Specialty Immunoassay Automation
IDS - iSYS Multi-Discipline Automated System
Our Current Endocrinology Clinical Areas

Bone Metabolism

Throughout life, old bone is constantly removed (resorption) and replaced by new bone (formation). This continual process is essential for the maintenance of healthy bone mass and micro-architecture. The IDS complete bone offering provides the tools for research and routine clinical laboratories, to provide highly accurate and reliable results.

Calcium Metabolism

Vitamin D deficiency results in abnormalities in calcium, phosphorus and bone metabolism and affects one billion people worldwide across all ethnicities and age groups. Our comprehensive calcium metabolism panel enables laboratories to measure Vitamin D deficiencies in line with the Clinical Practice Guidelines set by the Endocrine Society.

Hypertension

Hypertension is one of the most common chronic diseases and a risk factor for cardiovascular morbidity and mortality. 10% of hypertensive patients suffer from endocrine hypertension such as Primary aldosteronism and Cushing’s syndrome. The IDS fully automated hypertension panel provides laboratories with simple and fast quantitative results.

Chronic Kidney Disease-Mineral Bone Disorder

Is a systematic disorder of mineral and bone metabolism due to CKD manifested by either one or a combination of the following: a) Abnormalities of calcium, phosphorus, PTH, or vitamin D metabolism; b) Abnormalities in bone turnover, mineralization, volume, linear growth or strength; c) Vascular or other soft tissue calcification. Building on our expertise in calcium and bone testing, IDS provides a CKD-MBD panel which comprises of bone and calcium metabolism markers.

Growth

Accurate determination of circulating GH, IGF-I and IGFBP-3 concentrations is crucial in the diagnosis and monitoring of growth disorders such as acromegaly and growth hormone deficiency. The IDS Growth panel can be used to identify these diseases and conditions, evaluate pituitary function and monitor the effectiveness of growth hormone (GH) treatment.

Fertility

Approximately 1 in 8 couples have trouble getting pregnant or sustaining pregnancy. As part of a diagnosis of infertility, doctors will perform physical examinations and discuss the health of both partners. Following which a series of additional tests, including blood tests measuring levels of specific hormones may be required. The IDS Fertility panel was launched in April 2016, with subsequent launches to follow in due course.

References:
The IDS-iSYS Multi-Discipline Automated System:

A unique, efficient concept

The IDS-iSYS is a unique instrument based on chemiluminescence and absorbency technology. As a fully-automated solution, the IDS-iSYS provides quality and efficiency throughout the complete testing process.

**Efficiency**
- A complete instrument solution based on simplicity and reliability
- A fully automated walk-away system
- Compact, bench-top design
- Continuous loading with batch, random, and STAT flexibility
- Easy operation with auto start-up and shut-down
- Ready-to-use reagents
- On-board refrigeration of reagents

**Quality**
- 20 years of IVD medical device manufacturing
- Excellent correlation against gold-standard methods
- Independent cuvette processing
- Clot system to prevent measurement interruption
- Decontamination concept, preventing sample carry-over
- Samples, reagents and consumable lot traceability
The IDS-iSYS: Automation to Enhance Performance and Productivity

Reagent Module
- Ready-to-use barcoded reagent cartridges
- Holds up to 15 different immunoassay cartridges
- On-board controlled stable temperature (12-15 °C)
- Continuous loading and unloading

Sample Loader
- Up to 120 samples (6 racks of 20 samples each)
- Supports multiple tube sizes
- Paediatric micro-tubes capability

Assay Processing Module
- Individual cuvettes
- Acridinium ester, magnetic particle chemiluminescence detection
- Enzyme activity measurement capability (Spectrophotometer with LED technology)
- Two point calibration with stored master curve
- Enhanced throughput with 4 independent washers

Sample Handling
- Liquid level sensing & iCM technology
- Decontamination process prevents sample carry-over
- Wide range of sample volumes
- Sample mixed in cuvette
- On-board sample pre-treatment
**Design Innovations**
Enhancing Performance and Productivity

1. The IDS-iSYS Intelligent clot management “iCM” is a robust concept to prevent measurement interruption and enhance your productivity via maximised hands on time.
   - Detect clot down to 4μL of sample volume, ideal for paediatric samples
   - Real time detection. All pipetting and dispensing volumes are checked (sample cuvette, reagent, rinsing)
   - Managed by intelligent software, notifies the operator, trace and flag sample result
   - No extra maintenance

2. The IDS-iSYS active carry-over prevention management is an effective decontamination concept without extra maintenance. Included is a unique High Pressure Rinsing and a dedicated cleaning solution.
   - High pressure rinsing: 4-5 bars pulse rinsing into the rinsing well
   - Optimised rinsing speed for liquid interaction and rinsing
   - Automatic maintenance management (needle and washers)
   - Step wise aspiration (optimised liquid interaction)

3. The easy handling is based on a real walk-away system and continuous loading. Immediate random access for samples, reagents and ancillary product during a run.
   - Automatic start-up and shut down. Always ready to use
   - Reagent & ancillary product ready to use. Limited hands on time
   - Uncompromised productivity
Innovation In Software:
Simplicity and Traceability

Software Interface

- Real-time level detection monitoring for consumables and reagents
- Guided assay calibration and maintenance schedules
- Ethernet connection for remote diagnostics
- Bi-directional L.I.S. compatibility
- Calibration and QC monitoring with complete traceability

Software Management

- Total traceability on one screen. Simple monitoring of results, reagents and consumables with one click of your mouse
- Total L.I.S. capability: Results, reagent lots, washer use, QC, messages, comments, order new run giving a total overview for control and validation
- Automatic re-run and/or dilution. Intelligent results management and ease of use
- Rapid servicing by Webex remote control

Commitment to innovation

pioneering research
and development
### Calcium Metabolism

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Product Code</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IDS-iSYS 25 Vit D&lt;sup&gt;®&lt;/sup&gt;</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2500</td>
<td>HC/FDA</td>
</tr>
<tr>
<td></td>
<td>Control 2 concentration levels</td>
<td>IS-2530</td>
<td></td>
</tr>
<tr>
<td><strong>IDS-iSYS 1,25-Dihydroxy Vitamin D</strong></td>
<td>Reagent 100 test cartridge, calibrators &amp; immunoextraction included</td>
<td>IS-2400</td>
<td>HC/FDA</td>
</tr>
<tr>
<td></td>
<td>Control Assay and extraction controls, 2 concentration levels</td>
<td>IS-2430</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diluent A 1 vial of 12 mL ready to use</td>
<td>IS-10DA</td>
<td></td>
</tr>
<tr>
<td><strong>IDS-iSYS 1,25 VitD&lt;sup&gt;®&lt;/sup&gt;</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2000</td>
<td>HC</td>
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<td>Control 2 concentration levels</td>
<td>IS-2030</td>
<td>HC/FDA</td>
</tr>
<tr>
<td></td>
<td>Diluent A 1 vial of 12 mL ready to use</td>
<td>IS-10DA</td>
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<tr>
<td><strong>IDS-iSYS Intact PTH</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-3200</td>
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<tr>
<td></td>
<td>Control 3 concentration levels</td>
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### Bone Metabolism

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<tr>
<td><strong>IDS-iSYS CTX-I (CrossLaps&lt;sup&gt;®&lt;/sup&gt;)</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-3000</td>
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<td>Control 3 concentration levels</td>
<td>IS-3030</td>
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<td><strong>IDS-iSYS Intact PINP</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-4000</td>
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<td>Control 3 concentration levels</td>
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<tr>
<td><strong>IDS-iSYS N-MID&lt;sup&gt;®&lt;/sup&gt; Osteocalcin</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2900</td>
<td>HC</td>
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<td>Control 3 concentration levels</td>
<td>IS-2930</td>
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<tr>
<td><strong>IDS-iSYS Ostase&lt;sup&gt;®&lt;/sup&gt; BAP</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2800</td>
<td>HC</td>
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<td>Control 3 concentration levels</td>
<td>IS-2830</td>
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<tr>
<td><strong>IDS-iSYS TRAcP 5b (BoneTRAP&lt;sup&gt;®&lt;/sup&gt;)</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-4100</td>
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### Hypertension

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<tbody>
<tr>
<td>IDS-iSYS Direct Renin</td>
<td>Reagent: 100 test cartridge, calibrators included</td>
<td>IS-3400</td>
<td>HC/FDA</td>
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<td>Control: 3 concentration levels</td>
<td>IS-3430</td>
<td></td>
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<tr>
<td></td>
<td>Diluent B: 1 vial of 12 mL ready to use</td>
<td>IS-10DB</td>
<td>HC/FDA</td>
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### Bone Metabolism

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<th>Description</th>
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<tbody>
<tr>
<td>IDS-iSYS PTH (1-34)</td>
<td>Reagent: 100 test cartridge, calibrators included</td>
<td>IS-3600</td>
<td>Research Use Only</td>
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<td>Control: 3 concentration levels</td>
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### Growth

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<th>Product</th>
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<tbody>
<tr>
<td>IDS-iSYS Human Growth Hormone (hGH)</td>
<td>Reagent: 100 test cartridge, calibrators included</td>
<td>IS-3700</td>
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<td>External Supplier</td>
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<tr>
<td>IDS-iSYS Insulin-like Growth Factor-I (IGF-I)</td>
<td>Reagent: 100 test cartridge, calibrators included</td>
<td>IS-3900</td>
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<td>Control: 3 concentration levels</td>
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<tr>
<td>IDS-iSYS Insulin-like Growth Factor Binding Protein-3 (IGFBP-3)</td>
<td>Reagent: 100 test cartridge, calibrators included</td>
<td>IS-4400</td>
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<td>Control: 3 concentration levels</td>
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## Chronic Kidney Disease – Mineral Bone Disorder (CKD-MBD)

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<tr>
<td><strong>IDS-iSYS 25 Vit D&lt;sup&gt;8&lt;/sup&gt;</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2500</td>
<td>HC/FDA</td>
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<td>Control 2 concentration levels</td>
<td>IS-2530</td>
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</tr>
<tr>
<td><strong>IDS-iSYS 1,25-Dihydroxy Vitamin D</strong></td>
<td>Reagent 100 test cartridge, calibrators included &amp; immunoextraction included</td>
<td>IS-2400</td>
<td>HC/FDA</td>
</tr>
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<td></td>
<td>Control Assay and extraction controls, 2 concentration levels</td>
<td>IS-2430</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diluent A 1 vial of 12 mL ready to use</td>
<td>IS-10DA</td>
<td></td>
</tr>
<tr>
<td><strong>IDS-iSYS 1,25 VitDX&lt;sup&gt;2&lt;/sup&gt;</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-2000</td>
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<td>Diluent A 1 vial of 12 mL ready to use</td>
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<td>HC/FDA</td>
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<tr>
<td><strong>IDS-iSYS Intact PINP</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-4000</td>
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<td>IS-2800</td>
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<td></td>
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<tr>
<td><strong>IDS-iSYS Intact PTH</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-3200</td>
<td>HC/FDA</td>
</tr>
<tr>
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<td>Control 3 concentration levels</td>
<td>IS-3230</td>
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<tr>
<td><strong>IDS-iSYS InaKtif MGP (dp-ucMGP)</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-4700</td>
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<tr>
<td></td>
<td>Control 3 concentration levels</td>
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</tr>
</tbody>
</table>

**KEY:** FDA = FDA Cleared / Listed | HC = Health Canada Cleared | Ostase<sup>®</sup> is a registered trademark of Hybritech Incorporated, a subsidiary of Beckman Coulter, Inc.
## Fertility

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>IDS-iSYS 17-OH Progesterone</strong></td>
<td>Reagent 100 test cartridge, calibrators included</td>
<td>IS-5100</td>
<td>HC/FDA</td>
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<tr>
<td></td>
<td>Control 3 concentration levels</td>
<td>IS-5130</td>
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</table>

| **IDS-iSYS Total Testosterone**  | Reagent 100 test cartridge, calibrators included | IS-5000      | HC           |
|                                  | Control 3 concentration levels                   | IS-5030      |              |

| **IDS-iSYS Free Testosterone**   | Reagent 100 test cartridge, calibrators included | IS-5300      | HC           |
|                                  | Control 3 concentration levels                   | IS-5330      |              |

## Consumables

<table>
<thead>
<tr>
<th>Product</th>
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</thead>
<tbody>
<tr>
<td><strong>IDS-iSYS Cartridge Check System (CSS)</strong></td>
<td></td>
<td>IS-6010</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>IDS-iSYS Cuvettes</strong></td>
<td>Pack of 960 cuvettes</td>
<td>IS-CC100</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>Sample Cups 500 μL</strong></td>
<td>0.5mL (1000 pieces)</td>
<td>IS-CSC105</td>
<td>HC/FDA</td>
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<tr>
<td><strong>IDS-iSYS Triggers Set</strong></td>
<td>2 x 250 mL (Sufficient for 1000 tests depending on priming)</td>
<td>IS-CT100</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>IDS-iSYS System Liquid (Syst.I)</strong></td>
<td>1 x 5 L (Sufficient for 4000 tests depending on assay protocol &amp; priming)</td>
<td>IS-CS100</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>IDS-iSYS Wash Solution (Wash S)</strong></td>
<td>1 x 10 L (Sufficient for 1500 tests depending on assay protocol &amp; priming)</td>
<td>IS-CW100</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>IDS-iSYS D-SORB Solution</strong></td>
<td>2 x 1 L (Stable on board up to expiration date)</td>
<td>IS-DS200</td>
<td>HC/FDA</td>
</tr>
<tr>
<td><strong>IDS-iSYS Cleaning Solution</strong></td>
<td>15 x 45 mL (Maintenance product solution, stable up to expiration date)</td>
<td>IS-HS100</td>
<td>N/A</td>
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</tbody>
</table>
IDS-iSYS
Instrument Specifications

System
- Multi-discipline Immunoassay System
- Stand-alone walk-away system

Throughput
- Random access
- Time to first result: < 25 minutes (assay dependent)
- Up to 120 tests/hour (assay dependent)
- > 600 results per day (assay dependent)

Immunoassay Detection

Luminometer
- Wavelengths: from 300 to 500 nm
- Linearity: Up to 10 million RLU

Spectrophotometer
- Spectrophotometer with LED technology
- Linearity: Up to 3 Abs.
- Bi-chromatic mode availability
- Light sources: multiple LEDs.

Samples
- Serum, plasma, urine or saliva
- Sampling from Primary Tubes, Secondary Tubes, Micro cups, paediatric tubes
- Default Sample tube library:
  Primary Tubes: 4.5 mL, 6 mL, 8.5 mL and 10 mL
  Secondary Tube: 5 mL
  Micro cups: 500 mL, 2 mL
- Further sample tubes can be easily configured
- 120 positions for samples, calibrators and controls
  (6 racks with 20 positions)
- Possibility of STAT sample at any position
- Positive sample tube identification from built-in automated barcode reader.
- Barcode types supported:
  Code 2/5, EAN/UPC, Code 39, Code 128 and Codabar
- On-board dilution and automatic pre-treatment

Reagent Module
- Load up to 15 different immunoassay tests simultaneously
- Integrated reader for automatic reading of reagent cartridge barcodes
- On-board storage: 12 - 15 °C during operation 8 - 10 °C in standby mode (configuration depending)

Sample Handling
- Single pipetting arm for samples and reagents
- Liquid level detection by capacitance (samples and reagents)
- Clot detection (by pressure transducer)
- Internal and external rinsing between each pipetting of sample
- Possibility of specific rinses using D-SORB Solution
- Preheating of sampling (reagents & samples)
- Sample volumes: from 4 μl to 300 μl (assay dependent)

Carousel
- Temperature regulated at 37°C ± 0.5°C
- 90 positions for disposable cuvettes
- Automatic cuvette supply by cuvette loader
- 4 Independent washers

Cuvette Loader
- Loader for 1 x cube of cuvettes
- 1 x cube contains 960 disposable cuvettes
- 960 cuvettes on board
- Preheated loader

Ancillary Reagents
- IDS-iSYS Liquid System (5 L)
- IDS-iSYS Wash solution (10 L)
- IDS-iSYS Triggers
- D-SORB Solution

Reader on system front face for barcode identification, cuvettes and ancillary reagents

Waste collection
- 10 litre container for liquid waste
- Used cuvettes disposed of in solid waste drawer

Graphic User Interface
- System access controlled via User Access Level management
- Continuous access to programming
- Full traceability: patient results, calibrations and controls
- Automatic calibration. QC management: up to 4 levels, analysis by Levey-Jennings and Westgard rules (configurable) Lot management of reagents, calibrators and controls by barcodes
- Reagent stability management
- Local storage of 5000 patient results (including traceability)
- Host Connection: Bi-directional interface via ASTM protocol

Operating System
- Windows XP Pro Service Pack 2
- Windows Vista Service Pack 1
- Windows 7

Dimensions
- System: L 105 x H 70 x W 75 cm
- Weight: 103 kg
- PC: L 60 x H 40 x W 50 cm

Power Supply
- Voltage: 100 – 240 V
- Frequency: 50 – 60 Hertz
- Maximum power consumed: 750 VA
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