans the IGH region (chr14:104736507-106339460; March 2006 assembly).[6]

Results of Hybridization

The expected normal signal pattern of the Vysis LSI IGH/MALT1 Dual Color Dual Fusion Probes is two orange and two green signals. The expected abnormal pattern of the Vysis LSI IGH/MALT1 Dual Color Dual Fusion Probes is one orange, one green and two fusions. Other abnormal signal patterns may occur and metaphase analysis may be helpful in characterization of such patterns.

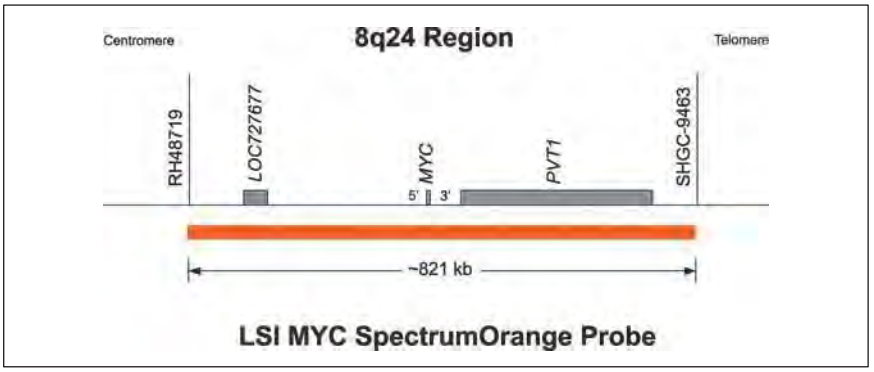
Ordering Information	Quantity	Order No.
Vysis IGH/MALT1 DF FISH Probe Kit	20 µl	05N47-020

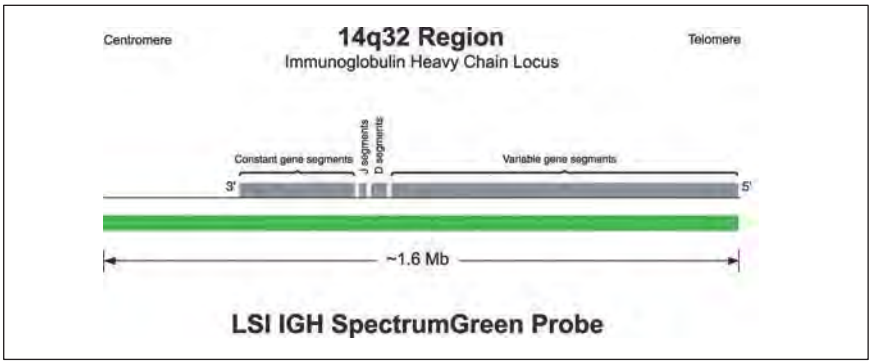
References

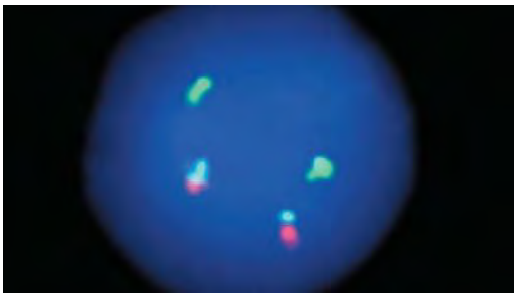
1. Streubel B, Simonitsch-Klupp I, Müllauer L, et al Leukemia 2004;18(10):1722-6.
2. Streubel B, Lamprecht A, Dierlamm J, et al Blood 2003;101(6):2335-9.
3. Gomyo H, Kajimoto K, Maeda A, et al. Hematology 2007;12(4):315-8.
4. Zelenetz AD, Abramson JS, Advani RH, et al. J Natl Compr Canc Netw. 2010;(8)3:288-334.
5. Bhagavathi S, Greiner TC, Kazmi SA, et al. J Hematopathol 2008;1(2):131-7.
6. Kent WJ, Sugnet CW, Furey TS, et al. Genome Research 2002;12(6):996-1006.
7. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Genet Med 2006;8(1):16-23.

Vysis IGH/MYC/CEP 8 Tri-Color DF FISH Probe Kit

previously: Vysis LSI IGH/MYC, CEP 8 Tri-color, Dual Fusion Translocation Probe







IGH/MYC/CEP 8 Tri-Color FISH Probe Kit hybridized to a normal nucleus showing the expected 202G2A signal pattern.

The Vysis IGH/MYC/CEP 8 Tri-Color Dual Fusion FISH probes are intended to detect the t(8;14)(q24;q32)reciprocal translocation involving the IGH and MYC gene regions.

The t(8;14)(q24;q32) translocation is a hallmark of Burkitt's Lymphoma (BL) and occurs in about 80 % of BL cases.[1] As such, testing for t(8;14)(q24;q32) or variants is indicated as an essential test for BL.[2] TheVysis LSI IGH/MYC/CEP 8 Tri-color Dual Fusion probe has been used to identify the t(8;14)(q24;q32) translocation in published reports.[3,4] The aqua CEP 8 probe serves as a control for the copy number of chromosome 8.

Results of Hybridization

In a normal cell the expected pattern for a nucleus hybridized with the LSI IGH/MYC, CEP 8 probe is the two aqua, two orange, and two green signal pattern. A cell harboring the reciprocal t(8;14) with the 8q24 breakpoint well within the MYC probe target is expected to produce a pattern of one orange, one green, two orange/green fusions, and two aqua signals (1O1G2F2A). If the cell contains a breakpoint very far 5' of MYC, a fusion on the der(8) may not be visible or may be very weak, as little or no orange probe target would remain on the der(8).

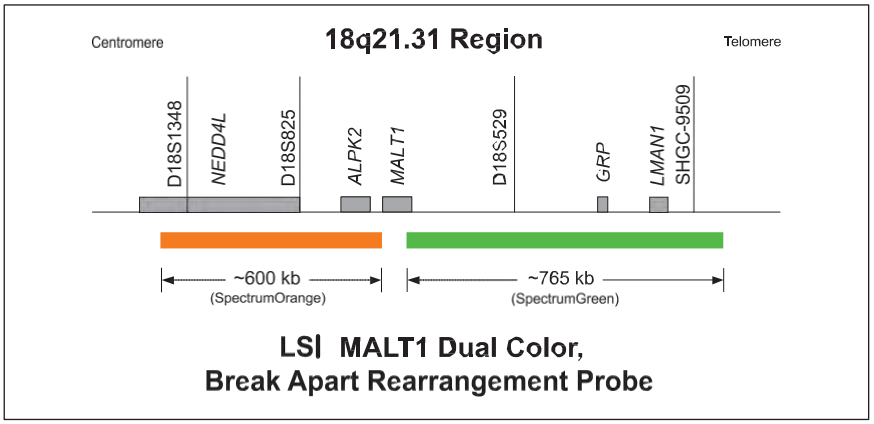
Ordering Information	Quantity	Order No.
Vysis IGH/MYC/CEP 8 Tri-Color DF FISH Probe Kit	20 µl	04N10-020

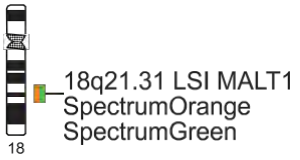
References

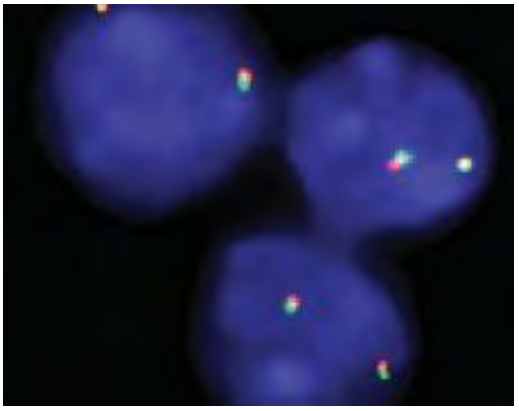
1. Perkins AS, Friedberg JW. Am Soc Hematol Educ Program. 2008;341-8.
2. Zelenetz AD, Abramson JS, Advani RH, et al. National Comprehensive Cancer Network. 2009;3:1-156. Available at: http://www.nccn.org
3. Paternoster SF, Brockman SR, McClure RF, et al. Am J Pathol. 2002;160(6):1967-72.
4. Einerson RR, Law ME, Blair HE, et al. Leukemia. 2006;20(10):1790-9.
5. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002:12(6):996-1006.

Vysis MALT1 Break Apart FISH Probe Kit

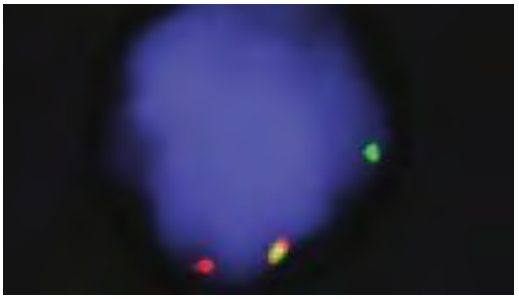
previously: Vysis LSI MALT1 (18q21) Dual Color, Break Apart Rearrangement Probe







Result of the hybridization of the MALT1 Break Apart FISH Probe Kit as observed in three normal interphase cells.



An abnormal cell hybridized with the LSI MALT1 (18q21) Dual Color, Break Apart Rearrangement Probe. The cell in this image shows the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the MALT1 gene region.

The Vysis MALT1 Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements at the MALT1 locus on chromosome 18q21 using the fluorescence in situ hybridization (FISH) technique.

In gastric MALT lymphoma 1/3 or less of cases have been reported to carry the t(11;18) BIRC3-MALT1 translocation. This translocation is usually indicative of unresponsiveness to H.Pylori eradication and is present in advanced disease state.
The Vysis LSI MALT1 Dual Color Break Apart Rearrangement probe has been used to detect MALT1 gene region rearrangements in a study of 90 diagnostic specimens from gastric MALT lymphoma patients. This same study also found some patients to have extra copies of the intact MALT1 gene indicated by greater than two copies of the fusion signal and this to be an indicator of poor prognosis.[1] Another study performed to determine the clinical activity of Rituximab in 27 patients resistant to, or not eligible for, anti-H. pylori therapy also utilized the Vysis LSI MALT1 Dual Color Break Apart Rearrangement probe to detect rearrangements in the MALT1 gene region.[2]

The approximately 600 kb (chr18:53915334-54515608; March 2006 assembly, UCSC Genome Browser)[3] SpectrumOrange probe lies centromeric to the MALT1 breakpoint region.
The approximately 765 kb (chr18:54554621-55319759; March 2006 assembly, UCSC Genome Browser)[3] SpectrumGreen probe lies telomeric to the MALT1 breakpoint region.

Results of Hybridization

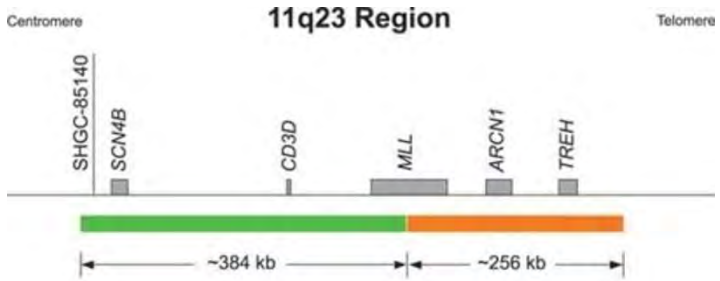
The expected normal signal pattern of the MALT1 Dual Color Break Apart Rearrangement Probe is two fusion signals.
The expected abnormal pattern of the MALT1 Dual Color Break Apart Rearrangement Probe is one orange, one green, and one fusion. Other abnormal signal patterns may occur including those with greater than two copies of the fusion signals described by Nakamura.[1]

Ordering Information	Quantity	Order No.
Vysis MALT1 Break Apart FiSH Probe Kit	20 µl	05N48-020

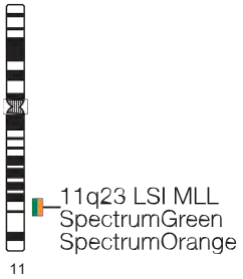
References

1. Nakamura S, Ye H, Bacon CM, et al. Clinical impact of genetic aberrations in gastric MALT lymphoma: a comprehensive analysis using interphase fluorescence in situ hybridization. Gut 2007;56:1358-63.
2. Martinelli G, Laszlo D, Ferreri AJM, et al. Clinical activity of rituximab in gastric marginal zone non-Hodgkin's lymphoma resistant to or not eligible for anti-Helicobacter pylori therapy. J Clin Oncol 2005;23(9):1979-83.
3. Kent WJ, Sugnet CW, Furey TS, et al. The Human Genome Browser at UCSC. Genome Res 2002;2(6):996-1006.
4. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med 2006;8(1):16-23.

Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe

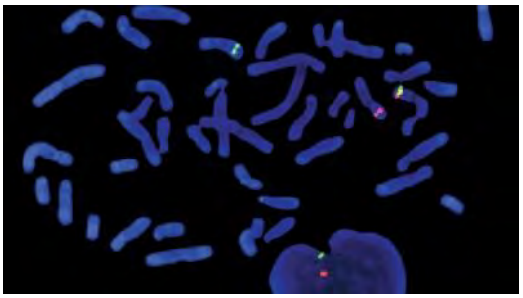


**LSI MLL Dual Color,
Break Apart Rearrangement Probe**



The LSI MLL Dual Color, Break Apart Rearrangement Probe is designed to detect the 11q23 rearrangement associated with various translocations involving the MLL gene. Translocations disrupting the MLL (ALL-1,HRX) gene are among the most common cytogenetic abnormalities observed in hematopoietic malignancies. Although over 30 variant translocations have been seen involving MLL translocations, the most common abnormalities are t(4;11)(q21;q23), t(9;11)(p22;q23), and t(11;19)(q23;p13).

The LSI MLL Dual Color, Break Apart Rearrangement Probe consists of a 350 kb portion centromeric of the MLL gene breakpoint cluster region (bcr) labeled in SpectrumGreen and approximately 190 kb portion largely telomeric of the bcr labeled in SpectrumOrange. In approximately 25 % of 11q23 translocations, a region beginning at the MLL breakpoint and extending distally is deleted. This probe can provide a better indication of the presence of the 11q23 translocation than a single color probe design.



LSI MLL Dual Color, Break Apart Rearrangement Probe hybridized to abnormal cells possessing a t(9:11) (p22;q23) and exhibiting the expected one orange, one green and one orange/green fusion signal pattern (1O1G1F).

Results of Hybridization

The signal pattern observed in a cell lacking the MLL rearrangement is expected to show a two orange/green (yellow) fusion signal pattern (2F). In a cell possessing a MLL translocation, the expected pattern is one green/orange (yellow) fusion signal, one orange signal, and one green (1O1G1F) signal. With the MLL Dual Color, Break Apart Rearrangement Probe, a large deletion occurring distally from the MLL breakpoint might weaken or totally eliminate one of the two orange signals, potentially producing a FISH pattern characteristic of concomitant translocation and deletion, i. e., one orange/green fusion and one isolated green signal.

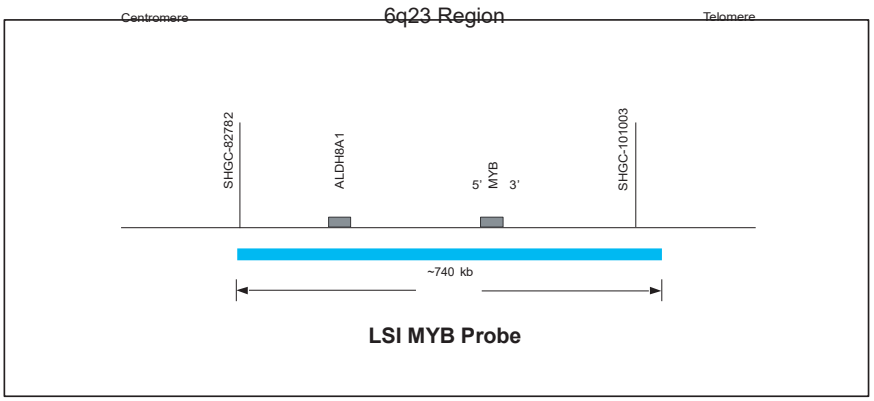
Ordering Information	Quantity	Order No.
Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe	20 µl	08L57-020

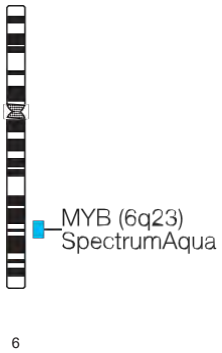
References

1. Pui C, Gaynon PS, Boyett JM, et al. Lancet 2002; 359:1909-15.
2. Schoch C, Schnittger S, Klaus M, et al. Blood 2003;102:2395-2402.
3. Li Z-Y, Liu D-P, Liang C-C.Leukemia 2005;19:183-190.
4. Barber KE, Ford AM, Harris RL, et al. Genes Chromosomes Cancer 2004;41:266-71.
5. Corral J, Forster A, Thompson S, et al. Proc Natl Acad Sci 1993;90:8538-42.
6. Arnaud B, Douet-Guilbert N, Morel F, et al. Cancer Genetics Cytogenetics 2005;161:110-15.
7. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

Vysis MYB SpectrumAqua FISH Probe Kit

previously Vysis LSI MYB (6q23) SpectrumAqua Probe





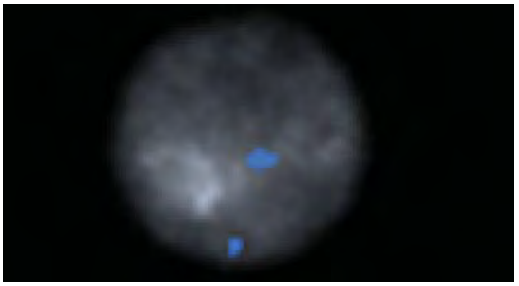
This Vysis MYB SpectrumAqua FISH Probe is intended to detect the copy number of the LSI MYB probe target located at chromosome 6q23.

The Vysis LSI MYB SpectrumAqua Probe was used to detect deletion of its target at 6q23 in a study of 143 chronic lymphocytic leukemia patients.1 In this study, approximately 5% of patients were found to have this deletion.

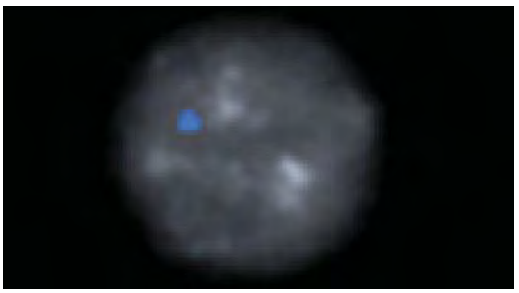
Results of Hybridization

Hybridization of this probe to interphase and metaphase nuclei of normal cells is expected to be seen as two aqua signals. The anticipated signal pattern in individuals with a deletion of the 6q23 region would be seen as a single aqua signal. Other patterns may be observed if additional genetic alterations are present.

Ordering Information	Quantity	Order No.
Vysis MYB SpectrumAqua FISH Probe Kit	20 µl	05N40-020



Normal cell hybridization using the Vysis LSI MYB (6q23) Probe.



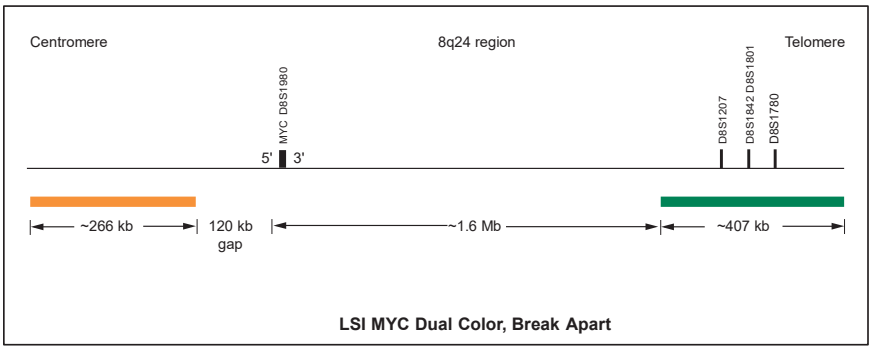
Abnormal cell hybridization using the Vysis MYB Probe.

References

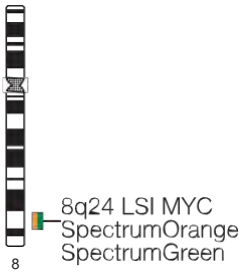
1. Qiu H, Xu W, Cao X, et al. Leukemia & Lymphoma. 2008;49(10):1887-1892.
2. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002;2(6):996-1006.

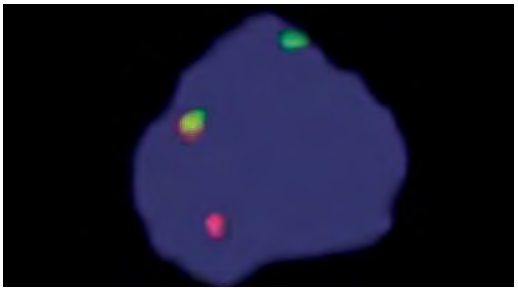
Vysis MYC Break Apart FISH Probe Kit

previously Vysis LSI MYC Dual Color, Break Apart Rearrangement Probe



LSI MYC Dual Color, Break Apart





LSI MYC Dual Color Break Apart Rearrangement Probe hybridized to an abnormal nucleus showing a one orange, one green and one orange/green fusion (1O1G1F) signal pattern.

The Vysis LSI MYC Dual Color Break Apart Rearrangement probe is intended to detect chromosomal rearrangements involving the MYC gene region on chromosome 8q24. It is particularly useful for detection of aberrations with breakpoints located far telomeric to MYC such as those that can occur in the variant t(8;22)(q24.1;q11.2)IGL-MYC and t(2;8)(p11.2;q24.1)IGK-MYC rearrangements.

Translocations involving the MYC region have diagnostic and prognostic importance in B-cell malignancies. In Burkitt's lymphoma approximately 75% to 80% of cases carry t(8;14)IGH-MYC and the remainder are associated with t(8;22)IGL-MYC or t(2;8)IGK-MYC.[1] In approximately5 to 10% of diffuse large B-cell lymphoma (DLBCL) patients also have MYC region rearrangements, and detection of these rearrangements with the MYC Dual Color Break Apart Rearrangement Probe has been associated with a poor prognosis.[2,3] It has been suggested that FISHanalysis for MYC rearrangements should be performed on all DLBCL patients.[3]

Results of Hybridization

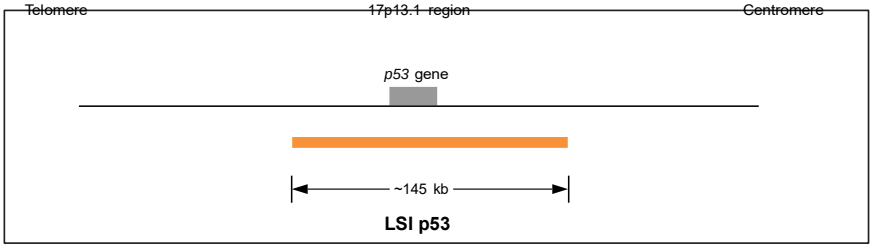
A normal nucleus hybridized with the LSI MYC Dual Color Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) pattern. A one orange, one green, and one fusion pattern (1O1G1F) is expected from a sample with a t(2;8), t(8;22) or t(8;14) having a breakpoint within the gap between the hybridization targets of the LSI MYC probes A normal nucleus hybridized with the Vysis MYC Break Apart FISH Probe

Ordering Information	Quantity	Order No.
Vysis MYC Break Apart FISH Probe Kit	20 µl	01N63-020

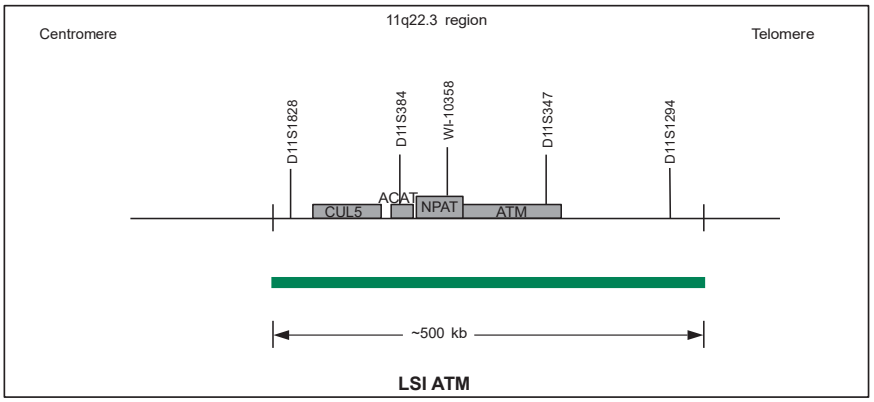
References

1. Perkins AS, Friedberg JW. HematologyAm Soc Hematol Educ Program. 2008;341-8.
2. Klapper W, Stoecklein H, Zeynalova S, et al. Leukemia. 2008;22(12):2226-9.
3. Savage KJ, Johnson NA, Ben-Neriah S, et al. Blood. 2009;114(17):3533-7.
4. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002:12(6):996-1006.
5. Einerson RR, Law ME, Blair HE, et al. Leukemia. 2006;20(10):1790-9.

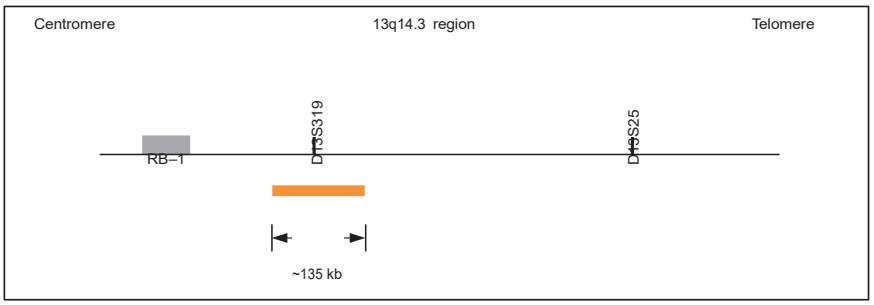
Vysis LSI p53/LSI ATM and Vysis LSI D13S319/Vysis LSI 13q34/ CEP 12 Multi-color Probe



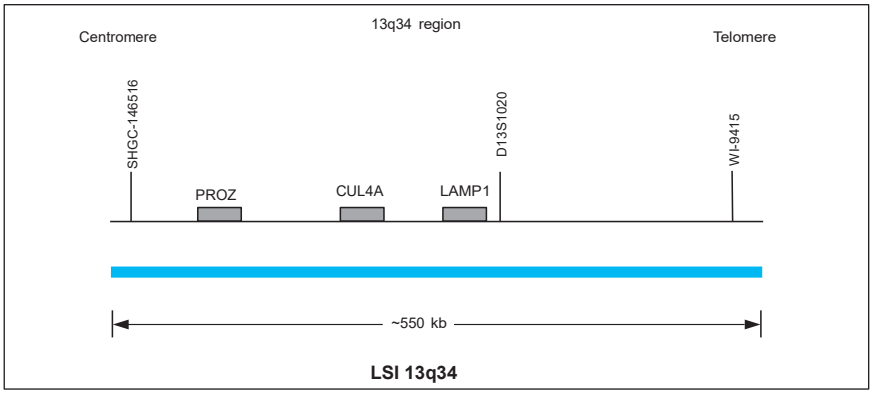
LSI p53



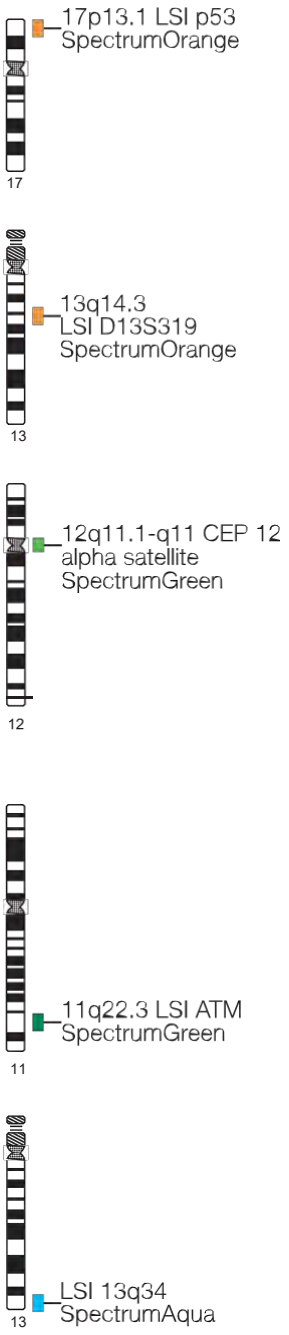
LSI ATM



LSI D13S319



LSI 13q34



The leukemias are a diverse group of diseases that are often characterized by multiple genetic aberrations distributed across the genome. In some cases, the same genetic aberrations are shared by different types of leukemia. Trisomy 12 and deletions of chromosomes 13q (primarily the 13q14 region), 17p13.1, and 11q22.32-4, for example, have all been observed in several types of leukemia. Probe vial 1 contains LSI p53 in SpectrumOrange and LSI ATM in SpectrumGreen. Probe vial 2 contains LSI D13S319 in SpectrumOrange, LSI 13q34 in SpectrumAqua, and CEP 12 in SpectrumGreen.

The LSI p53 (17p13.1) probe is a ~145 kb unique sequence probe that is labeled in SpectrumOrange.

Continuation on the following page >

Continuation:
Vysis LSI p53/LSI ATM and Vysis LSI D13S319/Vysis LSI 13q34/CEP 12 Multi-color Probe

The LSI ATM probe is a ~500 kb unique sequence probe that hybridizes to the 11q22.3 region of chromosome 11. This probe spans the entire ~184 kb Ataxia telangiectasia mutated (ATM) gene and several others. The probe is labeled in SpectrumGreen.

The LSI D13S319 probe is a ~130 kb unique sequence probe that is labeled in SpectrumOrange.

The LSI 13q34 probe is a ~550 kb unique sequence probe that hybridizes to the 13q34 region containing the Lysosomal-associate Membrane Protein (LAMP1) gene and several others. The probe is labeled in SpectrumAqua.

The CEP 12 DNA probe hybridizes to the alpha satellite (centromeric) region (12p11.1-q11) of chromosome 12. The probe is labeled in SpectrumGreen.

Results of Hybridization
This multi-color probe set is provided in a two-mixture format. A description of the hybridization results expected with each mixture follows:

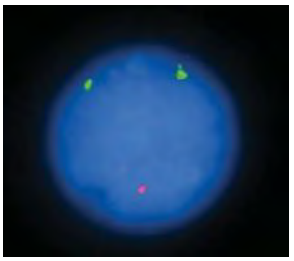
Probe 1:
This probe allows status assessment of the following two chromosome regions: 17p13.1 (p53) and 11q22.3 (ATM). In a normal cell with two intact copies of chromosomes 17 and 11, two orange, and two green signals will be observed. In an abnormal cell with a deletion in the p53 region, fewer than two orange signals will be observed. In an abnormal cell with a deletion in the ATM region on chromosome 11, one will observe fewer than two green signals.

Probe 2:
This probe allows status assessment of the following three chromosome regions: 13q14.3 (D13S319), 13q34, and 12p11.1-q11. In a normal cell with two intact copies of chromosome 13 and chromosome 12, a two orange, two aqua, and two green signal pattern will be observed. In an abnormal cell with chromosome 13 aberrations only, more complex signal patterns may be expected depending upon the nature of the aberration. Monosomy 13 or 13q- will both appear as a one orange, one aqua, two green signal pattern. An interstitial deletion of the 13q14.3 region will appear as either a one orange, two aqua, two green signal pattern (hemizygous deletion) or a two aqua, two green signal pattern (homozygous deletion) (data not shown). In an abnormal cell with chromosome 12 copy number changes, one will observe greater or less than two green signals.

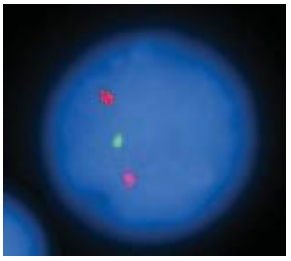
Ordering Information	Quantity	Order No.
Vysis LSI p53/LSI ATM and LSI D13S319/ LSI 13q34/CEP 12 Multi-color Probe	200 µl	04N02-021

premixed with Hybridization Buffer

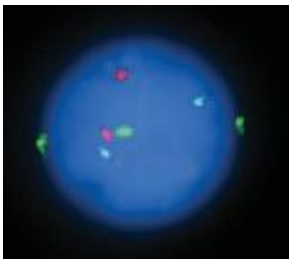
References
1. Anastasi, J., et al. Blood 79 (1992): 1796-1801.
2. Dohner, H., et al. New Eng Jour Med. 343 (2000): 1910-1916.
3. Bennarji, R., Byrd, J.C. Curr. Opin Oncol 12 (2000): 22-29.
4. Stilgenbauer, S., et al. Leukemia 16 (6) (2002): 993-1007.
5. Pettitt, A.R., et al. Blood 98 (3) (2001): 814-822.
6. Stankovic, T., et al. Blood 99 (1) (2001): 300-309.



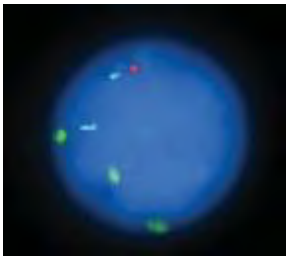
An abnormal cell hybridized with Probe Set 1. One copy of the p53 region has been deleted as indicated by the single orange signal. Both copies of the ATM gene region are present as indicated by the two green signals.



An abnormal cell hybridized with Probe Set 1. One copy of the ATM gene region has been deleted as indicated by the single green signal. Both copies of the p53 gene region are present as indicated by the two orange signals.



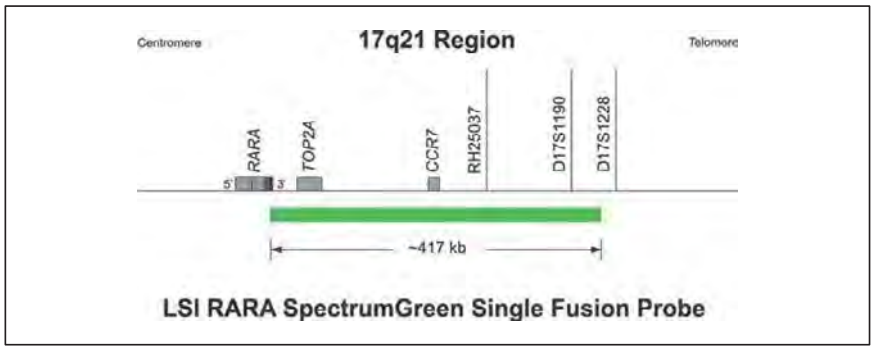
An abnormal cell hybridized with Probe Set 2. Both copies of chromosome thirteen and its q arm are intact as indicated by the two orange (LSI D13S319) and two aqua (LSI 13q34) signals. One extra copy of chromosome 12 (trisomy 12) is present as indicated by the three green signals.

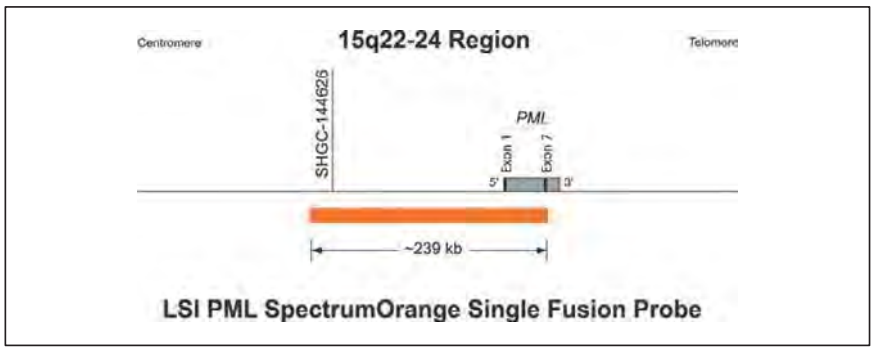


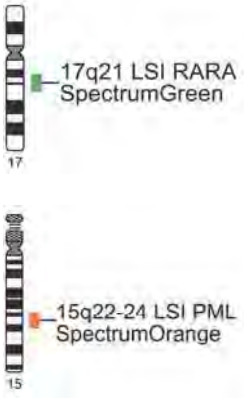
An abnormal cell hybridized with Probe Set 2. One copy of chromosome 13 is deleted for the D13S319 region as indicated by the single orange signal (LSI D13S319) and the two aqua signals (LSI 13q34). One extra copy of chromosome 12 (trisomy 12) is present as indicated by the three green signals.

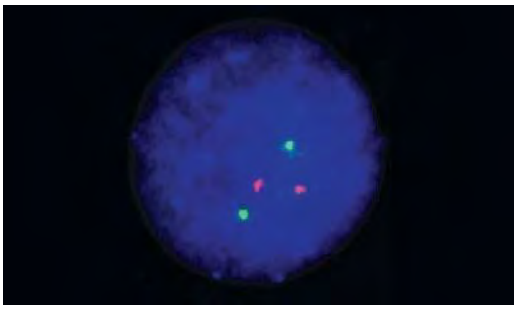
Vysis PML/RARA SF FISH Probe Kit

previously Vysis LSI PML/RARA Dual Color Translocation Probe









LSI PML/RARA SF FISH Probe hybridized to a normal nucleus, showing a two orange, two green (2O2G) signal pattern.

The Vysis PML/RARA SF FISH Probes are intended to detect the t(15;17)(q22;q21.1) reciprocal translocation involving the PML and RARA gene regions.

The vast majority of cases of acute promyelocytic leukemia (APL) have a t(15;17)(q22;q21.1) translocation which fuses the promyelocytic leukemia gene (PML) on chromosome 15q22-q24 to the retinoic acid therapy.[1] The PML/RARA fusion is associated with a good response to all-trans retinoic acid therapy.[1]
The Vysis PML/RARA Dual Color Translocation Probe Kit was used in a study of 260 acute myeloid leukemia patients and detected 11 positive samples.[2] In the same study, conventional banding analysis resulted in only 7 positive results due to cytogenetic failure and one case of a cryptic translocation.

The approximately 239 kb (chr15:71877721-72116436; March 2006 assembly, UCSC Genome Browser)3 SpectrumOrange probe lies centromeric to the PML gene.The approximately 417 kb (chr17:35762877-36180271; March 2006 assembly, UCSC Genome Browser)3 SpectrumGreen probe lies telomeric to the RARA gene.

Results of Hybridization

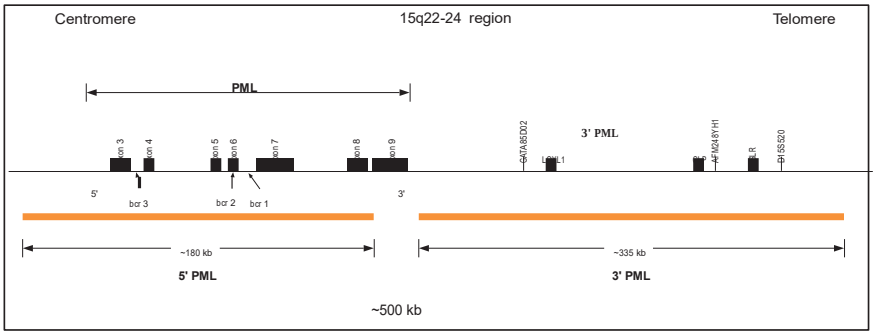
In a normal cell, the expected pattern for a nucleus hybridized with the LSI PML/RARA probe is a two orange and two green (2O2G) signal pattern. In an abnormal cell containing a PML/RARA fusion, the one green (RARA), one orange (PML), and closely adjacent or fused green/orange (yellow) signal pattern (1O1G1F) is observed.

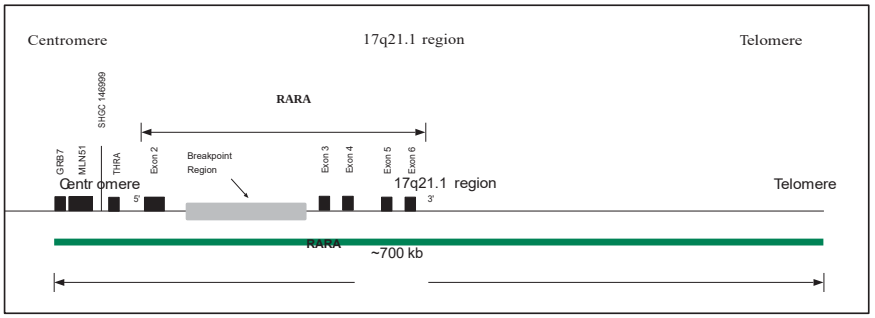
Ordering Information	Quantity	Order No.
Vysis PML/RARA SF FISH Probe Kit	20 µl	05N45-020

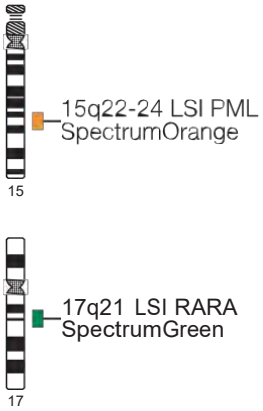
References

1. Reiter A, Sausele S, Grimwade D, et al. Genes, Chromosomes and Cancer. 2003;36:175-188.
2. Cox MC, Panetta P, Venditti A et al. The Hematology J. 2003; 4,263-270.
3. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002; 2(6):996-1006.
4. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Genet Med. 2006; 8(1):16-23.

Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe







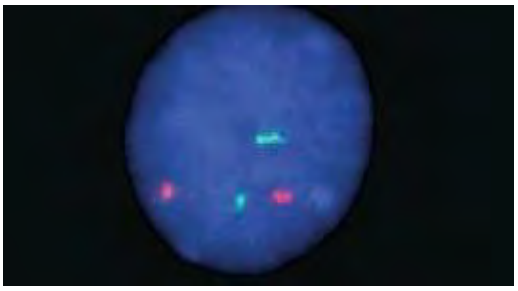
The reciprocal and balanced t(15;17), involving the PML (promyelocytic leukemia) gene on chromosome 15q22-24 and the RARA (retinoic acid receptor alpha) gene on chromosome 17q21.1 is a characteristic molecular feature of certain types of leukemia. Two gene fusion products result from this translocation, each of which encodes a functional chimeric protein: PML/RARA and RARA/PML.

The breakpoints in the 15q22-24 region of chromosome 15 occur within a 13 kb region of the PML gene that contains three breakpoint cluster regions (bcr): bcr 3 extends from intron 3 through the 5' end of intron 4, bcr 2 extends from exon 5 to exon 6, and bcr 1 extends from intron 6 into exon 7. Break frequency is highest in bcr 1, followed by bcr 3 and bcr 2. The breakpoints on chromosome 17 occur within the approximately 17 kb intron 2 of the RARA gene.

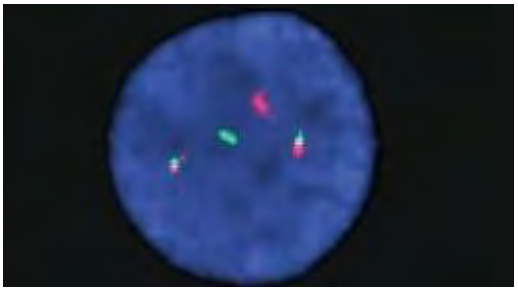
The LSI PML/RARA Dual Color, Dual Fusion Translocation Probe is a mixture of two FISH DNA Probes. The first, LSI PML, is an ~500 kb unique sequence probe that hybridizes to the 15q22-24 region containing the PML gene and is labeled in SpectrumOrange. The second, LSI RARA, is an ~700 kb unique sequence probe that hybridizes to the 17q21 region containing the RARA gene and is labeled in SpectrumGreen.

Results of Hybridization

This probe is provided for those interested in identifying the t(15;17). In a normal cell that lacks the t(15;17), a two orange and two green signal pattern will be observed reflecting the two intact copies of RARA and PML, respectively. In an abnormal cell containing the t(15;17), one orange (PML), a one green (RARA), and two fusion (PML/RARA and RARA/PML) signal pattern is observed.



Result of the hybridization of the LSI PML/RARA Dual Color, Dual Fusion Translocation Probe as observed in a normal interphase cell.



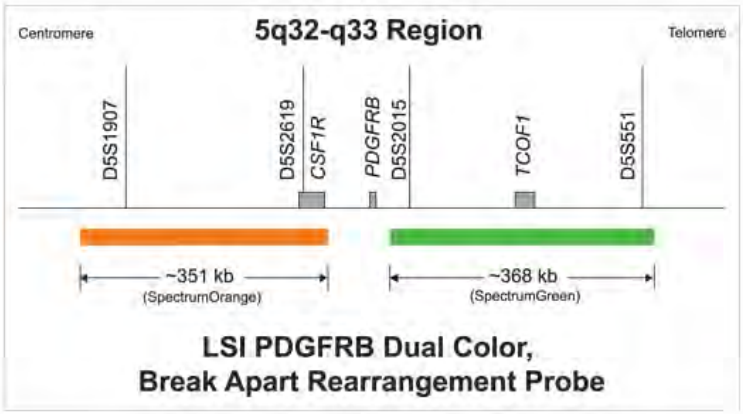
Abnormal cell hybridized with the LSI PML/RARA Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one orange (PML), one green (RARA), two fusion (PML/RARA and RARA/PML) signal pattern indicative of the t(15;17).

Ordering Information	Quantity	Order No.
Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe	20 µl	01N36-020

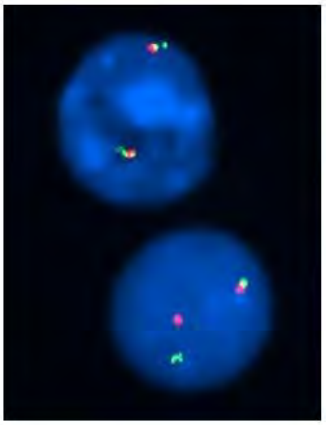
References

1. Rowley, J.D., et al. Lancet 1 (1977): 549-550.
2. Harris, N.L., et al. J. Clin. Oncol. 12 (1999): 3835-3849.
3. He, L.Z., et al. Nat. Genet. 18 (1998): 126-135.
4. Pandolfi, P.P. Oncogene 20. (2001): 5726-5735.
5. Piazza, F., et al. Oncogene 20 (2001): 7216-7222.
6. Benoit, G., et al. Oncogene 20 (2001): 7161-7177.

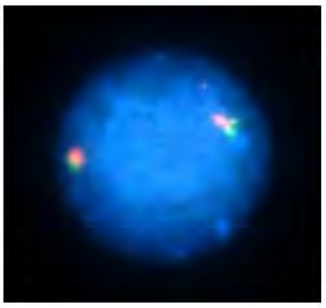
Vysis PDGFRB Break Apart FISH Probe Kit



The approximately 351 kb SpectrumOrange probe is positioned centromeric to the PDGFRB gene. The approximately 368 kb SpectrumGreen probe is positioned telomeric to the PDGFRB gene.



Vysis LSI PDGFRB Dual Color Break Apart Rearrangement Probe hybridized to abnormal nuclei containing one orange, one green and one fusion (1O1G1F) signal pattern and normal nuclei containing two fusion (2F) signal pattern.



Vysis LSI PDGFRB Dual Color Break Apart Rearrangement Probe hybridized to normal nuclei containing two fusion (2F) signal pattern.

The Vysis PDGFRB Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements involving the platelet derived growth factor receptor beta (PDGFRB) gene at chromosome 5q32-q33 using the fluorescence in situ hybridization (FISH) technique.

Rearrangement of the PDGFRB gene is a recurring abnormality in the semi-molecular myeloproliferative disease category of myeloid and lymphoid neoplasms with eosinophilia and abnormalities of the PDGFRA, PDGFRB, or FGFR1 genes.[1,2] A rearrangement of the PDGFRB gene can result from a gene fusion to one of as many as fifteen different known partner genes.[3]

The Vysis PDGFRB Break Apart FISH Probe Kit identifies rearrangements involving the PDGFRB gene by detecting the separation of the LSI PDGFRB SpectrumOrange and LSI PDGFRB SpectrumGreen probe signals resulting from chromosomal breakage between the hybridization targets of the two probes.

Results of Hybridization

The expected normal signal pattern of the Vysis LSI PDGFRB Break Apart Rearrangement Probe is two orange/green fusion signals that may be seen as adjacent orange/green signals slightly separated due to the gap between the two probes.

The expected abnormal pattern of the Vysis LSI PDGFRB Break Apart Rearrangement Probe with a rearrangement involving the PDGFRB gene is one orange, one green, and one fusion signal. Other abnormal signal patterns may occur, and metaphase analysis may be helpful in characterization of such patterns.

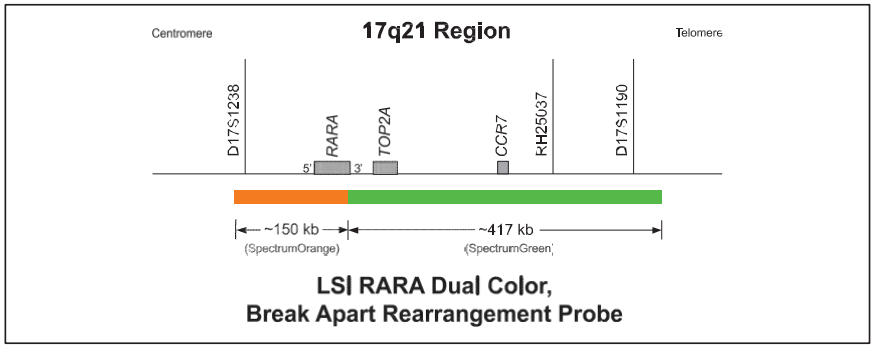
References

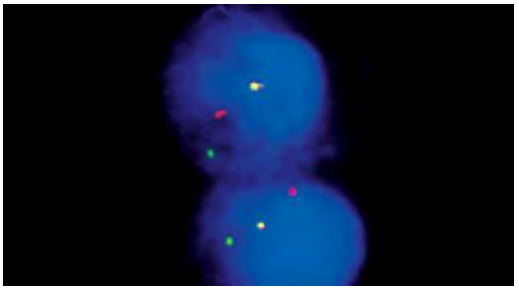
1. The International Agency for Research on Cancer.WHO Classification of Tumours of Haematopoietic and Lymphoid Tissue. Swerdlow S, Campo E, Harris NL, et al, eds. 4th ed. World Health Organization; 2008.
2. Leirman E, Cools J. Recent breakthroughs in the understanding and management of chronic eosinophilic leukemia. Expert Rev Anticancer Ther. 2009;9(9):1295-1304.
3. Heim S, Mitelman F. Cancer Cytogenetics. 3rd ed. Wiley-Blackwell; 2009.

Ordering Information	Quantity	Order No.
Vysis PDGFRB Break Apart FISH Probe Kit	10 µl	06N24-010

Vysis RARA Break Apart FISH Probe Kit

previously Vysis LSI RARA Dual Color, Break Apart Rearrangement Probe





Vysis RARA Break Apart FISH Probe hybridized to abnormal nuclei containing the RARA gene rearrangement. A one orange, one green and one fusion (1O1G1F) signal pattern is observed.

The Vysis RARA Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements involving the RARA gene region at chromosome 17q21 using the fluorescence in situ hybridization (FISH) technique.

Acute promyelocytic leukemia (APL) is associated with chromosomal rearrangements involving the retinoic acid receptor α (RARA) gene on chromosome 17q21 and variable partner genes.[1,3,4] In the vast majority of APL cases, the RARA gene fuses with the promyelocytic leukemia gene (PML) located on chromosome 15q22 resulting in a t(15;17) translocation. RARA fusions with promyelocytic leukemia zinc finger (PLZF, 11q13), nucleophosmin (NPM, 5q35), nuclear mitotic apparatus (NuMA,11q23), signal transducer and activator of transcription 5b (STAT5B, 17q21), and PRKAR1A (protein kinase, cAMP-dependent, regulatory, type I, alpha, 17q23-q24) genes are also described.[1,3,4] The Vysis RARA Break Apart FISH Probe Kit has been used in several studies to detect chromosome 17q21 rearrangements involving the RARA gene.[4,5,6,7]

The approximately 150 kb (chr17:35612650-35762683; March 2006 assembly, UCSC Genome Browser)[8] SpectrumOrange probe lies mostly centromeric to the RARA gene breakpoint region which occurs in intron 2.[1,2] The probe does extend about 4 kb telomeric beyond intron 2. The approximately 417 kb (chr17:35762877-36180271; March 2006 assembly, UCSC Genome Browser)[8] SpectrumGreen probe lies telomeric to the RARA breakpoint region.

Results of Hybridization

The signal pattern observed in a cell that is lacking a RARA gene rearrangement consists of two orange/green (yellow) fusion signals (2F). The two fusion signals represent the normal (non-rearranged) RARA genes located on both 17 chromosomes. A signal pattern indicative of the RARA gene rearrangement is one orange, one green, and one green/orange (yellow) fusion signal. The separation of orange and green signals from one fusion (1O1G1F) indicates that the RARA gene has split apart. The remaining single fusion signal represents the normal (non-rearranged RARA) gene on the normal chromosome extends approximately 400 kb toward the telomere of chromosome 17.

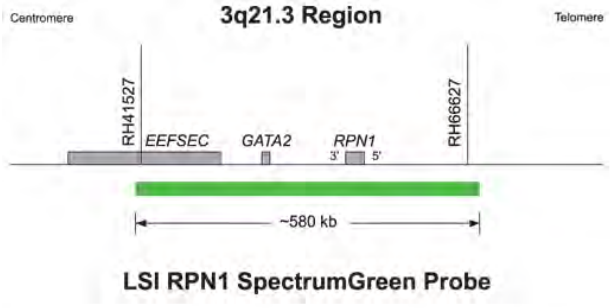
Ordering Information	Quantity	Order No.
Vysis RARA Break Apart FISH Probe Kit	20 µl	05N46-020

References

1. Redner R. Variations on a theme: the alternate translocations in APL. Review. Leukemia. 2002;16:1927-32.
2. Hasan S, Mays A, Ottone T, et al. Blood. 2008;112: 3383-90.
3. Grimwade D, Biondi A, Mozziconacci MJ, et al. Blood. 2000;96:1297-1308.
4. Catalano A, Dawson M, Somana K, et al. Blood. 2007;110:4073-76.
5. Park TS, Kim JS, Song J, et al. Cancer Genetics and Cytogenetics. 2009;188:103-107.
6. Kang L, Smith S, Kaiser-Rogers K, et al. Cancer Genetics and Cytogenetics. 2005;159:168-173.
7. Lee G, Christina S, Tien S, et al.

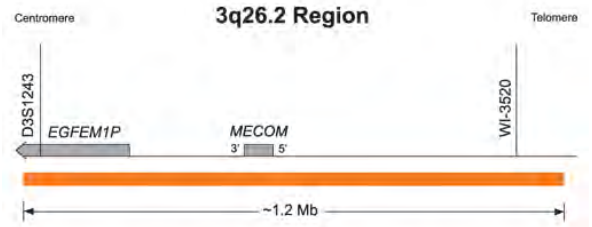
   Cancer Genetics and Cytogenetics. 2005;159:129-136.

Vysis RPN1/MECOM FISH Probe Kit



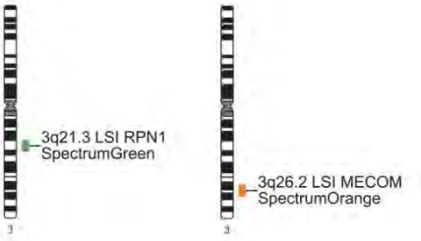
LSI RPN1 SpectrumGreen Probe

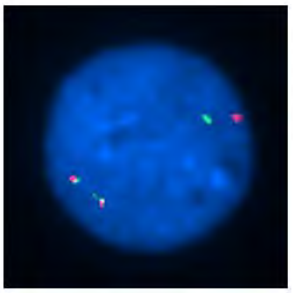
The approximately 580 kb SpectrumGreen LSI RPN1 probe spans the RPN1 gene area on chromosome 3q21.



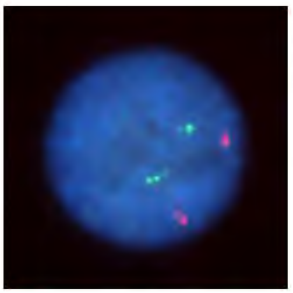
LSI MECOM SpectrumOrange Probe

The approximately 1.2 Mb SpectrumOrange LSI MECOM probe encompasses the entire MECOM (MDS1 and EVI1 complex) locus on chromosome 3q26.2.





Vysis LSI RPN1/MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing a simple balanced t(3;3) (q21.3;q26.2). One orange, one green and two orange/green fusion signals are observed.



Vysis LSI RPN1/MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing non-rearranged RPN1 and MECOM regions. Two orange and two green signals are observed.

The Vysis RPN1/MECOM DF FISH Probe Kit is intended to detect a fusion between the ribophorin I gene (RPN1) and the MDS1 and EVI1 complex locus gene (MECOM) using the fluorescence in situ hybridization (FISH) technique.

Acute myeloid leukemia (AML) with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2) represents 1 to 2% of all AML.[1] It has an aggressive disease course with short survival and poor response to chemotherapy. AML with inv(3)(q21;q26.2) or t(3;3)(q21;q26.2) is associated with an unfavorable prognosis. These abnormalities may also be found in a similar percentage of myelodysplastic syndromes (MDS).[1] Due to the subtle appearance of this rearrangement, particularly inv(3), conventional cytogenetic chromosome analysis may miss these abnormalities.[2]

The Vysis RPN1/MECOM DF FISH Probe Kit identifies rearrangements between the RPN1 gene and the MECOM locus by detecting the fusion of the Locus Specific Identifier (LSI) RPN1 SpectrumGreen and LSI MECOM SpectrumOrange probe signals resulting from chromosomal rearrangement between the hybridization targets of the 2 probes.

Results of Hybridization

The most commonly expected signal pattern of the Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes in normal specimens is 2 orange and 2 green signals. Due to the proximity of the 2 probes on the q arm of chromosome 3, however, the orange and green signals may sometimes appear as a fusion in a normal nucleus. This effect can produce a pattern of 1 orange, 1 green, and 1 orange/green fusion signal or, more rarely, 2 orange/green fusion signals.[2] The most frequently expected signal pattern of the Vysis LSI RPN1/MECOM Dual Color Dual Fusion Probes in abnormal specimens is 1 orange, 1 green, and 2 orange/green fusion signals. Other signal patterns may occur in abnormal specimens, and metaphase analysis may be helpful in characterization of such patterns.

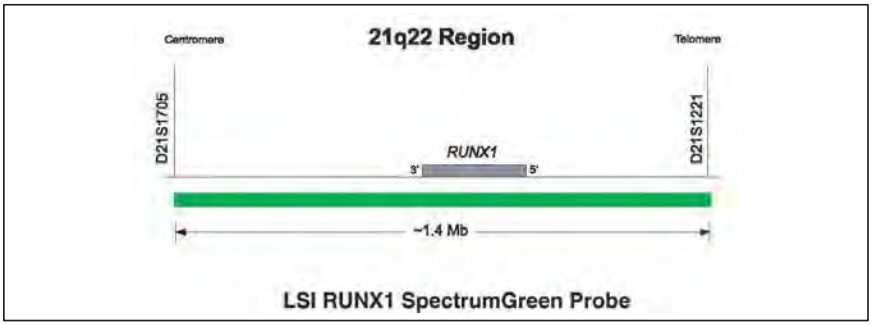
Ordering Information	Quantity	Order No.
Vysis RPN1/MECOM FISH DF Probe Kit	10 µl	06N60-010

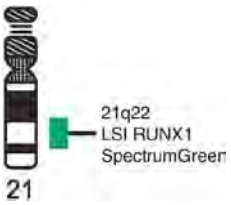
References

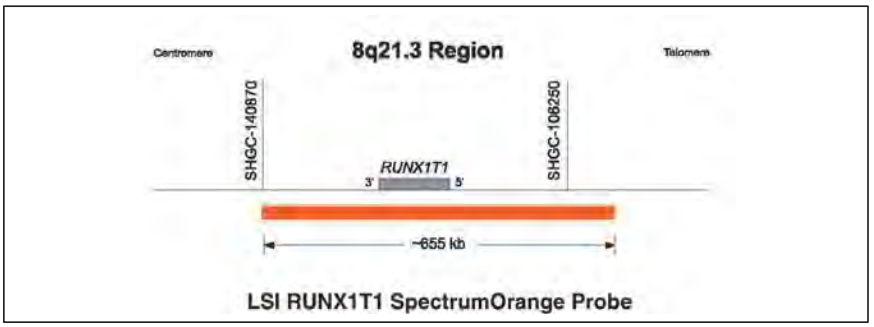
1. The International Agency for Research on Cancer. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Swerdlow S, Campo E, Harris NL, et al, eds. 4th ed. World Health Organization; 2008.
2. Shearer BM, Sukov WR, Flynn HC, Knudson RA, Ketterling RP. Development of a dual-color, double fusion FISH assay to detect RPN1/EVI1 gene fusion associated with inv(3), t(3;3), and ins(3;3) in patients with myelodysplasia and acute myeloid leukemia. Am J Hematol. 2010;85(8):569-574.

Vysis RUNX1/RUNX1T1 DF FISH Probe Kit

previously Vysis LSI AML1/ETO Dual Color, Dual Fusion Translocation Probe







These fluorescence in situ hybridization (FISH) probes are intended to detect the t(8;21)(q21.3;q22) reciprocal translocation involving the RUNX1 and RUNX1T1 gene regions.

A translocation between chromosomes 8 and 21, t(8;21)(q21.3;q22), is seen in approximately 8% of adult patients and 12% of children with Acute Myeloid Leukemia (AML).[1,2] Patients with t(8;21) alone have betterrisk status than patients with normal karyotype or with multiple molecular abnormalities.[3,4] The Vysis LSI RUNX1/RUNX1T1 Dual Color Dual Fusion-Probes have been used in several studies to detect t(8;21).[5,6]

The approximately 1.4 Mb SpectrumGreen probe spans the RUNX1 gene (chr21:34452353-35813329; March 2006 assembly, UCSC Genome Browser)[7]. The approximately 655 kb SpectrumOrange probe spans the RUNX1T1 gene (chr8:92827265-93482325; March 2006 assembly, UCSC Genome Browser).

Results of Hybridization

The expected normal signal pattern of the Vysis LSI RUNX1/RUNX1T1 Dual Color Dual Fusion Probes is two orange signals and two green signals.

The expected abnormal pattern of the Vysis LSI RUNX1/RUNX1T1 Dual Color Dual Fusion Probes is one orange, one green, and two fusions. Other abnormal signal patterns may occur, and metaphase analysis may be helpful in characterization of such patterns.

The Vysis RUNX1/RUNX1T1 DF FISH Probe hybridized to an abnormal nucleus showing a one orange, one green and two fusion (1O1G2F) signal pattern.

Ordering Information	Quantity	Order No.
Vysis RUNX1/RUNX1T1 DF FISH Probe Kit	20 µl	08L70-020

References

1. Grimwade D, Walker H, Oliver F, et al. Blood. 1998;92:2322-33.
2. Raimondi SC, Chang MN, Ravindranath Y, et al. Blood. 1999;94:3707-16.
3. NCCN AML Guidelines V.I. 2010.
4. Byrd JC, Mrozek K, Dodge RK, et al. . Blood. 2002;100:4325-36.
5. Vance GH, Kim H, Hicks GA, et al. Leuk Res. 2007;31:605-09
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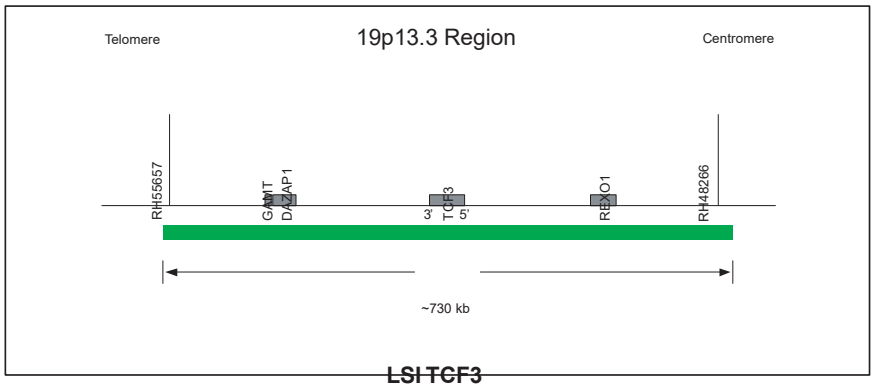
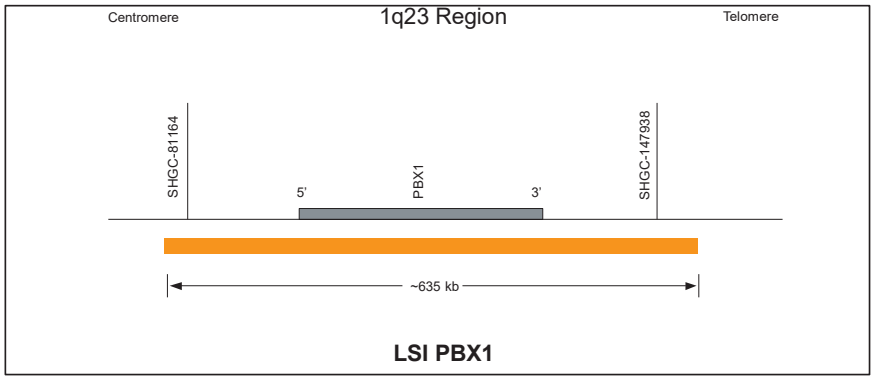
7. Kent WJ, Sugnet CW, Furey TS, et al. The Human Genome Browser at UCSC. Genome Res. 2002;12(6):996-1006.
8. Wiktor AE, Van Dyke DL, Stupka PJ, et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. Genet Med. 2006;8(1):16-23.

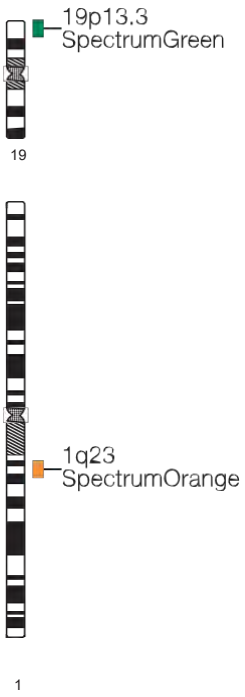
Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe



LSI TCF3



LSI PBX1



Translocations occur between the TCF3 locus at chromosome 19p13.3 and the PBX1 locus at chromosome 1q23. The translocation event t(1;19)(q23;p13) produces a fusion of two genes on the derivative 19 chromosome that results in a novel chimeric gene, TCF3/PBX1.

The TCF3 SpectrumGreen probe is 730 kb in size and extends beyond the TCF3 gene to cover a larger region on chromosome 19p13.3. The PBX1 SpectrumOrange probe is 635 kb in size and covers the entire PBX1 gene on chromosome 1q23.

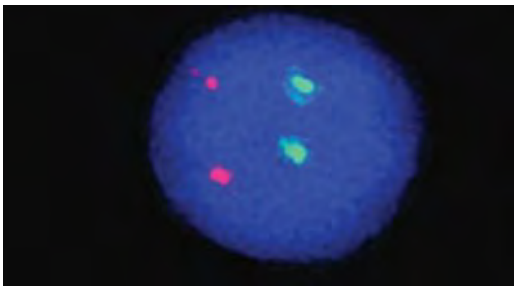


Figure 1. Normal hybridization showing two orange and two green signals.

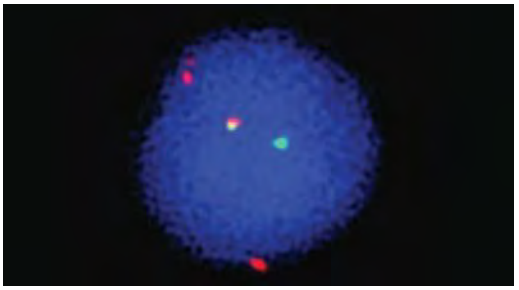
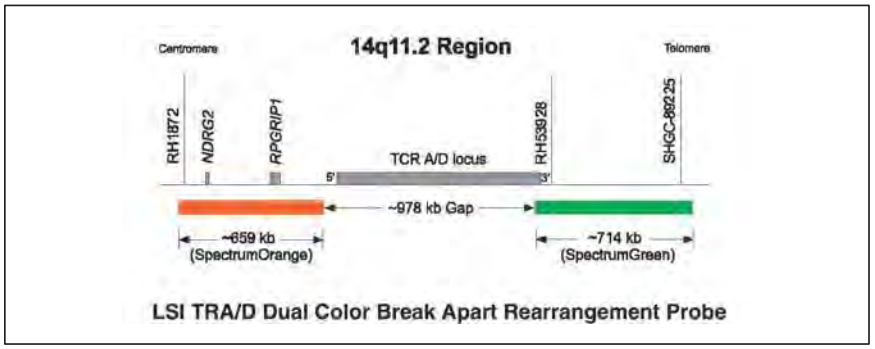


Figure 2. Example abnormal hybridization of an unbalanced (t(1;19) showing two orange, one green and one fusion signals.

Ordering Information	Quantity	Order No.
LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe	20 µl	01N24-020

Vysis TRA/D Break Apart FISH Probe Kit

previously Vysis LSI TCR alpha/delta Dual Color Break Apart Rearrangement Probe

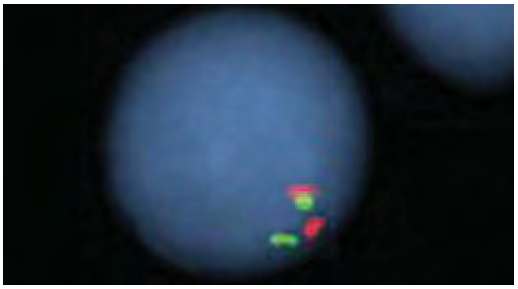


LSI TRA/D Dual Color Break Apart Rearrangement Probe

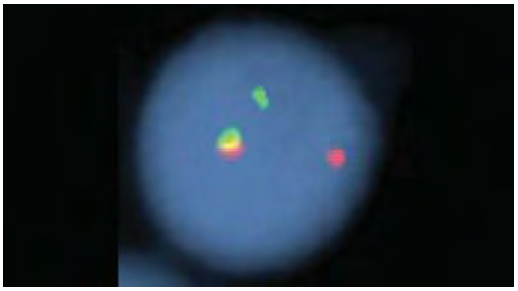
The Vysis TRA/D Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements involving the T-cell receptor alpha/delta locus at chromosome 14q11.2 using the fluorescence in situ hybridization (FISH) technique.

Acute Lymphoblastic Leukemia (ALL) accounts for 25 % of all pediatric cancer and 15 % of pediatric ALL is of T-Cell lineage (T-ALL).[1] T-ALL and T-Cell Lymphoblastic Lymphoma (T-LBL) are described by the World Health Organization classification as similar entities that are discerned by the relative percentage of bone marrow infiltration.[2] The Vysis TRA/D Dual Color Break Apart Rearrangement Probe was used in a study to detect TCR alpha/delta rearrangements in 22 randomly selected patients for the Children's Oncolgy Group.[3]

The SpectrumOrange probe spans approximately 659 kb (chr14:20433430-21092293; March 2006 assembly)[4] centromeric of the T-cell receptor alpha/delta locus. The SpectrumGreen probe spans approximately 714 kb (chr14:22069931-22784042; March 2006 assembly)[4] telomeric of the T-cell receptor alpha/delta locus.



Normal nucleus showing the two green/orange fusion signals. Note the gap that can occur between the green and orange signals in some normal samples.



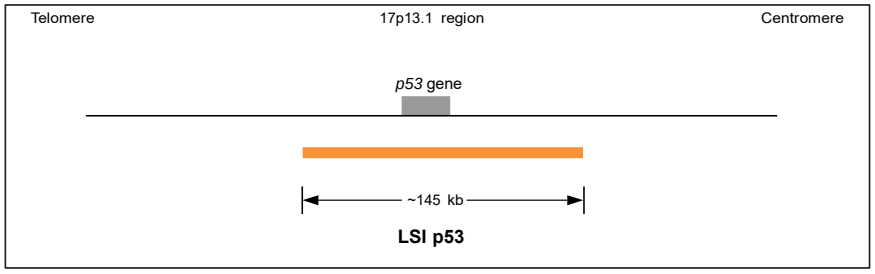
Abnormal nucleus showing the one green/orange fusion, one green and one orange signal pattern.

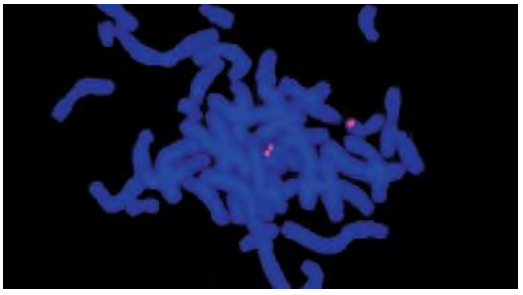
Ordering Information	Quantity	Order No.
Vysis TRA/D Break Apart FISH Probe Kit	20 µl	05N41-020

References

1. Heim S, Mitelman F. Cancer Cytogenetics. 3rd ed. Hoboken, New Jersey: John Wiley & Sons, Inc; 2009.
2. Swerdlow SH, Campo E, Harris NL, et al. Lyon, France: IARC Press; 2008:265-6.
3. Smock KJ, Nelson M, Tripp SR, et al. Characterization of childhood. Pediatr Blood Cancer. 2008;51(4):489-94.
4. Kent WJ, Sugnet CW, Furey TS, et al. Genome Res. 2002:12(6):996-1006.

Vysis LSI TP53 (17p13.1) SpectrumOrange Probe





LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.

The LSI TP53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

Results of Hybridization

In a cell containing a deletion of the LSI TP53 locus, one orange LSI TP53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.

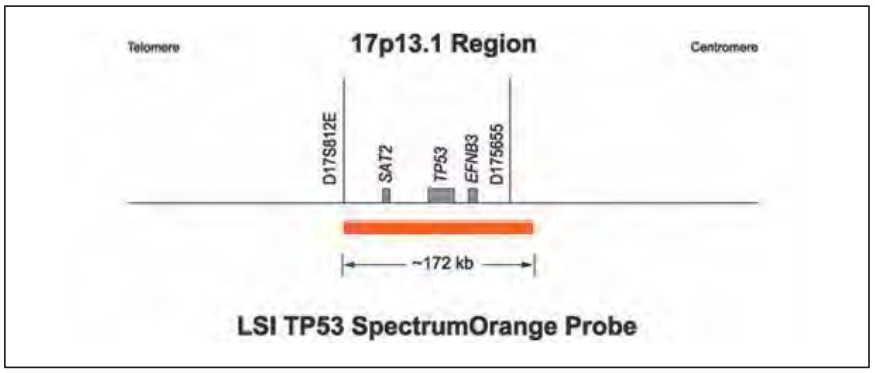
Ordering Information	Quantity	Order No.
Vysis LSI TP53 (17p13.1) SpectrumOrange Probe	20 µl	08L64-020

References

1. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed. New York City, NY, JohnWiley & Sons, Inc

Vysis TP53/CEP 17 FISH Probe Kit

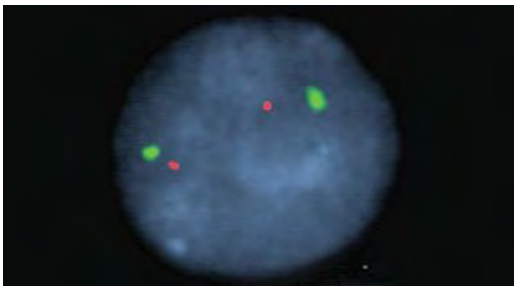
previously Vysis LSI TP53 SpectrumOrange/CEP 17 SpectrumGreen Probe



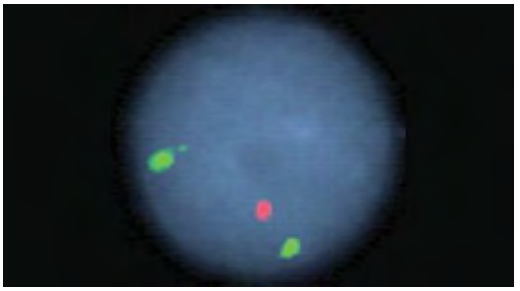
The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma.[1,2] The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.[3,4,5]

Approximately 172 kb SpectrumOrange TP53 probe contains the complete TP53 gene and is located at chromosome 17p13.1. The SpectrumGreen CEP 17 probe is a control probe which hybridizes to the centromere region of chromosome 17p11.1-q11.1.



Normal nucleus showing the two green and two orange signals.



Abnormal nucleus showing the two green and one orange signal.

Ordering Information	Quantity	Order No.
Vysis TP53/CEP 17 FISH Probe Kit	20 µl	05N56-020

References

1. Shanafelt T, Geyer SM, and Kay NE. Blood. 2004;103(4):1202-10.
2. Avet-Loiseau H, Attal M, Moreau P, et al. Blood. 2007;109(8):3489-95.
3. Dewald GW, Brockman SR, Paternoster SF, et al. Br J Haematol. 2003;121:287-95.
4. Grever MR, Lucas DM, Dewald GW, et al. J Clin Oncol. 2007;25(7):799-804.
5. Fonseca R, Blood E, Rue M, et al. Blood. 2003;101(11):4569-75.

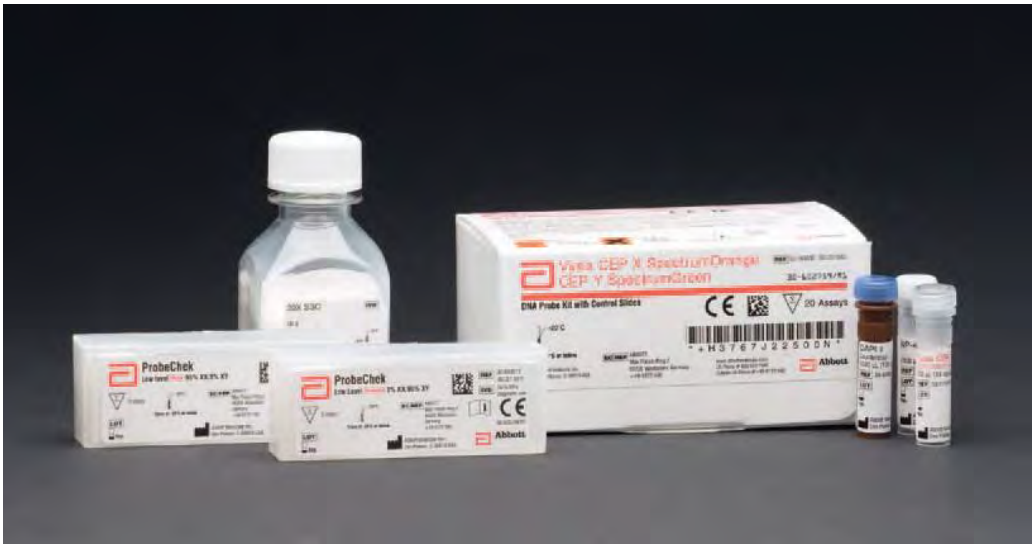
Oncology

Enumeration and Identification

Chromosome enumeration probes (CEP) are chromosome-specific FISH probes that hybridze to highly repetitive human satellite DNA sequences, usually located near centromeres. CEP signals are bright, and enable the identification and enumeration of human chromosomes in interphase and metaphase cells from fresh and archived samples. CEPs are used commonly to study polar bodies, blastomeres, prenatal samples, tumors,and hematologic malignancies.

The Locus Specific Identification (LSI) probes consist of DNA probe sequences homologous to specific DNA regions, gene sequence or loci and are directly labeled with one of the Vysis fluorophores. Unlabeled blocking DNA is included with the probe to suppress sequences contained within the loci that are common to other chromosomes. When hybridized and visualized, these probes show specific changes, such as amplifications, deletions or translocations, to specific genes, loci, or chromosomal regions.

CEP 8, 12 and X/Y probes, as indicated, are all intended for *in vitro* diagnostic use.



Product description	Quantity	Order No.	Page Number
Vysis CEP and LSI Probes			7-3
Vysis LSI 13 (13q14) SpectrumGreen	20 µl	08L67-020	7-5
Vysis LSI 13 (RB1) SpectrumOrange	20 µl	08L65-020	7-5
Vysis LSI 21 SpectrumOrange	20 µl	08L54-020	7-6
Vysis LSI 22 SpectrumGreen	20 µl	05J17-024	7-6

Quantities of 200 µl are prediluted with Hybridisation Buffer

CEP and LSI Probes

Product description	Sequence Type	Chromosome Band or Region	Quantity	Order No.
CEP 1 (D1Z5) SpectrumOrange Probe	Alpha Satellite DNA	1p11.1-q11.1	20 µl	06J39-036
CEP 1 SpectrumOrange Probe	Satellite III DNA	1q12	20 µl	06J36-091
CEP 2 (D2Z1) SpectrumOrange Probe	Alpha Satellite DNA	2p11.1-q11.1	20 µl	06J36-037
CEP 3 (D3Z1) SpectrumOrange Probe	Alpha Satellite DNA	3p11.1-q11.1	20 µl	06J36-013
CEP 4 SpectrumAqua Probe	Alpha Satellite DNA	4p11-q11	20 µl	06J54-014
CEP 4 SpectrumGreen Probe	Alpha Satellite DNA	4p11-q11	20 µl	06J37-014
CEP 4 SpectrumOrange Probe	Alpha Satellite DNA	4p11-q11	20 µl	06J36-014
CEP 6 (D6Z1) SpectrumAqua Probe	Alpha Satellite DNA	6p11.1-q11	20 µl	06J54-016
CEP 6 (D6Z1) SpectrumGreen Probe	Alpha Satellite DNA	6p11.1-q11.1	20 µl	06J37-016
CEP 6 (D6Z1) SpectrumOrange Probe	Alpha Satellite DNA	6p11.1-q11	20 µl	06J36-016
CEP 7 (D7Z1) SpectrumAqua Probe	Alpha Satellite DNA	7p11.1-q11.1	20 µl	06J54-017
CEP 7 (D7Z1) SpectrumGreen Probe	Alpha Satellite DNA	7p11.1-q11.1	20 µl	06J37-017
CEP 7 (D7Z1) SpectrumOrange Probe	Alpha Satellite DNA	7p11.1-q11.1	20 µl	06J36-017
CEP 8 SpectrumAqua Probe	Alpha Satellite DNA	8p11.1-q11.1	20 µl	06J54-018
CEP 8 (D8Z2) SpectrumGreen Probe	Alpha Satellite DNA	8p11.1-q11.1	20 µl	06J37-018
CEP 8 (D8Z2) SpectrumOrange Probe FDA Cleared	Alpha Satellite DNA	8p11.1-q11.1	200 µl	07J20-008
CEP 9 SpectrumAqua Probe	Alpha Satellite DNA	9p11-q11	20 µl	06J54-019
CEP 9 SpectrumGreen Probe	Alpha Satellite DNA	9p11-q11	20 µl	06J37-019
CEP 9 SpectrumOrange Probe	Alpha Satellite DNA	9p11-q11	20 µl	06J36-019
CEP 10 SpectrumAqua Probe	Alpha Satellite DNA	10p11.1-q11.1	20 µl	06J54-020
CEP 10 SpectrumGreen Probe	Alpha Satellite DNA	10p11.1-q11.1	20 µl	06J37-020
CEP 10 SpectrumOrange Probe	Alpha Satellite DNA	10p11.1-q11.1	20 µl	06J36-090
CEP 11 (D11Z1) SpectrumAqua Probe	Alpha Satellite DNA	11p11.11-q11.11	20 µl	06J54-021
CEP 11 (D11Z1) SpectrumGreen Probe	Alpha Satellite DNA	11p11.11-q11	20 µl	06J37-021
CEP 11 (D11Z1) SpectrumOrange Probe	Alpha Satellite DNA	11p11.11-q11	20 µl	06J36-021
CEP 12 (D12Z3) SpectrumGreen Probe	Alpha Satellite DNA	12p11.1-q11	20 µl	06J37-022
CEP 12 (D12Z3) SpectrumOrange Probe FDA Cleared	Alpha Satellite DNA	12p11.1-q11	200 µl	07J20-012
Vysis LSI 13 (13q14) SpectrumGreen		13q14	20 µl	08L67-020
Vysis LSI 13 (RB1) SpectrumOrange		13q14	20 µl	08L65-020
CEP 15 (D15Z1) SpectrumAqua Probe	Satellite III DNA	15p11.2	20 µl	06J54-025
CEP 15 (D15Z1) SpectrumGreen Probe	Satellite III DNA	15p11.2	20 µl	06J37-025
CEP 15 (D15Z4) SpectrumOrange Probe	Alpha Satellite DNA	15p11.1-q11.1	20 µl	06J36-025
CEP 16 (D16Z3) SpectrumAqua Probe	Satellite II DNA	16q11.2	20 µl	05J09-026
CEP 16 (D16Z3) SpectrumGreen Probe	Satellite II DNA	16q11.2	20 µl	05J10-026
CEP 16 (D16Z3) SpectrumOrange Probe	Satellite II DNA	16q11.2	20 µl	05J08-026
CEP 17 (D17Z1) SpectrumAqua Probe	Alpha Satellite DNA	17p11.1-q11.1	20 µl	06J38-027
CEP 17 (D17Z1) SpectrumGreen Probe	Alpha Satellite DNA	17p11.1-q11.1	20 µl	06J37-027
CEP 17 (D17Z1) SpectrumOrange Probe	Alpha Satellite DNA	17p11.1-q11.1	20 µl	06J36-027
CEP 18 (D18Z1) SpectrumAqua Probe	Alpha Satellite DNA	18p11.1-q11.1	20 µl	05J09-028

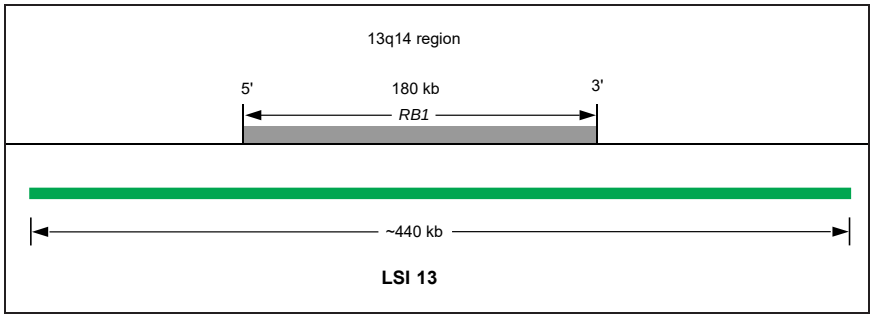
Quantities of 200 µl are prediluted with Hybridisation Buffer

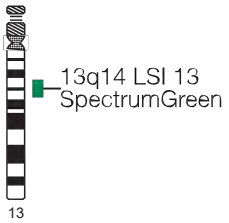
Continuation: CEP and LSI Probes

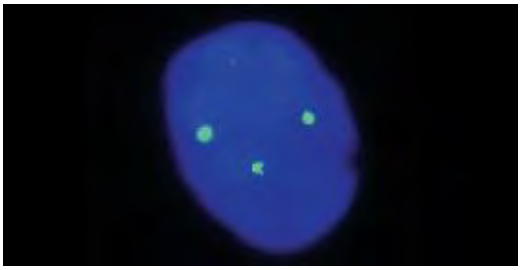
Product description	Sequence Type	Chromosome Band or Region	Quantity	Order No.
CEP 18 (D18Z1) SpectrumGreen Probe	Alpha Satellite DNA	18p11.1-q11.1	20 µl	05J10-028
CEP 18 (D18Z1) SpectrumOrange Probe	Alpha Satellite DNA	18p11.1-q11.1	20 µl	05J08-028
CEP 20 (D20Z1) SpectrumOrange Probe	Alpha Satellite DNA	20p11.1-q11.1	20 µl	06J36-030
Vysis LSI 21 SpectrumOrange		21q22.13-q22.2	20 µl	08L54-020
Vysis LSI 22 (BCR) SpectrumGreen Probe			20 µl	05J17-024
CEP X (DXZ1) SpectrumAqua Probe	Alpha Satellite DNA	Xp11.1-q11.1	20 µl	05J09-033
CEP X (DXZ1) SpectrumGreen Probe	Alpha Satellite DNA	Xp11.1-q11.1	20 µl	05J10-033
CEP X (DXZ1) SpectrumOrange Probe	Alpha Satellite DNA	Xp11.1-q11.1	20 µl	05J08-033
CEP X (DXZ1)/Y (DYZ1)	Alpha Satellite DNA Satellite III DNA	Xp11.1-q11.1 Yq12	200 µl	07J20-050
CEP X (DXZ1)/Y (DYZ3)	Alpha Satellite DNA Alpha Satellite DNA	Xp11.1-q11.1 Yp11.1-q11.1	20 µl	05J10-051
CEP Y (DYZ1) SpectrumAqua Probe	Satellite III DNA	Yq12	20 µl	05J09-034
CEP Y (DYZ1) SpectrumGreen Probe	Satellite III DNA	Yq12	20 µl	05J10-034
CEP Y (DYZ1) SpectrumOrange Probe	Satellite III DNA	Yq12	20 µl	05J08-034
CEP Y (DYZ3) SpectrumOrange Probe	Alpha Satellite DNA	Yp11.1-q11.1	20 µl	05J08-035

Quantities of 200 µl are prediluted with Hybridisation Buffer

Vysis LSI 13 (13q14) SpectrumGreen







LSI 13 (13q14) SpectrumGreen hybridized to an amniocyte. Three green signals indicate three copies of chromosome 13.

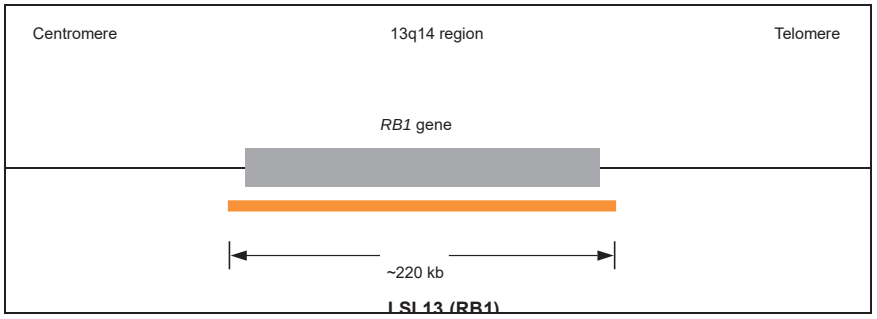
LSI 13 (13q14) consists of a set of overlapping clones that contain the RB1 gene and flanking regions. The RB1 gene is 180 kb. The probe extends beyond the gene for 110-170 kb in the 5' direction and approximately 120 kb in the 3' direction. The entire probe is approximately 440 kb in size.

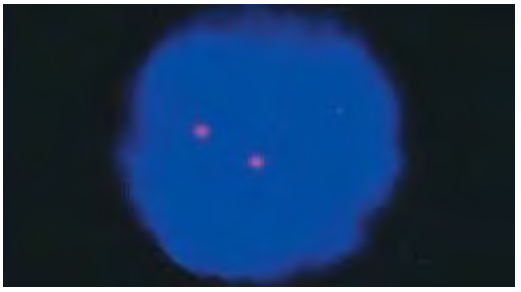
Ordering Information	Quantity	Order No.
Vysis LSI 13 (13q14) SpectrumGreen	20 µl	08L67-020

References

1. Tepperberg J, Pettenati MJ, Rao PN, et al. Prenat Diagn 2001;21:293-301.
2. Fonseca R, Oken MM, Harrington D, et al. Leukemia 2001;15:981-86.
3. Elnenaei MO, Hamoudi RA, Swansbury J, et al. Genes Chromosomes Cancer 2003;36:99-106.
4. Kalachikov S, Migliazza A, Cayanis E, et al Genomics 1997;42:369-77.
5. Stilgenbauer S, Nickolenko J, Wilhelm J, et al. Oncogene 1998;16:1891-97.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

Vysis LSI 13 (RB1) SpectrumOrange





LSI 13 (RB1) SpectrumOrange hybridized to a cultured amniocyte.

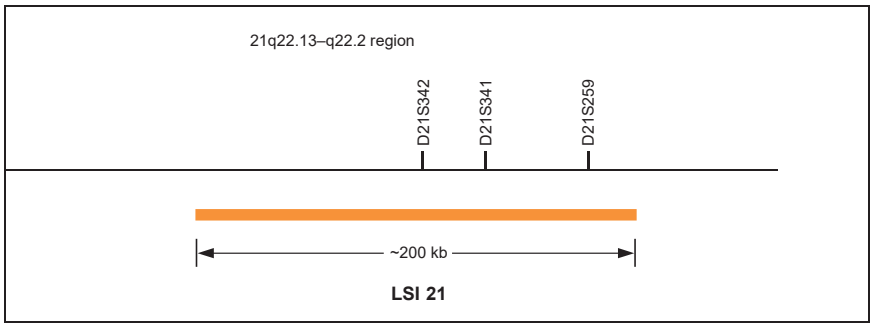
The LSI 13 (RB1) SpectrumOrange Probe is approximately 220 kb and contains the entire RB1 gene.

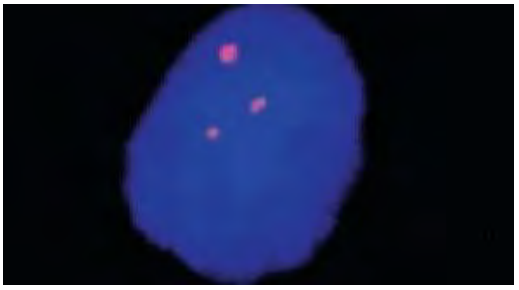
Ordering Information	Quantity	Order No.
Vysis LSI 13 (RB1) SpectrumOrange	20 µl	08L65-020

References

1. Amare PS, Ghule P, Jose J, et al. Cancer Genet Cytogenet 2004;150:33-43.
2. Elnenaei MO, Hamoudi RA, Swansbury J, et al. Genes Chromosomes Cancer 2003;36:99-106.
3. Fonseca R, Oken MM, Harrington D, et al. Leukemia 2001;15:981-86.
4. Kalachikov S, Migliazza A, Cayanis E, et al. Genomics 1997;42:369-77.
5. Stilgenbauer S, Nickolenko J, Wilhelm J, et al. Oncogene 1998;16:1891-97.
6. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

Vysis LSI 21 SpectrumOrange





LSI 21 SpectrumOrange hybridized to a cultured amniocyte.

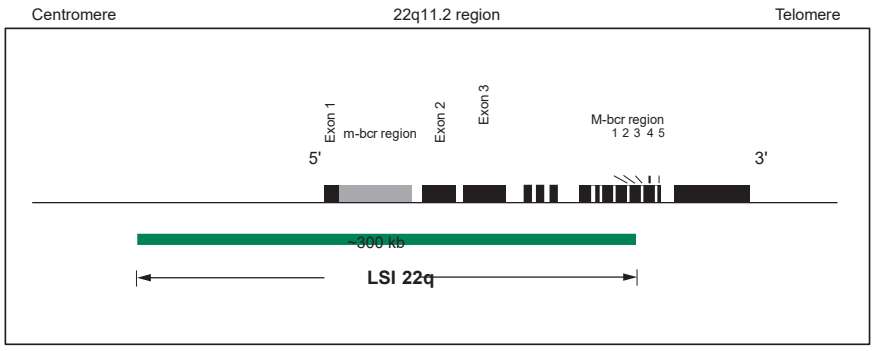
LSI 21 is approximately 200 kb and contains unique DNA sequences complementary to the loci D21S259, D21S341, and D21S342 (21q22.13-q22.2).

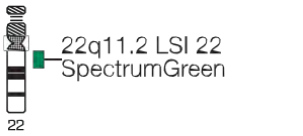
Ordering Information	Quantity	Order No.
Vysis LSI 21 SpectrumOrange	20 µl	08L54-020

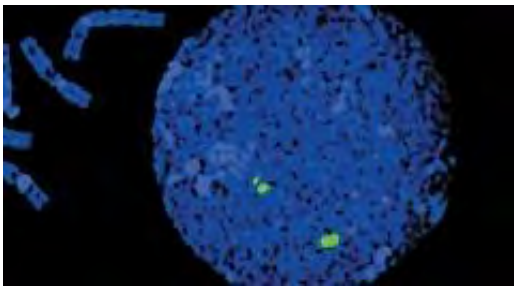
References

1. Delabar J, Theophile D, Rahmani Z, et al. Eur J Hum Genet1993;1:114-24.
2. Korenberg JR, Chen XN, Schipper R, et al. Proc Natl Acad Sci 1994;91:4997-5001.
3. Ohira M, Ichikawa H, Suzuki E, et al. Genomics 1996;33:65-74.
4. Dahmane N, Ghezala GA, Gosset P, et al. Genomics 1998:48(1):12-23.
5. Toyoda A, Noguchi H, Taylor T, et al. Genome Research 2002;12:1323-32.
   Available at: http://www.genome.org. Accessed February 23, 2006.
6. Mitelman Database of Chromosome Aberrations in Cancer (2006).
   Mitelman F, Johansson B and Mertens F (Eds.) http://cgap.nci.nih.gov/Chromosomes/Mitelman.
7. Mitelman S, Heim F. Cancer Cytogenetics. 2nd ed. New York: Wiley-Liss,1995:209-10.
8. Mitelman F, Heim S, Mandahl N. Trisomy 21 in neoplastic cells. Am J Med Genet Suppl 1990;7:262-6.
9. Wiktor AE, Van Dyke DL, Stupca PJ, et al. Genet Med 2006;8:16-23.

Vysis LSI 22 SpectrumGreen







LSI 22 (BCR) SpectrumGreen hybridized to an interphase cell.

The LSI 22 (BCR) Probe is an approximately 300 kb SpectrumGreen probe corresponding to 22q11.2.

Ordering Information	Quantity	Order No.
Vysis LSI 22 SpectrumGreen	20 µl	05J17-024

References

1. Heim, S. & Mitelman, F. (1995) Cancer Cytogenetics 2nd ed. New York City, NY, JohnWiley & Sons, Inc.

FISH Accessories

Abbott Molecular delivers best in class products and services to meet the diverse needs of your laboratory. In addition to FISH automation, Abbott Molecular provides quality instrumentation and reagents that optimize laboratory effectiveness when processing FISH probes.

The following section highlights FISH Accessories by product category:

- **FISH Pretreatment Reagent** Kits include ready-to-use reagents used to prepare specimens for hybridization
- **In Situ Hybridization Reagents** offer an a la carte menu of reagents essential to FISH processing
- **Fluorescence Labeling Reagents** used in nick translation protocols to incorporate individual fluorophore-conjugated dUTPs into DNA
- **FISH Assay Control Slides** serve as controls and training tools to ensure high quality specimen processing and accurate enumeration
- **VP 2000 Reagents** are specifically designed for automated deparaffinization and pre-treatment protocols for Vysis FISH assays
- **Filter Sets** are custom-manufactured to meet the exact specifications of Abbott Molecular FISH products and your microscope

FISH

Ordering Information	Quantity	Order No.
FISH Control Slides		
ProbeChek Control Slides for CEP 8 or CEP 12 DNA Probes 0% trisomy 8/12 – FDA Cleared	5 Slides	07J21-001
ProbeChek Control Slides for CEP 8 or CEP 12 DNA Probes 10% trisomy 8/12 – FDA Cleared	5 Slides	07J21-002
ProbeChek Prenatal Control Slides for Amniocyte; Male Amniocyte Control – FDA Cleared	5 Slides	05J39-005
ProbeChek Prenatal Control Slides for Positive Control – FDA Cleared	5 Slides	05J36-005
ProbeChek Control Slides for CEP X SpectrumOrange/ CEP Y SpectrumGreen Low-Level Female 5% XX/95% XY FDA Cleared	5 Slides	07J21-011
ProbeChek Control Slides for CEP X SpectrumOrange/ CEP Y SpectrumGreen Low-Level Male 95% XX/5% XY – FDA Cleared	5 Slides	07J21-012
MultiVysion Control Slides	5 Slides	05J07-001
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Normal Control – FDA Approved	5 Slides	02J05-030
ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit – Cut-Off Control – FDA Approved	5 Slides	02J04-030
ProbeChek Control Slides for UroVysion FDA Approved	3 Slides	02J27-011
ProbeChek ALK Negative Control Slides IVD	5 Slides	06N38-005
ProbeChek ALK Positive Control Slides IVD	5 Slides	06N38-010
Fluorescence Labeling Reagents		
Aqua dUTP	50 nmol, lyophilized	02N35-050
Gold dUTP	50 nmol, lyophilized	05N18-050
Green dUTP	50 nmol, lyophilized	02N32-050
Orange dUTP	50 nmol, lyophilized	02N33-050
Red dUTP	50 nmol, lyophilized	02N34-050
Nick Translation Kit	50 Reactions	07J00-001

FISH

Ordering Information	Quantity	Order No.
CGH Reagents		
CGH Metaphase Target Slides	10 Slides	06J96-001
CGH Cotrolled DNA (MPE 600) Unlabeled	200 ng/µl x15 µl	06J40-001
SpectrumGreen Control DNA (MPE 600)	300 ng/µl x 25 µl	06J45-001
CGH Nick Translation Kit with Control DNA (MPE 600)	50 Reactions	06J40-020
CGH Hybridization Reagents		06J40-010
Labeled Reference DNA		
SpectrumGreen Female Total Human Genomic DNA	300 ng/µl x 25 µl	07J03-001
SpectrumGreen Male Total Human Genomic DNA	300 ng/µl x 25 µl	07J03-005
SpectrumRed Female Total Human Genomic DNA	100 ng/µl x 25 µl	07J04-001
SpectrumRed Male Total Human Genomic DNA	100 ng/µl x 25 µl	07J04-005
Hybridization Reagents		
NP-40	1000 µl x 2	07J05-001
20X SSC	500 g	02J10-032
Vysis LSI/WCP Hybridization Buffer	150 µl x 2	06J67-001
Vysis LSI/WCP Hybridization Buffer	500 µl x 2	06J67-011
Vysis CEP Hybridization Buffer	150 µl x 2	07J36-001
Human COT-1 DNA	250 µg (1 µg/µl)	06J31-001
Antifade Solution	240 µl x 2	06J29-010
Antifade II Solution	60 µl x 2	06J29-001
Propidium Iodide Counterstain	500 µl x 2	07J06-001
DAPI I Counterstain (1000 ng/ml)	500 µl x 2	06J49-001
DAPI II Counterstain (125 ng/ml)	500 µl x 2	06J50-001
DAPI III Counterstain (42 ng/ml)	500 µl x 2	06J49-010
Nick Translation Kit	50 Reactions	07J00-001
Pretreatment Kits		
FISH Pretreamtment Kit	1 Kit	02J03-032
Paraffin Pretreatment Kit I	1 Kit	02J02-032
Paraffin Pretreatment Kit II	1 Kit	07J02-002
Paraffin Pretreatment Kit III	1 Kit	07J02-003
Paraffin Pretreatment IV & Post-Hybridization Wash Buffer Kit	1 Kit	01N31-005

FISH

Ordering Information	Quantity	Order No.
Reagents (General Purpose Reagents)		
Reagents – Pretreatment Reagent	500 ml	02J06-030
Reagents – Protease Buffer	500 ml	02J07-030
Reagents – Protease I	250 mg x 2	02J08-032
Reagents – Protease II	750 mg	06J93-001
Reagents – 2M MgCl 2	120 ml	02J09-030
Reagents – 20X SSC	500 g	02J10-032

Single Bandpass Filter Sets

Orange
The Orange filter set is designed to excite and transmit SpectrumOrange fluorescence. All of the Vysis SpectrumOrange labeled DNA FISH probes can be viewed, analyzed, and imaged using this filter set. The SpectrumRed fluorophore will be visible using this filter set, but will be dim.

Red
The Red filter set is designed to excite and transmit SpectrumRed fluorescence. This filter set can be used to view, analyze, and image SpectrumRed labeled probes, or for TexasRed labeled DNA FISH probes that are available from other probe manufacturers. The SpectrumRed filter set is not recommended for viewing SpectrumOrange labeled probes.

Yellow
The Yellow filter set is designed to excite and transmit SpectrumGold fluorescence. The Vysis SpectrumGold labeled DNA FISH probes (Vysis UroVysion) can be viewed, analyzed, and imaged using this filter set. SpectrumOrange probe fluorescence will also be visible with the Yellow filter set. SpectrumRed fluorescence may be visible, yet very dim.

Green
The Green filter set is designed to excite and transmit SpectrumGreen fluorescence. This filter set can be used to view, analyze, and image SpectrumGreen and fluorescence labeled DNA FISH probes.

Aqua
The Aqua filter set is designed to excite and transmit SpectrumAqua fluorescence. This filter set is specifically required for viewing, analyzing, and imaging Vysis SpectrumAqua DNA probes. Filter sets that excite and transmit DAPI fluorescence are not appropriate for SpectrumAqua labeled probes. In some instances,when hybridization signal is very intense for the SpectrumAqua labeled DNA probe, the aqua fluorescence may be visible through a DAPI filter set.However, this will not provide a reliable method for analysis of SpectrumAqua labeled probes. In addition, on specimens counterstained with DAPI, extremely weak DAPI fluorescence may be observed when viewing or imaging through an Aqua single bandpass filter set.

Blue
The Blue filter set is designed to excite and transmit SpectrumBlue fluorescence and is useful when viewing the SpectrumBlue fluorophore alone.DAPI fluorescence will also be visible with this filter set. SpectrumAqua fluorescence will be visible through the Blue filter set, but will be dim. In order to view the SpectrumBlue and SpectrumAqua fluorophores simultaneously, the Aqua/Blue dual bandpass filter set should be used.

DAPI Longpass
The DAPI longpass filter set is designed to excite and transmit DAPI counterstain fluorescence. This filter set transmits more in the red range of the color spectrum than the DAPI bandpass filter set.

DAPI Bandpass
The DAPI bandpass filter set is designed to excite and transmit DAPI counterstain. This filter set does not transmit as much of the spectrum as the DAPI Longpass filter set, and is recommended over the DAPI Longpass for imaging applications.

Dual Bandpass Filter Sets

DAPI/Orange
The DAPI/Orange filter set is designed to excite and transmit SpectrumOrange and DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumOrange fluorophore must be viewed concurrently. This filter set is recommended for many of the Vysis SpectrumOrange labeled DNA FISH probes that can be analyzed simultaneously while viewing the DAPI counterstain.

DAPI/9-Orange (NB)
The DAPI/9-Orange (NB) filter set is designed to excite and transmit SpectrumOrange and the DAPI counterstain fluorescence simultaneously. This filter set is designed to minimize autofluorescence from paraffin-embedded specimens and is recommended for the PathVysion HER-2 DNA Assay. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumOrange fluorophore must be viewed concurrently.

DAPI/Green
The DAPI/Green filter set is designed to excite and transmit SpectrumGreen and DAPI fluorescence simultaneously and is recommended for the PathVysion DNA Assay. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumGreen fluorophore must be viewed concurrently. This filter set is recommended for many of the Vysis SpectrumGreen labeled DNA FISH probes that can be analyzed simultaneously while viewing the DAPI counterstain.

Blue/Aqua
The Blue/Aqua filter set is designed to excite and transmit SpectrumBlue and SpectrumAqua fluorophores simultaneously.

Microscope Filters

Triple Bandpass Filter Sets

DAPI/Green/Orange
The DAPI/Green/Orange filter set is designed to excite and transmit SpectrumGreen, SpectrumOrange, and DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the two fluorophores SpectrumGreen and SpectrumOrange must be viewed concurrently. This filter set is recommended for most of the Vysis dual color probe mixtures when hybridized to specimens that are not imbedded in paraffin. Products such as CEP X/Y should be viewed using this filter set.

DAPI/Green/Orange (V.2)
The DAPI/Green/Orange (V.2) filter set is designed to excite and transmit SpectrumGreen, SpectrumOrange and the DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumGreen and SpectrumOrange fluorophores must be viewed simultaneously.

The DAPI/Green/Orange (V.2) filter design may provide better color distinction and brightness of the SpectrumOrange and SpectrumGreen fluorophores when viewing paraffin-embedded specimens. This filter set is not optimized for viewing dual-color translocation probes where a blending of the SpectrumGreen and SpectrumOrange fluorophores creates a yellow color. This is the recommended triple bandpass filter set for viewing and analyzing the PathVysion HER-2 DNA Assay.

DAPI/Green/Red
The DAPI/Green/Red filter set is designed to excite and transmit SpectrumGreen, SpectrumRed, and the DAPI counterstain fluorescence simultaneously. This filter is optimal for viewing probes labeled with SpectrumRed fluorophore while concurrently viewing SpectrumGreen and DAPI.

Quad Bandpass Filter Set

DAPI/Aqua/Green/Orange
The quad bandpass filter set is designed to excite and transmit DAPI, SpectrumAqua, SpectrumOrange and SpectrumGreen fluorophores simultaneously. This filter set is optimal for viewing all three probe labels simultaneously, plus the DAPI counterstain. This filter set is not recommended for viewing the AneuVysion Assay on uncultured amniocytes.

Required Vysis Filter Set Configurations

The following filter set configurations are required for the specific Vysis FISH products, as indicated. The recommended filter sets provide the most optimal viewing conditions. If not indicated, contact your local Abbott Molecular Technical Service representative for more information on appropriate filter set configurations for imaging.

PathVysion HER-2 DNA Assay Filter Sets
The following filter sets are recommended for viewing and enumeration of the PathVysion HER-2 Assay. These filter sets are optimized both for Vysis SpectrumGreen and SpectrumOrange fluorophores and for paraffin-embedded specimen autofluorescence. The dual bandpass filter sets allow the user to view signals of each respective individual color fluorophore and the DAPI counterstain. The triple bandpass filter set allows the user to visualize the SpectrumGreen, SpectrumOrange, and DAPI fluorescent signals simultaneously.

Vysis Filter Set	Fluorophores Detected
DAPI/9-Orange (NB) dual bandpass	SpectrumOrange and DAPI
DAPI/Green dual bandpass	SpectrumGreen and DAPI
DAPI/Green/Orange (V.2) triple bandpass	SpectrumGreen/SpectrumOrange/DAPI (specifically designed for viewing paraffin sections)

AneuVysion Assay Filter Sets
The following filter set configuration provides the best microscope filter set-up for viewing and analysis of the AneuVysion Assay on uncultured amniocytes.

Vysis Filter Set	Fluorophores Detected
Aqua single bandpass	SpectrumAqua
Green single bandpass	SpectrumGreen
Orange single bandpass	SpectrumOrange
DAPI/Green/Orange triple bandpass	SpectrumGreen/SpectrumOrange/DAPI

UroVysion Assay Filter Sets

Vysis Filter Set	Fluorophores Detected
DAPI single bandpass	DAPI
Aqua single bandpass	SpectrumAqua
Yellow single bandpass	SpectrumGold
Red/Green dual bandpass	SpectrumRed/SpectrumGreen

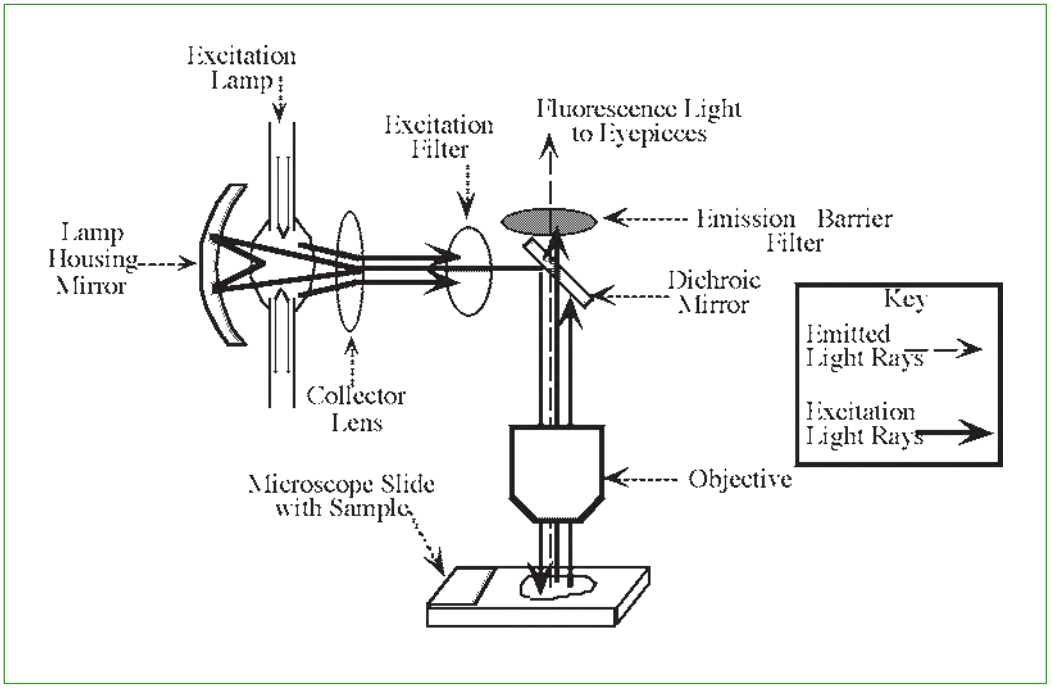
Filter Sliders/Holders

Vysis filter sets can be specified for most microscope types and models. Some of the most common filter holders and sliders are available through Abbott Molecular. Abbott Molecular currently does not supply the new 8 position turret for the Olympus AX-70.

Microscope Filters

Diagram of the Fluorescence Microscope

The critical components of the fluorescence microscope optical train are depicted in the diagram below.



Microscope filter sets are custom manufactured to fit the dimensions required by each type of microscope and filter wheel. Filters are manufactured as matched sets consisting of the excitation filter, dichroic filter, and emission filter. As such, it is necessary to provide all of the required information, as requested below,when ordering filter sets. Without the appropriate information, the correct microscope filter cannot be manufactured. In addition, delays in order processing due to inaccurate or incomplete information will delay the fulfillment of the filter set order. Contact Vysis Technical Service for more information on microscope filter sets and the appropriate configuration for your laboratory's specific needs.

Order Information

Please contact your Inter Medico representative or Order/Entry.

Microscope Filters

Abbott Molecular Filter Specification & Order Form for Fluorescence Microscopes

Fax to: Inter Medico Technical Service, Fax number 905-470-2381
Phone number: 800-387-9643 – 800-268-1150 Français – 905-470-2520 Local
E-mail address: technical@inter-medico.com

Microscope filter sets are designed to meet specifications that are exact for your microscope. Filters are manufactured as matched sets consisting of the excitation filter, dichroic (or barrier) filter and emission filter. It is very important that you provide the following information in order to ensure that the correct microscope filter is manufactured for your microscope. Missing information or incorrect information will cause a delay in delivery of your filter set(s), or in manufacture of an incorrect filter set.

Account Information

Date

Institute Name

Contact Name

Customer Number

Shipping Address

Purchase Order Number

Phone Fax

E-mail

1. Microscope manufacturer:_____(e.g. Nikon, Zeiss, Olympus, etc.)

2. Type or model of microscope:_____
(e.g. Axioplan, Laborlux, etc. Include version numbers such as I or II, etc.)

3. Approximate age of microscope (check one): ☐ < 1 year ☐ 1-3 years ☐ 4-10 years ☐ > 10 years

4. Check all the statements that apply to your microscope:

☐ All filter sets are mounted on individual cubes that can be placed in a revolving turret on the microscope.
The turret holds a maximum of _____(number) filters.
There are currently _____(number) of filters in the unit.

☐ All filter sets are mounted in a slider which moves from left to right.
The slider bar holds a maximum of _____(number) of filters.
There are currently _____(number) of filters in the slider bar.

☐ Filter sets are part of a detached unit separate from microscope and filter unit is part of a computerized system known as a Filter Wheel.
If a filter wheel is used to house the exciter filters: The exciter filters are ☐ 25mm, or ☐ 32mm diameter.

☐ If the filter cube is for a Zeiss Axio model microscope, the cubes are:
☐ clip in, or ☐ screw in.

I am ordering the following filter sets for the microscope that is described above:

Bandpass Single, dual, triple or quad bandpass	**Fluorophores** Indicate fluorophores that will be excited and emitted	**Mounting** Do the filters need to be mounted in a new holder (yes, no)? If No, customer is requested to supply filter holder.	**Quantity**	**Part No.** (For Abbott Molecular Technical Service use.)	**List Price** (For Abbott Molecular Technical Service use.
Example: Triple	*(DAPI/Green/Orange)*	*Yes*	*1*		

AM Technical Services Representative _____ Date: _____

Ordering Information

Inter Medico
50 Valleywood Drive
Markham, Ontario
L3R 6E9
CANADA

info@inter-medico.com

1.800.387.9643 – Toll Free (English)
1.905.470.2520 – Local Telephone
1.800.268.1150 – Sans Frais (Français)
1.905.470.2381 – Facimile

How To Order:

Orders may be placed by phone, fax, mail or e-mail. We request that you use both the catalogue number and the product description when ordering. To obtain information concerning product availability, please contact us via e-mail or telephone and we will be glad to assist.

Phone and Fax Orders:

Please call or Fax our Customer Service department at the numbers listed.

Mail Orders:

Please send orders by mail to our corporate address.

E-Mail Orders:

Please E-mail order to: orders@inter-medico.com

Technical Support via the Telephone:

Phone support provided 24 hours a day, 7 days a week.

English: 1.800.387.9643 – Option 2

Français: 1.800.268.1150 – Option 2

Technical Support via E-Mail:

The technical support mail box is monitored between 8:30 AM and 4:30 PM (EST), Monday through Friday.

Please E-Mail the Technical Support Team: technical@inter-medico.com

Product Use

All products manufactured and/or distributed by Vysis or Abbott Molecular should be used in accordance with the products' labeled intended use. Products labeled "Research Use Only" should be used for research applications, not for use in diagnostic procedures.

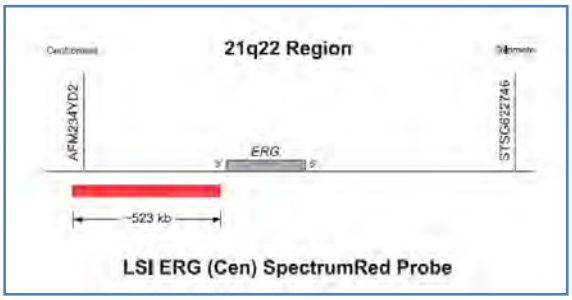
Trademarks

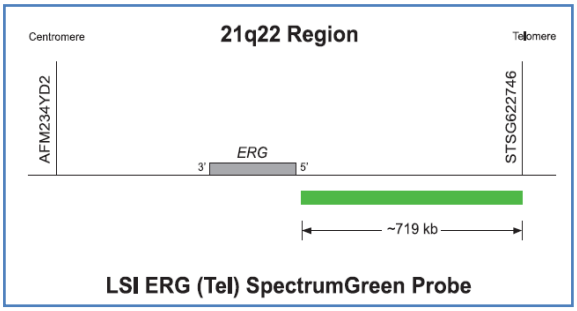
The information provided is accurate as of June 2013 based on the current information available. Our business is dynamic and we are continuously updating our catalog and websites adding new products, content, and information to service our customers better. As such, the information may have slight variations and may include typographical errors or inaccuracies due to these changes to our business. Please contact your customer service or sales person for the latest information.

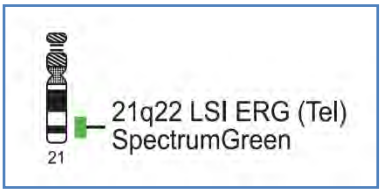
New Products

Oncology - Hematology

Vysis LSI ERG (Cen) SpectrumRed Probe (07N69-020) and Vysis LSI ERG (Tel) SpectrumGreen Probe (07N70-020)



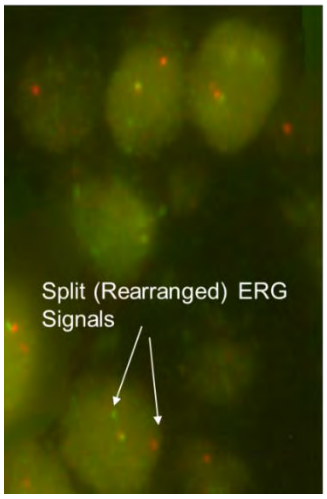


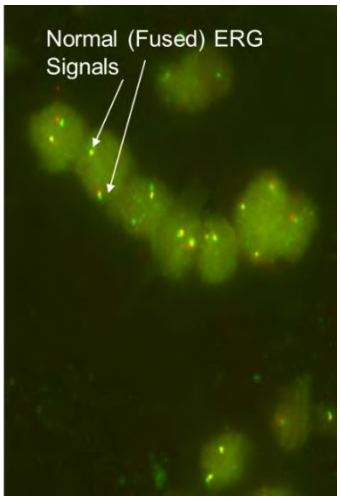


Vysis LSI ERG (Cen) SpectrumRed is a fluorescence in situ hybridization (FISH) assay for the identification of the centromeric part (3' of gene) of the 21q22 of the ERG gene locus

Vysis LSI ERG (Tel) SpectrumGreen is a fluorescence in situ hybridization (FISH) assay for the identification of the telomeric part (5' of gene) of the 21q22 of the ERG gene locus

Results of Hybridization
In a normal cell, the expected result is 2F signals. In an abnormal cell the expected result is 1G1R1F.



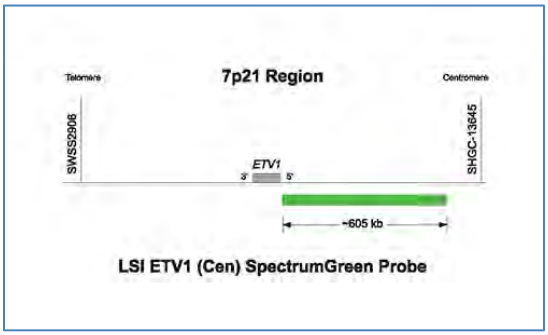


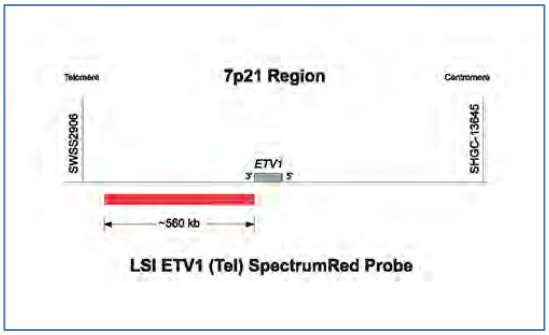
PRODUCT	QUANTITY	ORDER #	GTIN
Vysis LSI ERG (Cen) SpectrumRed Probe	20 µL	07N69-020	00884999036475
Vysis LSI ERG (Tel) SpectrumGreen Probe	20 µL	07N70-020	00884999036468

New Products

Oncology – Solid Tumor Probes

Vysis LSI ETV1 (Cen) SpectrumGreen Probe (07N71-020) and Vysis LSI ETV1 (Tel) SpectrumRed Probe (07N72-020)





Vysis LSI ETV1 (Cen) SpectrumGreen is a fluorescence in situ hybridization (FISH) assay for the identification of the centromeric part (3' of gene) of the 7p21 region of the ETV1 gene locus

Vysis LSI ETV1 (Tel) SpectrumRed is a fluorescence in situ hybridization (FISH) assay for the identification of the telomeric part (5' of gene) of the 7p21 region of the ERG gene locus

Results of Hybridization (When probes combined)

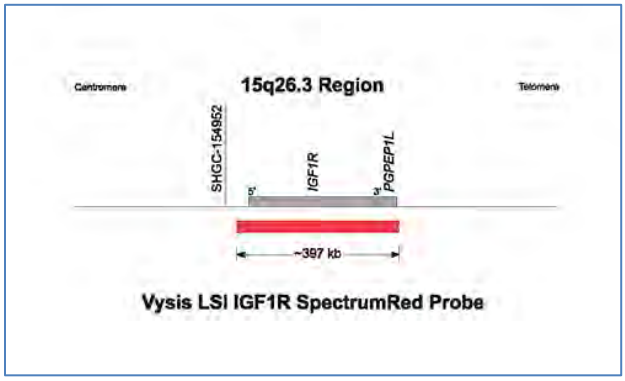
In a normal cell, the expected result is 2F signals. In an abnormal cell the expected result is 1G1R1F.

Ordering Information	Quantity	Order No.
Vysis LSI ETV1 (Cen) SpectrumGreen Probe	20µL	07N71-020
Vysis LSI ETV1 (Tel) SpectrumRed Probe	20µL	07N72-020

New Products

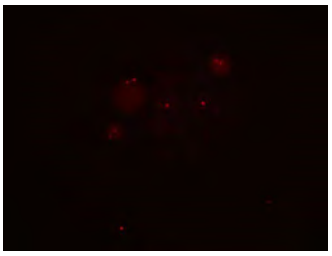
Oncology – Solid Tumor Probes

Vysis LSI IGF1R SpectrumRed Probe



Vysis LSI IGF1R SpectrumRed is a fluorescence in situ hybridization (FISH) assay for the identification of the 15q26.3 region of the IFR1R gene locus

Results of Hybridization



NORMAL

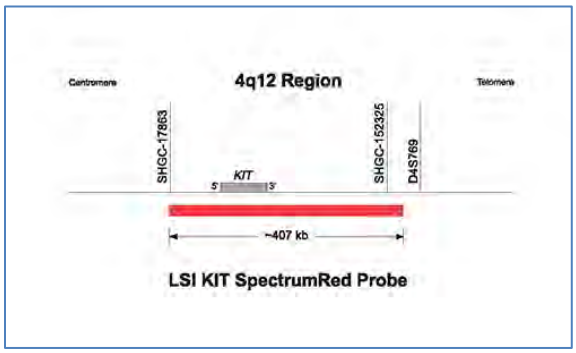
Cell hybridization using the Vysis LSI IGF1R SpectrumRed Probe.

Ordering Information	Quantity	Order No.
Vysis LSI IGF1R SpectrumRed Probe	20µL	06N68-001

New Products

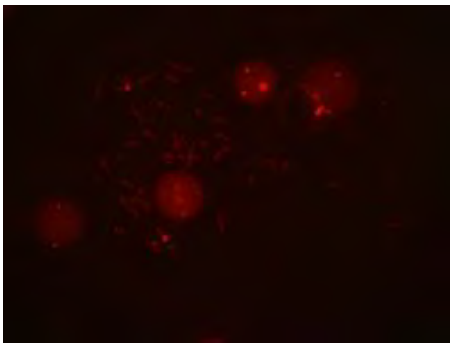
Oncology - Hematology

Vysis LSI KIT SpectrumRed Probe



Vysis LSI KIT SpectrumRed is a fluorescence in situ hybridization (FISH) assay for the identification of the 4q12 region containing the KIT gene locus.

Results of Hybridization



NORMAL

Normal diploid nuclei or metaphase chromosome sets are expected to exhibit two red fluorescent KIT signals, which correspond to two target loci on chromosome homologues to which the KIT fluorescent probe is bound: 4q12. A chromosome set that has an extra copy (copies) of KIT (4q12) will exhibit more than two red fluorescent signals.

Ordering Information	Quantity	Order No.
Vysis LSI KIT SpectrumRed Probe	20µl	06N71-001