In Focus

New Director International Sales and Marketing

Dr. Ingeborg Mühldorfer succeeds Dr. Jörg Ruppert in the export department

After successfully establishing Immundiagnostik’s export business in the past 4 years by exploring global markets for immundiagnostics and building relationships to distributors around the world, Dr. Jörg Ruppert left Immundiagnostik in July to pursue new professional opportunities. He is succeeded by Dr. Inge Mühldorfer who joined Immundiagnostik in April 2010 as head of scientific marketing.

Dr. Mühldorfer will continue to expand our global business activities, utilizing her extensive experience in the life science industry: From end of 2007 until March 2010 she held a staff position in the strategic management of Rentschler Biotechnologie. Her previous engagement in the pharmaceutical industry includes the development of anti-infective agents and biopharmaceuticals at Altana Pharma AG.

Dr. Mühldorfer will be supported by the export team, introducing Dr. Karl Florian Wintgens as international sales manager who will assume operative tasks and responsibilities. Gudrun Gutschalk and Claudia Wandesleben will provide – as previously – international customer service. "I am looking forward to fostering established relationships and to expanding Immundiagnostik’s international sales network by forging new business alliances with interested parties around the world", Dr. Mühldorfer is appreciating her new task. "Immundiagnostik is an attractive partner with its innovative, comprehensive product portfolio which is highly competitive in the international laboratory diagnostics market".

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**INNOVATIONS IN VITAMIN D ANALYSIS**

**D-Vital ID® now enables vitamin D diagnostics from capillary blood**

**Sampling kit delivers dried blood spots for vitamin D status analysis with the 25-OH Vitamin D ELISA**

Vitamin D is a routine parameter which is increasingly recognized as a key player in the pathogenesis of many diseases including cancer, diabetes, cardiovascular or autoimmune diseases. To facilitate preparation and shipping of blood samples, Immundiagnostik has developed the **D-Vital ID®** sampling kit for dried blood spots from capillary blood. This material can be mailed to a laboratory for analysis via conventional couriers without cooling. Vitamin D determination of the **D-Vital ID®** samples is exclusively coupled to Immundiagnostik’s 25-OH Vitamin D ELISA. This market-proven assay delivers reliable vitamin D data which are comparable in their diagnostic accuracy with reference methods such as HPLC or LC-MS/MS.

The **D-Vital ID®** complements Immundiagnostik’s prime quality vitamin D diagnostics portfolio with a product, which significantly simplifies preparation and shipping of blood samples, thus enabling a widespread and convenient monitoring of patients’ vitamin D status.

- **D-Vital ID® Dried blood spot sampling system (includes matrix, lancet & pipet) (DZ 9002)**
- **D-Vital ID® Dried blood spot matrix (DZ 9001)**

**ImmunoTube® LC-MS/MS Kit:**

**Exact vitamin D analysis due to superior sample preparation**

**1,25-(OH)2 vitamin D determination without ion suppression by interfering matrix components**

The determination of 1,25-(OH)2 vitamin D is challenging since its level in the circulation is very low and its extraction is inhibited by binding proteins and vitamin D metabolites. The sensitive and specific LC-MS/MS is therefore considered gold standard in routine diagnostics. However, data quality is to a high degree dependent on sample preparation.

Our kit extracts 1,25-(OH)2 vitamin D in a specific single-step affinity purification with the **ID ImmunoTube®** (s. flow chart to the right), thereby separating it from disturbing matrix components and isobaric interferences. This extraction is significantly more effective than a protein precipitation (s. figure below from Yuan et al., 2011: Rapid Commun Mass Spectrum 25: 1241-1249), enabling the detection of 1,25-(OH)2 vitamin D3 and D2 with high specificity and sensitivity and without ion suppression.

The **ImmunoTube® LC-MS/MS Kit** can be used on high-end instruments, e.g. from ThermoScientific, AB SCIEX or Waters. Before first use we recommend to optimize instrument calibrations with our **LC-MS/MS Tuning Kit**. In addition, all sample preparation components can be ordered separately as **ID ImmunoTube® Extraction Kit**.

These customized modules offer practical solutions for the determination of 1,25-(OH)2 vitamin D in clinical routine.

- **1,25-(OH)2 Vitamin D3/D2 ImmunoTube® LC-MS/MS Kit (KM1000)**
- **1,25-(OH)2 Vitamin D3/D2 LC-MS/MS Tuning Kit (KM1001)**
- **1,25-(OH)2 Vitamin D3/D2 LC-MS/MS Extraction Kit (KM1100)**
PRODUCT NEWS

**ADMAXpress ELISA - fast, easy, robust**

The quantitative determination of ADMA (asymmetric dimethyl arginine) as prognostic marker for heart attack and stroke is now fit for clinical routine: The new **ADMAXpress ELISA** is temperature robust, automatable, suitable for small sample volumes and delivers results in merely three hours. Due to its excellent correlation with LC-MS/MS (r=0.98) and the elimination of cross reactivity with other arginines, the direct, competitive ELISA is a reliable tool for the determination of ADMA in plasma and serum of cardiovascular risk patients.

- **ADMAXpress ELISA (K 7860)**

**PhiCal® Calprotectin ELISA Optimization**

The determination of calprotectin in stool is an established marker for intestinal inflammation which is used for primary diagnosis as well as for monitoring of inflammatory bowel diseases. To facilitate calprotectin determination in clinical routine, we have optimized our proven monoclonal **PhiCal® Calprotectin ELISA**: Incubation times were cut to 2 x 30 min., all steps can be done at room temperature and the kit contains ready-to-use conjugate. With a broad dynamic concentration range up to 2100 µg/g, the new **PhiCal® Calprotectin ELISA** now represents the leading assay in routine diagnostics of calprotectin.

- **PhiCal® Calprotectin ELISA (K 6927)**
- **PhiCal® Calprotectin ELISA, 1-pt. calibration (K 6967)**

**Rapid & direct EHEC detection by PCR**

We now offer the real time PCR kit **MutaFAST® VTEC (stx 1/2)** for the fast detection of potentially life-threatening enterohemorrhagic *Escherichia coli* (EHEC), e.g. during epidemic EHEC outbreaks. The test enables the qualitative determination of verotoxin producing *E. coli*, including EHEC/ HUSEC41 in less than two hours. It detects the pathogen-specific genes for verotoxin 1 and 2. The analysis therefore reliably identifies the pathogenic EHEC-bacteria, even before toxin-related symptoms occur. The **MutaFAST® VTEC** can be processed in all established open real time PCR-systems. Due to the high degree of sensitivity of this PCR-analysis, a time-consuming bacteria cultivation is not necessary, the determination occurs directly from stool samples – ideal for clinical routine!

- **MutaFAST® VTEC (stx 1/2), 96 tests (KP190096)**
- **MutaFAST® VTEC (stx 1/2), 32 tests (KP190032)**

**Gut bacteria PCR provides valuable clues to food exploitation**

In humans, the energy yield from consumed food is largely dependent on an individual’s composition and species variety of the intestinal bacteria population. Firmicutes (*Eubacterium rectale*) very efficiently digest complex carbohydrates and dietary fibres into sugars and fatty acids. Bacteroidetes in contrast do not exploit food as well and poorly digest especially complex carbohydrates. The microbial colonization therefore plays a role in the regulation of body weight. The ratio of "slenderizing" bacteroidetes and “fattening” eubacteria (usually approx. 3-5, in adipose individuals often smaller) critically influences the energy yield. We offer the following PCR products for the analysis of gut flora composition:

- **MutaPLATE® Bacteroides (KE19001)**
- **MutaPLATE® Eubacterium (KE19002)**

**DAO-ELISA: Meaningful, convenient determination of histamine intolerance**

Too much histamine can be the reason for a wide range of allergy-like symptoms. Histamine intolerance caused by a lack of the enzyme diamine oxidase (DAO) can now easily be detected with our worldwide unique **DAO-ELISA** in serum and stool. If the amount of DAO is sufficient, DAO activity in the circulation should be verified with our **DAO-REA (3H)**. These two test systems reliably detect either a lack or a malfunction of DAO and hence represent complementary tools for the diagnosis of histamine intolerance.

- **DAO-ELISA (K 8500)**
- **DAO-REA (3H) (K 8220)**
LITERATURE NEWS


Elevated 25-OH vitamin D data with the IDS EIA kit

Because they were alerted by recurring elevated 25-OH vitamin D concentrations (> 150 ng/ml) measured with the IDS EIA kit adapted on automated platforms, the authors of this study compared the IDS EIA with the Diasorin RIA as reference. The data revealed a systematic bias (higher levels with the IDS EIA) for concentrations > 50-60 ng/ml, presumably due to matrix effects. This error could potentially lead to a false diagnosis of vitamin D oversupply. The bias in the manual processing of the kit was less pronounced. The authors therefore suggest a cautious interpretation of 25(OH) data generated with the IDS EIA kit on automated platforms. If high values persist, an alternative method should be chosen.

25-OH Vitamin D direct, ELISA (K 2109)

ID-PRODUCTS PUBLISHED

Lembcke J et al. (2011). „The use of MRM® mode for rapid analysis of 1α,25(OH)2-vitamin D3 in serum and plasma“. Poster at the ASMS conference, June 5-9

Rapid, reliable determination of 1,25-(OH)2 vitamin D3 and D2

The authors tested the 1,25-(OH)2 Vitamin D3 / D2 ImmunoTube® LC-MS/MS Kit (see p. 2 of this newsletter) for the determination of 1α,25(OH)2 vitamin D3, in serum on a Waters Acquity UPLC system and a AB SCIEX QTRAP® 5500 LC/MS/MS instrument. For sample preparation they used the ready-to-use ImmunoTube® Kit and subsequently detected vitamin D with the highly selective MRM® (MS/MS/MS) method. This procedure provided excellent, very specific data for the determination of 1α,25(OH)2 vitamin D3 and D2 with a lower detection limit of 1.8 pg/ml and a dynamic measuring range of 10 - 1000 pg/ml (see fig. below).

Due to these data, the authors appraise the ImmunoTube® Kit as fast, robust and reliable method for the determination of 1α,25(OH)2 Vitamin D3 in serum or plasma.

EVENTS

• AACC 2011 Annual Meeting
  26.- 28. July, Atlanta / USA
  Booth No. 3461

• 11th International Nutrition & Diagnostics Conference
  28. - 31. August, Brünn / Czech Republic
  Booth No. yet to be determined

• ASBMR 2011 Annual Meeting
  16. - 20. September, San Diego / USA
  Booth No. 324

• UEGW 2011
  22. - 26. October, Stockholm, Sweden
  Booth No. yet to be determined

• MEDICA 2011
  16. - 19. November, Düsseldorf, Germany
  Hall 3, Booth No. 59

TIP: Regular cleaning of automate tube systems to ensure correct data

Contaminated tubes are a serious problem in automated ELISA processing, often causing elevated blanks and/or incorrect data. Common contaminations include bacteria, fungi and algae. In order to prevent microbial tube colonization, we recommend the daily use of STABSOL® in your washing system, a solution with microbialic components, which is connected and automatically applied to the system like any other rinsing solution. For automates with frequent use of microbial samples (e.g. in bacteriology or microbiology), a bi-weekly thorough cleaning with SETUP CLEAN® is advised. STABSOL® and SETUP CLEAN® including manuals as well as general tips on automation tube system maintenance can be obtained at Immundiagnostik: tech.support@immundiagnostik.com

01/2011