NOTHING
IS SIMPLE
IN ONCOLOGY.

NOTHING BUT THIS.

Idylla™ A revolutionary, fully automated system that makes molecular testing convenient and exceptionally fast. Suitable for any lab.

BIOCARTIS

BIOCARTIS' MISSION
IS TO OFFER **RAPID & EASY**
MOLECULAR DIAGNOSTIC SOLUTIONS
AIMED AT ENABLING
FASTER & MORE ACCURATE
TREATMENT DECISIONS FOR ONCOLOGY
PATIENTS ACROSS THE GLOBE.

THE NEED FOR IMPROVED, STANDARDIZED AND FAST DIAGNOSTICS

Cancer can hit anyone at any time and treatment remains a real challenge. Because cancer doesn't follow rules. It fights back against therapies. It adapts. It changes its path. It does whatever it can to stay ahead of us.

At the advanced edge of oncology, **rapid access** to **accurate data** about relevant cancer mutations and treatment resistance is vital and creates the opportunity for early disease interception[1,2] reducing the anxiety while waiting for results and the time before starting the best possible treatment.

Current technologies in molecular oncology are complex, require a lot of hands-on time and are often difficult to implement in the local laboratory. As a consequence, most laboratories do not perform molecular tests in-house, but send them out to specialized centers, where samples are batched in order to optimize costs.[3–5]

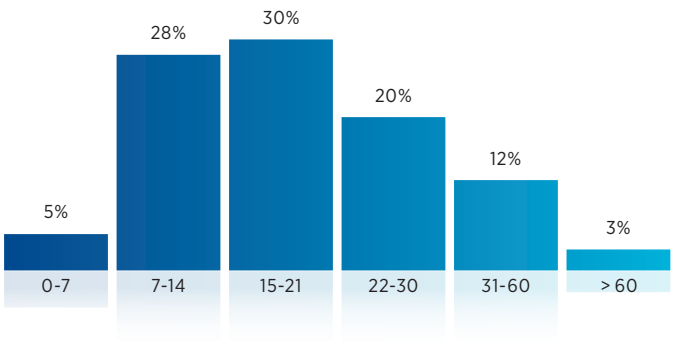
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

THE NEED FOR A RAPID TREATMENT INITIATION RESPONSE TOWARDS PATIENTS

Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates.[6-10] Timely detection of biomarkers therefore is very important.

Today, turnaround times of reference technologies are on average 18 days, with 14% of patients waiting longer than a month to be able to start treatment. Ninety-five percent of the patients have to wait more than a week in order to receive the biomarker results.[11]

This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.



TOTAL TURNAROUND TIME OF REFERENCE TECHNOLOGIES

IDYLLA™, THE NEXT LEVEL IN DISEASE INTERCEPTION

Idylla™, a **fully automated**, sample-to-result PCR based **molecular diagnostics** system, provides **same-day** results enabling physicians to make **timely decisions** on patients' therapy.

Idylla™ can be used with **multiple sample types**, including **solid** and **liquid biopsies**. This flexibility allows use of the system for **diagnostic**, **research**, and potentially future **monitoring** applications.

Idylla™, with its **compact scalable design** and **outstanding ease of use**, overcomes the traditional barriers of molecular diagnostics, allowing it to be used in virtually **any laboratory setting**.

IDYLLA™ IS THE FIRST AND ONLY MOLECULAR DIAGNOSTIC SYSTEM THAT COMBINES

FAST RESULTS
- < 3 minutes hands-on time
- Short turnaround time from 90 to 180 minutes

ACCURATE RESULTS
- High sensitivity
- Highly standardized technology
- Contamination-controlled design

ACCESSIBLE
- Access on demand - no need for pre-processing or batching

MULTIPLEXING CAPABILITY
- Detection of up to 51 relevant mutations in one cartridge
- Multiple genes and loci detection in one cartridge

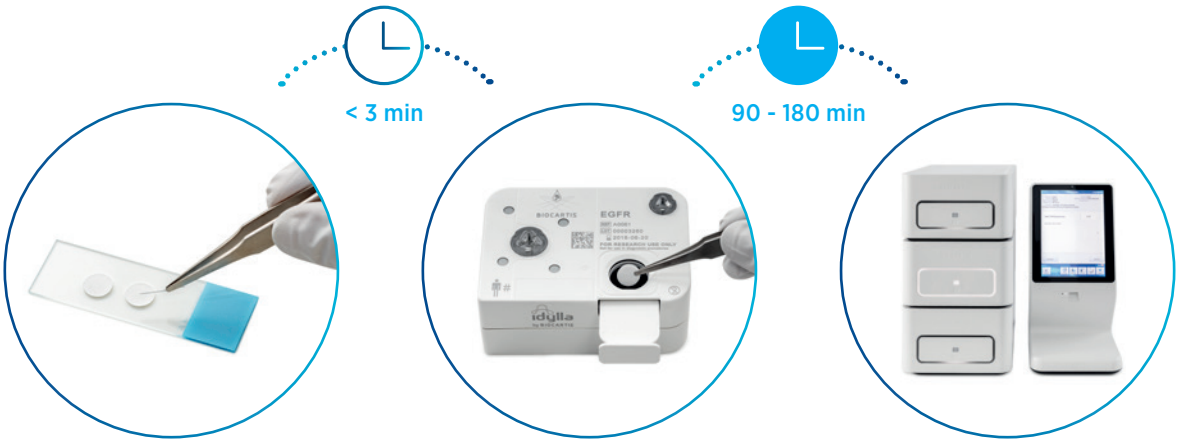
EASE OF USE
- Fully automated sample-to-result process
- Walk-away system (no need for any intervention during the automatic process)
- All reagents integrated in a single cartridge
- Storage and shipment at room temperature

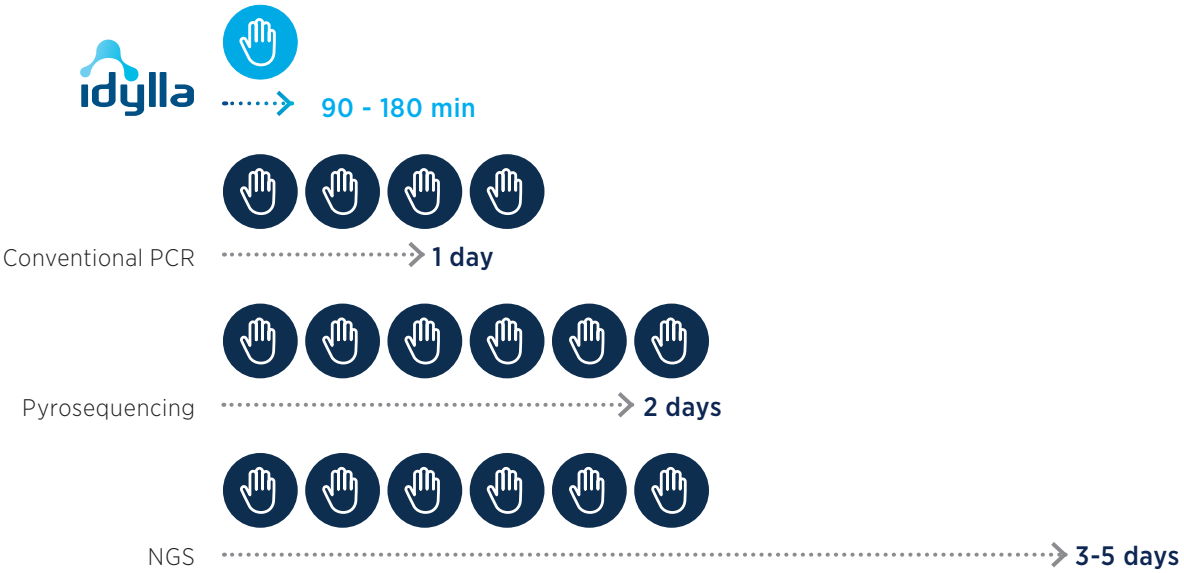
SAMPLE VERSATILITY
- For solid and liquid biopsy

CONNECTIVITY
- Remote assistance, monitoring and upgrading
- Bi-directional LIS

THE REVOLUTIONARY IDYLLA™ WORKFLOW

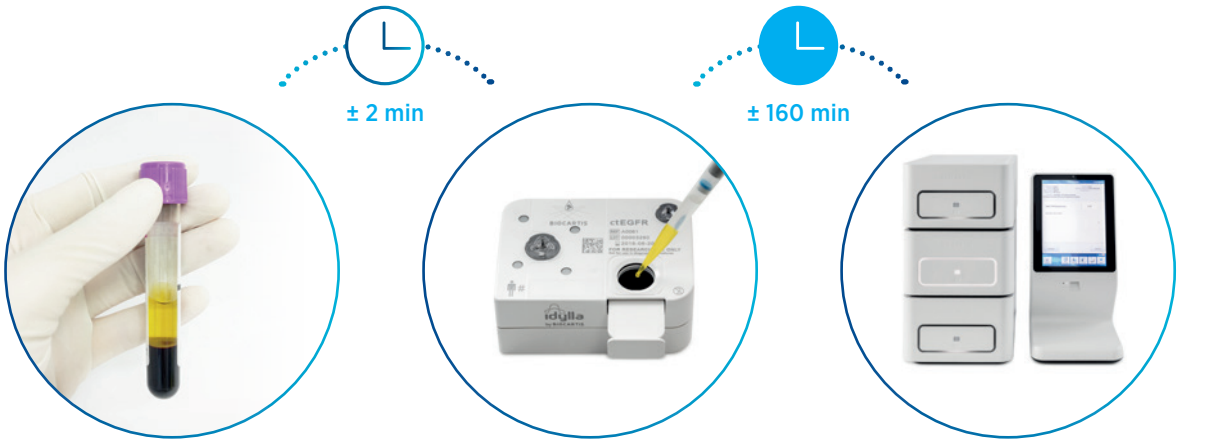
FFPE WORKFLOW

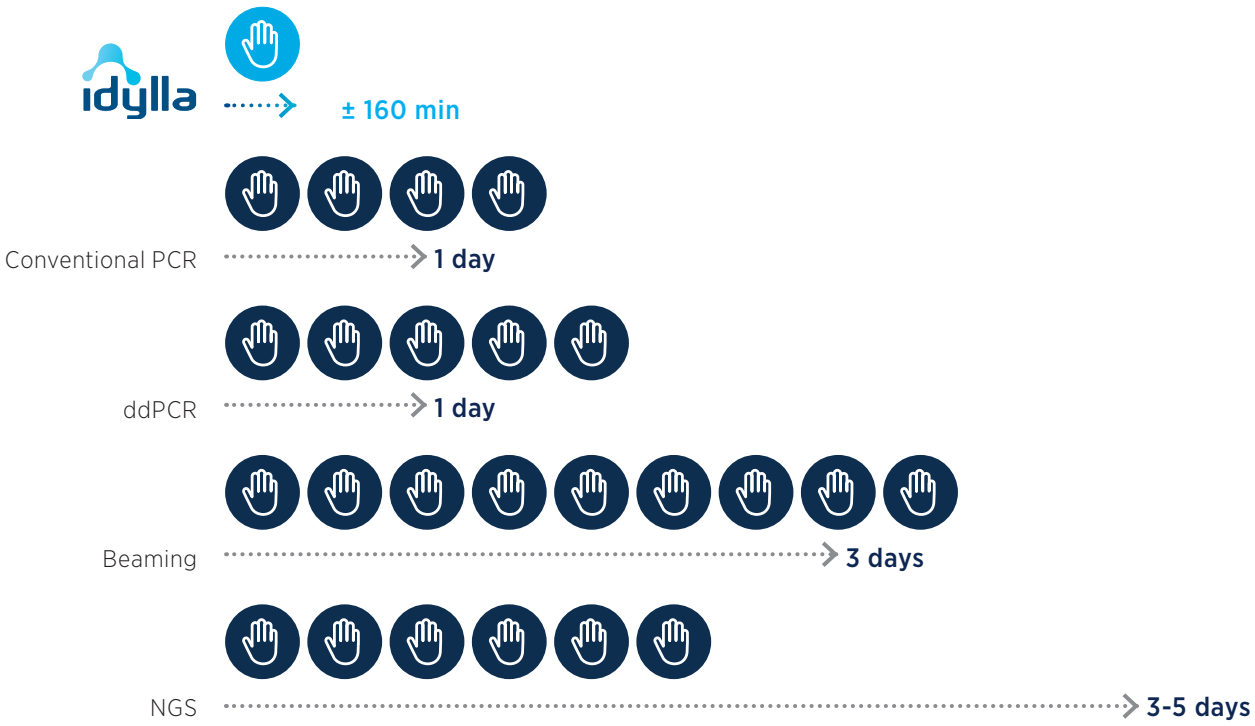




The Idylla™ System in combination with the Idylla™ Molecular Oncology Assays differs from other technologies in its outstanding **ease of use**, leading to an unsurpassed level of **standardization**, and its **short turnaround time**, allowing immediate access to the most appropriate therapy.

LIQUID BIOPSY WORKFLOW





INSTRUMENTS AND CONSUMABLES

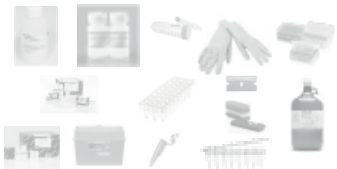
idylla

INSTRUMENTS	
CONSUMABLES	
LAB INFRASTRUCTURE (# OF ROOMS)	1

OTHER RT-PCR

INSTRUMENTS	
CONSUMABLES	
LAB INFRASTRUCTURE (# OF ROOMS)	3

PYROSEQUENCING

INSTRUMENTS	
CONSUMABLES	
LAB INFRASTRUCTURE (# OF ROOMS)	4

NEXT GENERATION SEQUENCING

INSTRUMENTS	
CONSUMABLES	
LAB INFRASTRUCTURE (# OF ROOMS)	4

CURRENT ONCOLOGY ASSAYS

FFPE IN - REPORT OUT

Diagnostic products (CE IVD)

Idylla™ BRAF Mutation Test
Idylla™ KRAS Mutation Test
Idylla™ NRAS-BRAF Mutation Test
Idylla™ EGFR Mutation Test
Idylla™ MSI Test
Idylla™ GeneFusion Panel

Research products (RUO)*

Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay
Idylla™ GeneFusion Assay
Idylla™ IDH1-2 Mutation Assay Kit

PLASMA IN - REPORT OUT

Research products (RUO)*

Idylla™ ctKRAS Mutation Assay
Idylla™ ctEGFR Mutation Assay
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay

* Research Use Only (RUO), not for use in diagnostic procedures

EGFR ctEGFR

IDYLLA™ EGFR MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*
Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types. 85% of lung cancers are non-small cell lung cancers (NSCLC), of which histologically adenocarcinoma is the most prevalent.

EGFR mutations are mainly observed in lung cancer. *EGFR* mutation testing in exons 18-21 is recommended in all patients with advanced NSCLC of a non-squamous subtype. Activating mutations in the *EGFR* gene have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.[8,9] Exon 19 deletion and exon 21 (L858R, L861), exon 18 (G719X), and exon 20 (S768I) mutations are associated with sensitivity to TKI's. Exon 20 insertion mutation may predict resistance to TKI's. EGFR T790M mutation is the main indicator of the patient's resistance to TKI therapy and has been reported in about 55% of patients with disease progression after initial response to 1st or 2nd generation TKI's.[8,9]

The prevalence of *EGFR* mutations in NSCLC adenocarcinomas is 10-15% of Western and up to 50% of Asian patients. Sensitizing *EGFR* mutations are predictive for response to *EGFR* tyrosine kinase inhibitors.[8,9,12]

*Idylla™ EGFR Mutation Test is validated for metastatic NSCLC

DIAGNOSTIC PRODUCT

Idylla™ **EGFR** Mutation Test (CE IVD)

EGFR

Diagnostic use

approx. 150 min — sample-to-result

< 2 min — hands-on time

51 — mutations in exons 18, 19, 20, 21

FFPE

Directly on 1 FFPE tissue section (5 µm) from **metastatic non-small-cell lung cancer**

Qualitative genotype call + Cq values

Mutation detection for **treatment assessment**

RESEARCH PRODUCT

Idylla™ **ctEGFR** Mutation Assay (RUO)

ctEGFR

Research Use Only, not for diagnostic use

approx. 160 min — sample-to-result

± 2 min — hands-on time

49 — mutations in exons 18, 19, 20, 21

plasma

Directly on 2 ml plasma

Qualitative genotype call + Cq values + Quality status

Applicable in NSCLC harboring EGFR mutations

"Today, EGFR testing is a cumbersome process and it often takes several weeks before results are analyzed. This may lead to the administration of anti-EGFR therapy as second-line agents, which is less efficient than their use in first-line therapy. The Idylla™ EGFR Mutation Test technology has the potential to change that: it is a cost-effective solution, ensuring reliable and fast detection of all relevant mutations"

Prof Giancarlo Troncone, University of Napoli Federico II, Naples

GeneFusion

IDYLLA™ GENEFUSION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION

Gene rearrangements represent an important class of somatic alterations in cancer. Due to their inherent expression in tumor tissue alone, rearrangements involving ALK, ROS1, RET, MET exon 14 and NTRK1/2/3 have become important biomarkers for cancer diagnosis, prognosis, and targeted therapies.[13-15]

The Idylla™ GeneFusion Panel (IVD)* detects ALK, ROS1, RET & MET exon 14 rearrangements and the Idylla™ GeneFusion Assay (RUO) additionally detects NTRK1/2/3 rearrangements. Both assays use two different detection technologies. Specific detection of ALK, ROS1, RET and MET exon 14 rearrangements is combined with expression imbalance detection for ALK, ROS1 and RET (& NTRK1/2/3 in the Idylla™ GeneFusion Assay). Expression imbalance detects gene fusions, irrespective of the fusion partner, based on the 3' kinase overexpression caused by the partner gene. Expression imbalance results are indicative for the presence of a fusion and should be confirmed with another technology.

Discovery and further understanding of fusion genes across multiple cancer types like NSCLC, CRC, thyroid cancer, pediatric cancers, ... may in the future provide more effective therapies for cancer patients.

*Idylla™ GeneFusion Panel is validated for use in NSCLC

DIAGNOSTIC PRODUCT

Idylla™ **GeneFusion** Panel (CE-IVD) GeneFusion

Diagnostic use

approx. 180 min sample-to-result

< 3 min hands-on time

ALK, ROS1, RET & MET EXON 14 SKIPPING

FFPE

Directly on 1-3 FFPE tissue sections (5-10 µm) from NSCLC

Qualitative genotype call for every biomarker

Fusion detection in NSCLC

RESEARCH PRODUCT

Idylla™ **GeneFusion** Assay (RUO) GeneFusion

Research Use Only, not for diagnostic use

approx. 180 min sample-to-result

< 3 min hands-on time

ALK, ROS1, RET, NTRK1/2/3 REARRANGEMENTS & MET EXON 14 SKIPPING

FFPE

Directly on 1-3 FFPE tissue sections (5-10 µm)

Qualitative genotype call for every biomarker

Fusion detection applicable in multiple cancer types

KRAS ctKRAS

IDYLLA™ KRAS MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *RAS* genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.[16] Cancers in which *KRAS* mutations are observed include: colorectal cancer, lung cancer and pancreatic cancer.

According to ESMO[6], NCCN[17], ASCO[18] and CAP/AMP/ASCO guidelines[19], genotyping of clinically actionable mutations at a sensitivity of 5% in *RAS* genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to certain anti-EGFR antibody therapies[6]. About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *KRAS* gene.[20] Several studies are ongoing to define the predictive impact of *KRAS* mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients.[21-23] Currently there is evidence that *KRAS* in lung cancer has a prognostic value, indicating poor survival for patients with NSCLC, compared to the absence of *KRAS* mutations.[8]

Using liquid biopsies for KRAS testing is minimally invasive, fast and easy to perform and provides an excellent solution to study the presence of KRAS mutations in different cancer types.

*Idylla™ KRAS Mutation Test is validated for use in mCRC

DIAGNOSTIC PRODUCT

Idylla™ **KRAS** Mutation Test (CE IVD)

KRAS

Diagnostic use

approx. 120 min — sample-to-result

< 2 min — hands-on time

21 — in codons 12, 13, 59, 61, 117, 146 — mutations

FFPE

Directly on FFPE tissue sections (5-10 µm) from **metastatic colorectal cancer**

Qualitative genotype call

Mutation detection for **baseline treatment**

RESEARCH PRODUCT

Idylla™ **ctKRAS** Mutation Assay (RUO)

ctKRAS

Research Use Only, not for diagnostic use

approx. 130 min — sample-to-result

< 1 min — hands-on time

21 — in codons 12, 13, 59, 61, 117, 146 — mutations

plasma

Directly on 1 ml plasma

Qualitative genotype call + Cq values

Applicable in multiple cancers harboring KRAS mutations

Beatriz Bellosillo
Laboratori de Biologia Molecular, Hospital del Mar, Barcelona

"Idylla™ allows very quick results with little hands-on time"

NRAS-BRAF ctNRAS3

IDYLLA™ NRAS MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *RAS* genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.[16] Cancers in which *NRAS* mutations are observed include colorectal, lung, thyroid cancers and melanoma.

According to ESMO[6], NCCN[17], ASCO[18] and the CAP/AMP/ASCO guidelines[19], genotyping of clinically actionable mutations at a sensitivity of 5% in *RAS* genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to certain anti-EGFR antibody therapies.[6] About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *NRAS* gene.[20] In metastatic colorectal cancer *BRAF* mutation status should be assessed alongside the assessment of tumor *RAS* mutational status for prognostic assessment (the presence of a *BRAF* mutation indicates poor prognosis). Using liquid biopsies for *NRAS* testing is minimally invasive, fast and easy to perform and provides an excellent solution to study these mutations in different cancer types and lesions. Recent research data[24,25] suggest that in about 16% of patients, mutations may develop in codon 492 of the *EGFR* gene as a mechanism of resistance, to the anti-EGFR antibody therapies such as cetuximab.

*Idylla™ NRAS-BRAF Mutation Test is validated for use in mCRC

NRAS-BRAF

DIAGNOSTIC PRODUCT

Idylla™ **NRAS-BRAF** Mutation Test (CE IVD)

Diagnostic use

- approx. 120 min — sample-to-result
- < 2 min — hands-on time
- 18 — in NRAS codons 12, 13, 59 61, 117, 146 — mutations
- 5 — in BRAF codon 600 — mutations
- FFPE — **Directly** on FFPE tissue sections (5-10µm) from **metastatic colorectal cancer**
- **Qualitative genotype call + Cq values**
- Mutation detection for **baseline treatment**

ctNRAS3

RESEARCH PRODUCT

Idylla™ **ctNRAS-BRAF-EGFR S492R** Mutation Assay (RUO)

Research Use Only, not for diagnostic use

- approx. 110 min — sample-to-result
- < 1 min — hands-on time
- 18 — in NRAS codons 12, 13, 59 61, 117, 146 — mutations
- 5 — in BRAF codon 600 — mutations
- 2 — in EGFR codon 492 — mutations
- **Directly** on 1 ml plasma
- **Semi-quantitative genotype call + Cq values**
- **Applicable in multiple cancers** harboring NRAS, BRAF or EGFR S492R mutations

MSI

IDYLLA™ MSI DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*
Microsatellite instability (MSI) is defined as a length variation of DNA repeat regions found in microsatellites or homopolymers. MSI is caused by deficiency of the DNA mismatch repair system (dMMR) resulting in a distinct accumulation of insertions and deletions in microsatellite and homopolymeric regions.[26]

MSI can be sporadic or hereditary. MSI-high (MSI-H) is detected in 15% of all colorectal cancers; 3% are associated with Lynch syndrome (LS), the other 12% have sporadic disease.[27]

Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types.[28]

In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%).[29]

Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch syndrome as well as for prognostic stratification and potential response to certain immunotherapies.[30-33]

Research studies have shown that MSI-H patients respond favorably to immune checkpoint inhibitors, and checkpoint blockade therapy has recently been incorporated into clinical care for gastrointestinal cancers.[34,35]

*Idylla™ MSI Test is only validated for CRC

DIAGNOSTIC PRODUCT

Idylla™ **MSI** Test (CE IVD)

MSI

Diagnostic use

approx. 150 min
sample-to-result

< 2 min
hands-on time

7 novel MSI Bio-markers*

FFPE

Directly on FFPE tissue sections (5-10 µm) from colorectal cancer. **No need** for **paired normal tissue sections**

Qualitative MSI call + MSI score

Determination of **MSI status** in **colorectal cancer**

*ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2

"We are delighted with the performance of the Idylla™ MSI Test providing high quality results from minimal amount of tissue. The ease of use allows even laboratories with minimal histopathology experience to perform MSI testing in-house."

Sarah L. McCarron
Cancer Molecular Diagnostics,
St. James' Hospital, Dublin, Ireland

BRAF

IDYLLA™ BRAF MUTATION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*
Activating mutations in the *BRAF* gene are observed in about 8% of all cancers[36] and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.

Cancers in which *BRAF* mutations are observed include: melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer.

BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the *BRAF* gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy.[37] In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor *RAS* mutational status for prognostic assessment (the presence of a *BRAF* mutation indicates poor prognosis). The prevalence of *BRAF* in mCRC is about 8-15%.[6]

*Idylla™ BRAF Mutation Test is validated for use in metastatic melanoma

DIAGNOSTIC PRODUCT

Idylla™ **BRAF** Mutation Test (CE IVD)

BRAF

Diagnostic use

approx. 90 min
sample-to-result

< 2 min
hands-on time

7 in codon 600
mutations

FFPE

Directly on FFPE tissue sections (5-10 µm) from **metastatic melanoma**

Qualitative genotype call

Mutation detection for **baseline treatment**

"The Idylla™ system has the potential to allow the start of targeted therapy within a time window of less than 24 hours following the diagnosis of metastasis, thereby saving precious time"

Prof. B. Neyns, M.D., Ph.D
Medical Oncology,
UZ Brussels, Belgium

IDYLLA™ CONNECT
ENGAGE IN THE FUTURE

IDYLLA™ EXPLORE

ADVANCED SERVICES

ADVANCED SERVICES TO ENSURE CONTINUITY IN YOUR LABORATORY WORKFLOW

AUTOMATIC SOFTWARE UPDATES

New releases of Assay and Console Software are sent to your Idylla™ Console and can be installed with a single touch on the screen.

IMMEDIATE AND REMOTE SERVICE AND SUPPORT

Idylla™ System parameters and error logs can be analyzed at anytime and anywhere to ensure swift actions and solutions.

MORE INSIGHT INTO YOUR DATA WITH IDYLLA™ EXPLORE

Get connected and enjoy **the advantages of Idylla™ Explore,**
a web-based application that allows you to analyze your data by providing

- Visualization of PCR curves from Idylla™ Test Results
- Cq values per target
- Direct Access to Console result reports

Idylla™ Explore can be accessed anywhere and anytime from your PC or tablet through the following link: **https://idyllaexplore.biocartis.com**

Subscribe today and **join the Idylla™ Explore community**
by sending an email to **explore@biocartis.com**

SAFE & SECURED DATAFLOW

ZOOM IN

IDYLLA™: NOTHING IS SIMPLE IN ONCOLOGY. NOTHING BUT THIS.

There's a clear need for improved, standardized and fast diagnostics that allow faster initiation of targeted therapy for cancer patients.

Idylla™, Biocartis' fully automated molecular diagnostics system, is the first and only molecular diagnostic system that combines unsurpassed ease of use, speed and accuracy on multiple sample types. With its compact, scalable design and outstanding ease of use, Idylla™ overcomes the traditional barriers of molecular diagnostics, allowing it to be used in virtually any laboratory setting.

And by providing same-day-results, Idylla™ enables physicians to make timely decisions on patients' therapy.

IDYLLA™ ORDER INFORMATION

DIAGNOSTIC PRODUCTS (CE-IVD)

Idylla™ BRAF Mutation Test	6 cartridges/box	Catalog# A0010/6
Idylla™ KRAS Mutation Test	6 cartridges/box	Catalog# A0020/6
Idylla™ NRAS-BRAF Mutation Test	6 cartridges/box	Catalog# A0030/6
Idylla™ EGFR Mutation Test	6 cartridges/box	Catalog# A0060/6
Idylla™ MSI Test	6 cartridges/box	Catalog# A0100/6
Idylla™ GeneFusion Panel	6 cartridges/box	Catalog# A0120/6

RESEARCH PRODUCTS (RUO)

Idylla™ BRAF Mutation Assay	6 cartridges/box	Catalog# A0011/6
Idylla™ KRAS Mutation Assay	6 cartridges/box	Catalog# A0021/6
Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0031/6
Idylla™ EGFR Mutation Assay	6 cartridges/box	Catalog# A0061/6
Idylla™ ctKRAS Mutation Assay	6 cartridges/box	Catalog# A0081/6
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0091/6
Idylla™ MSI Assay	6 cartridges/box	Catalog# A0101/6
Idylla™ ctEGFR Mutation Assay	6 cartridges/box	Catalog# A0111/6
Idylla™ GeneFusion Assay	6 cartridges/box	Catalog# A0121/6
Idylla™ IDH1-2 Mutation Assay (Vial)*	6 vials/box	Catalog# A0181/6
Idylla™ DNA Cartridge*	6 cartridges/box	Catalog# A0191/6

* The Idylla™ IDH1-2 Mutation Assay Kit consists of a Cartridge and a Vial.

PLATFORM (CE-IVD)

Idylla™ Instrument	1 unit	Catalog# P0010
Idylla™ Console	1 unit	Catalog# P1010

customerservice@biocartis.com

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Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc.

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