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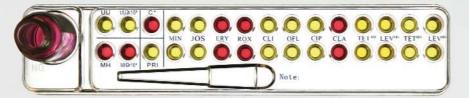


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JANUARY

Blood Test for Tuberculosis Less Reliable During Pregnancy

Interferon gamma release assays (IGRA) are used to detect *Mycobacterium tuberculosis* infections in pregnant women. The IGRA has replaced the traditional tuberculin skin test in some places as these assays are performed on blood samples in routine antenatal screening tests. Scientists studied the correlation between the skin test and the IGRA in detecting latent tuberculosis (TB). A Mantoux tuberculin skin test was performed after blood was taken for the QuantiFERON TB Gold In-Tube assay. Of the women tested, 23% had positive tuberculin skin tests and 14% had positive IGRA results, for a 77.4% rate of agreement. There were no statistically significant predictors of discordant results. The study was published in the December 2011 issue of the journal *Obstetrics and Gynecology*.

Serum Adipokines Associated with Diabetic Risk Factors

A bnormal levels of adipokines, cytokines produced by the adipose tissue, in the serum may be cardiovascular risk factors for diabetic patients. The relationship of the serum profile of adipokines, such as leptin, adiponectin, resistin, and interleukin 6 (IL-6) has been evaluated with these risk factors for obese patients with diabetes mellitus type 2 (DM2). In a prospective study, obese patients with DM2 were





77 Elektronika Kft. Fehérvári út 98. H-1116 Budapest, Hungary Phone: +36-1-206-1480 Fax: +36-1-206-1481 E-mail: sales@e77.hu Web: www.e77.hu enrolled and their blood was analyzed. A complete biochemical, anthropometric, and nutritional evaluation was performed. In the November 2011 issue of Journal *of Clinical Laboratory Analysis*, the investigators concluded that the serum profile of adipokines is related to different cardiovascular risk factors and anthropometrical variables in obese patients with diabetes type 2.

Nonfasting Screening Tests Evaluated for Dysglycemia

The performance of nonfasting tests to screen children for dysglycemia, either prediabetic or diabetic, has been appraised. The screening tests included a random glucose test, fructosamine and the glycosalated hemoglobin test, HbA1c, following a formal glucose tolerance test (OGTT) performed on a previous visit. Scientists conducted a cross-sectional study of overweight or obese children aged 10-17 years. The results of the study showed that there were 99 (39%) cases of prediabetes and 3 (1.2%) cases of diabetes. Urine dipstick, HbA1c, and fructosamine displayed poor discrimination for identifying children with dysglycemia. Both random glucose and 1-h GCT had better levels of test discrimination than HbA1c or fructosamine. The study was published the December 2011 issue of the journal *Diabetes Care.*

Five-Marker Panel Helps Diagnose Lupus

five-marker panel was designed to rule-in Systemic Lupus Erythematosus (SLE) and rule-out other rheumatic diseases to help establish an accurate SLE diagnosis. The Avise SLE panel from Exagen Diagnostics, Inc. (Albuquerque, NM, USA; www. Exagen.com) includes testing of antinuclear antibodies (ANA), anti-double-stranded DNA antibodies (dsDNA), antimutated citrullinated-vimentin antibodies (Avise MCV), EC4d, and BC4d. The cell-bound complements rule-in SLE because of their increased performance over soluble complements, which help to diagnose SLE accurately and consistently. ANA, dsDNA, and AntiMCV are measured using enzyme-linked immunosorbent assay (ELISA) whereas EC4d and BC4d are measured using flow cytometry. A negative result for ANA helps rule-out the possibility of SLE. A positive result for dsDNA rules-in SLE. Avise MCV rules-out Rheumatoid Arthritis.

Reasons for Rejecting Blood Samples Analyzed

A determination has been made of the types of preanalytical errors responsible for about 70% rejection of blood samples. Of the 77,051 blood samples that were collected during the three months period, 441 (0.57%) were rejected by some type of preanalytical error and therefore had to be recollected. A clot was found in 43.8% of disallowed samples and was found to be the major cause of rejection of samples, followed by 24% with insufficient sample volume. The third most frequent cause for rejecting samples were hemolyzed samples, which involved 17.9% of cases. Other reasons for rejection of samples were misidentification, inappropriate tube, lipemic samples, inadequate sample/additive ratio, and insignificant icteric samples. The study was published in January 2012 in the journal *Clinical Biochemistry*.

Mass Spectrometry Helps to Rapidly Detect Staph Infections

A laboratory test has been developed that can rapidly identify the bacterium responsible for *Staphylococcus aureus* infections. The test uses mass spectrometry to quantify the number of *S. aureus* organ-

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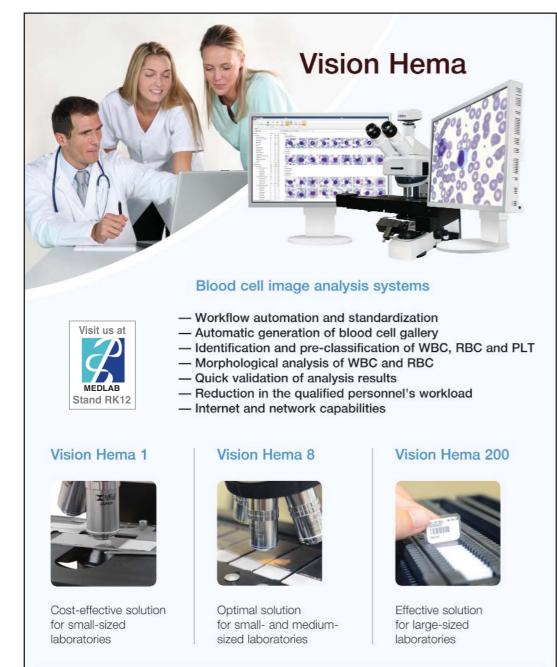
isms in a large number of samples in just a few hours, compared to a day or two for culturing techniques typically used to detect this bacterium. Developed by scientists from the Georgia Institute of Technology (Atlanta, GA, USA; <u>www.gatech.edu</u>) and the Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA; <u>www.cdc.gov</u>), the new test takes advantage of unique isotopic labeling combined with specific bacteriophage amplification to rapidly identify *S.aureus*. Details of the method were published in the January 2012 issue of the journal *Molecular and Cellular Proteomics*.

Immunochromatogenic Test Detects H. Pylori in Fecal Samples

A rapid visual assay has been developed for the detection of *Helicobacter pylori* in fecal samples. Called Pyloritop Ag+, the assay is an immunochromatogenic test that provides clinical laboratories with a cost-effective method to help meet current guidelines for the detection and treatment of *H. pylori*. Released by Pro-Lab Diagnostics (Bromborough, United Kingdom; <u>www.pro-lab.com</u>), the new assay is based on robust lateral flow technology. Individually wrapped Pyloritop Ag+ test cassettes are supplied with a sample collection tube for maximum convenience, and can be safely stored at room temperature for up to 12 months, providing a practical solution for *H. pylori* testing.

Blood Test Diagnoses Cause of Kidney Failure

Hemolytic uremic syndrome (HUS) is a potentially life-threatening condition and often occurs after gastrointestinal infection with *Escherichia coli* O157:H7, which produces Shiga toxins that cause hemolytic anemia, thrombocytopenia, and renal injury. Scientists discovered a biological pathway never before known to have played a role in the development of HUS. Specifically, they found that the toxin can increase the level of a chemokine, namely stromal cell-derived factor-1 (SDF-1), and its receptor, C-X-C chemokine receptor type 4 (CXCR4). Blood tests performed indicated that those who went on to develop HUS had as much as four times higher levels of the protein SDF-1, than those with *E. coli* who did not go on to develop HUS. The study was published on January 9, 2012, in the *Journal of Clinical Investigation*.



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FEBRUARY

Urinary Antigen Assay Detects Legionella

n antigen test has been evaluated for its ability to diagnose Legionnaires' disease using urine samples. Laboratory diagnosis of Legionella pneumophila infections in patients with pneumonia is based on culture, serological testing, molecular testing, and detection of soluble L. pneumophila antigen in urine. Results for the SD Bioline Legionella Urinary Antigen test were compared with those obtained by the BinaxNOW Legionella Urinary Antigen enzyme immunoassay. The SD Bioline test was positive for 46/58 samples with sensitivity of the assay estimated as 79%. The BinaxNOW urinary antigen test was positive 47/58, with a sensitivity of 81%. Both tests were negative in the 38 samples from the non-Legionella patients giving a specificity of 100% for both assays. The study was published in the January 2012 edition of the Journal of Infection.

Blood Test Helps Identify Depressed Patients

blood test that helps diagnose major depressive dis-A order (MDD) promises to become a useful clinical tool. The test, which analyzes levels of nine biomarkers, accurately distinguishes patients diagnosed with depression from control participants. There were no significant false-positive results. Developed by Ridge Diagnostics (Research Triangle Park, NC, USA; <u>www.ridgedx.com</u>), the test measures levels of biomarkers associated with factors such as inflammation, the development and maintenance of neurons, and the interaction between brain structures involved with stress response and other key functions. The measurements are combined to produce the MDDScore indicating the percentage likelihood that the individual has major depression. In clinical use, the MDDScore would range from 1 to 10. A report of the studies was published in the December 2011 journal Molecular Psychiatry.

IgM Autoantibodies Can Be Correlated in Cases of Atherosclerosis

ow levels of immunoglobulin-M (IgM) autoantibod-Lies against lipid phosphorylcholine (PC) add prognostic information in acute coronary syndromes (ACS). Scientists analyzed blood samples from patients within 24 hours of admission. Serum IgM anti-PC titers were measured by an enzyme-linked immunosorbent assay (ELISA) using a prototype of the Athera CVDefine kit. The assay is based on PCs covalently linked to bovine serum albumin coated onto 96-well microtiter plates. The detection limit was 0.5 U/L and coefficients of variation were less than 7%. The results of the analysis showed that patients with low levels of anti-PC in connection with ACS and refractory, unstable angina run a greater risk of complications and premature death. The study was published online on February 3, 2012, in the International Journal of Cardiology.

Electrical Sensors Diagnose Viruses

A technique has been developed that could form the basis of a noninvasive diagnostic method for Adenovirus. The biosensor technology developed can detect the presence of the virus, and it can identify the individual strain and the number of virus particles present. Scientists fabricated novel immunosensors using polyclonal antibodies raised against a human Adenovirus (Ad5) capsid protein, which were selectively cleaved into antibody fragments by 2-mercaptoethylamine. They demonstrated that the immunosensor constructed shows high affinity to its Ad5 virus ligand, detectable by

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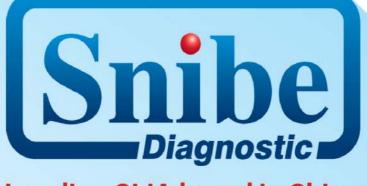
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electrochemical impedance spectroscopy over a broad range of concentrations from 10 to 1,012 virus particles/mL. The study was published on February 15, 2012, in the journal *Biosensors and Bioelectronics*.

Novel miRNA Assay Assesses Pancreatic Masses

A microRNA (miRNA) test aids physicians in the diagnosis and management of pancreatic ductal adenocarcinoma (PDAC) when cytology is inconclusive. The test analyzes the expression levels of small, regulatory fine needle aspirate (FNA) molecules known as miRNAs. An algorithm calculates a score between 0 and 1 by measuring the expression levels of seven miRNAs, and this determines whether PDAC has been identified. The Asuragen, Inc. (Austin, TX, USA; <u>www.asuragen.com</u>) miRNA assay, called the miRInform pancreas test, is available in the company's College of American Pathologists (CAP)-accredited Clinical Laboratory Improvement Amendments (CLIA) laboratory. miRInform pancreas is performed on FNA biopsies of solid lesions of PDAC patients.

Peripheral Blood Smear Confirms Leishmaniasis

A Peripheral buffy coat blood smears are a minimally invasive technique to diagnose the presence of the causative agents of visceral leishmaniasis (VL). From patients in a prospective study, two good-quality smears prepared from buffy coat and stained with Leishman stain were examined under an oil immersion light microscope. The results of the study showed that 92%, 95.5%, and 100% of VL patients were positive by buffy coat microscopy, buffy coat PCR, and spleen smear microscopy, respectively. Leishmania amastigotes were found by buffy coat microscopy in 93.5% of those positive by buffy coat PCR and in 92.4% of those positive for Leishmania amastigotes by spleen smear microscopy. The study was published in March 2012 in the *Journal of Clinical Microbiology*.

Molecular Test Screens for Drug Resistant Bacteria

laboratory-developed test, known as Lab Assay, A laboratory-developed test, known and real-time poly-combining enrichment broth and real-time polymerase chain reaction (rt-PCR) was developed specifically for the detection of vancomycin-resistant enterococci (VRE). Microbiologists investigated swabs sent to the laboratory for VRE screening in parallel by Lab Assay and the Roche LightCycler VRE kit. Two proven stains of Enterococcus faecium and 52 well-characterized clinical VRE isolates of different clones were tested in the study. Real-time PCR was performed for the detection of VanÁ and VanB genes. The diagnostic values for Lab Assay were as follows: 100% sensitivity, 79.92% specificity, 1.94% positive predictive value, and 100% negative predictive value, which were comparable to the results from the LightCycler kit-based assay. The study was published in March 2012 in the European Journal of Clinical Microbiology & Infectious Diseases.

Identifying Patients Treated with Tysabri at Risk for PML

The risk for a rare brain infection called progressive multifocal leukoencephalopathy (PML) occurs in people using the drug Tysabri (natalizumab) to treat multiple sclerosis (MS) or Crohn's disease (CD). The Stratify JCV antibody enzyme-linked immunosorbent assay (ELISA), when used with other clinical data from the patient, can help health care providers determine the risk of developing PML in MS and CD patients. This test, in conjunction with other factors, will enable physicians and patients to assess carefully the risks and benefits of continuing Tysabri treatment. The Stratify JCV antibody ELISA test is manufactured by Focus Diagnostics (Cypress, CA, USA; <u>www.focusdx.com</u>).

6 New Assays Added to Specialist Protein Analyzer

S ix automated assays were added to a specialist protein analyzer. They provide quantitative results to aid the assessment of a patient's immune system. The assays include four cerebrospinal fluid (CSF) assays: immunoglobulin G (IgG), IgA, IgM, and albumin. Complement 1 (C1) inactivator in plasma and serum for the investigation of hereditary angioedema and transferrin in serum for estimation of iron deficiency anemia were also added to the analyzer menu. Binding Site's (Birmingham, United Kingdom; <u>www.bindingsite.co.uk</u>) SPAplus specialist protein analyzer was designed to bring together instrument, reagents, and support as a package. A compact, turbidimetric platform, the fully automated SPAPLUS system enables laboratories to maintain the quality of results and high throughput required for specialized protein assays.

MARCH

Immunoassay Assessed for Diagnosis of Norovirus Gastroenteritis

n immunochromatographic test is based on reverse A transcription-polymerase chain reaction (RT-PCR) and the sensitive RT-nested PCR and was compared with another commercial real-time RT-PCR for detection of Norovirus in stool samples. The samples were tested for noroviruses using the commercial immunochromatographic test RIDA QUICK Norovirus, which uses biotin-streptavidin-peroxidase method. The the Scientists concluded that the RIDA QUICK Norovirus assay is appropriate to use for early diagnosis of acute gastroenteritis caused by noroviruses and for rapid screening of Norovirus infections in patients with acute gastroenteritis where the RT-PCR method has not been established for routine diagnosis. However, negative results where Norovirus is strongly suspected should be further tested by more sensitive molecular techniques. The study was published online on February 23, 2012, in the European Journal of Clinical Microbiology & Infectious Diseases.

Blood Test Predicts Sickle Cell Severity

Scientists at Massachusetts Institute of Technology (MIT; Cambridge, MA, USA; <u>web.mit.edu</u>) and others have developed a microfluidic system to measure changes in sickle cell blood flow after deoxygenation. The system included a microfluidic device with a capillary-sized channel that was diffusively coupled to a gas reservoir. This system allowed control over parameters that mimic physiological conditions during vaso-occlusion. Blood samples from patients with more benign disease showed a significantly slower decrease in the conductance after deoxygenation. The authors concluded that the strong correlation between blood rheodynamics and the clinical outcomes in the study population could possibly provide a tool for patient monitoring and clinical decision-making in sickle cell disease. The study was published on February 29, 2012, in the journal Science Translational Medicine.

Immunoassays for Human Saliva Need Validation

C ommercial enzyme-linked immunosorbent assays (ELISAs) have proven to be a powerful tool for fast and reliable sample analysis, however few ELISAs have been validated for use with saliva, or their validation is often incomplete. Scientists analyzed saliva and gingival crevicular fluid collected from healthy volunteers and validated commercially available assays for 13 common biomarkers of inflammation and bone resorption. They concluded that most ELISAs are suitable for analysis of saliva samples, even if this is not specifically recommended by the manufacturer. However, they believe that an independent validation of assays for saliva samples is important, as they have highlighted a number of cases in which validation and quality control analysis for some assays yielded questionable results when using saliva. The study was published in the March 2012 issue of the *Journal of Immunological Methods*.

Molecular Techniques Compared for Diagnosis of Rickettsioses

 \mathbf{T} he diagnosis and isolation of *Rickettsia* species from skin biopsies may be replaced by a real time polymerase chain reaction (rt-PCR). Scientists analyzed punch biopsies or scalpel incisions of eschars collected from patients with suspected rickettsial infections. Rickettsia species infection was diagnosed in 32% skin biopsies from patients with suspected rickettsiosis. By rt-PCR, a positive result was obtained for 28.8% skin biopsies. Rickettsia africae was the most common detected species. The study was published on March 6, 2012, in the journal Public Library of Science Neglected Tropical Diseases. The author concluded that for the diagnosis of Rickettsia infection the use of molecular and culture diagnostic tools, decreases the time of diagnosis and increases the sensitivity. However, a negative result using molecular assays does not exclude the diagnosis of Rickettsia infection.

Leukemia Patients' Prognoses Predicted with Genetic Profiling

A set of genetic abnormalities have been identified in individuals with acute myelogenous leukemia (AML). Oncologists examined blood or bone marrow samples from individuals with AML who took part in a clinical trial. The aim was to determine whether increasing the standard dose of chemotherapy would improve survival for individuals with AML under the age of 60. The scientists examined the samples for mutations, or abnormalities, within 18 genes known to have variations in individuals with AML for the relationship between the mutations present in each participant and how well they coped. With this analysis, they were able to determine specific risk levels for a range of gene-mutation combinations. The study was published on March 14, 2012, in the *New England Journal of Medicine* (*NEJM*).

Molecular Assays Evaluated for Influenza in Blood Donors

Sensitive molecular assays have been used to screen via ribonucleic acid (RNA) testing. The authors of the study published on March 15, 2012, in the *Journal of Infectious Diseases* reported that they failed to detect influenza A viremia using very sensitive tests in blood samples from donors collected during periods of high influenza transmission in the community, with the majority of the tested donors reporting symptoms of influenza-like illness. The preponderance of evidence from this and other studies thus suggests that influenza viremia is at most an exceedingly rare event in blood donors, who are healthy at the time of donation, and that influenza viremia only occurs in subjects with moderate to severe disease.

Biomolecular System Launched for Protein Quantitation

A system for rapid, simplified protein quantitation has been introduced that enables infrared-based measurement of amide bonds in protein chains. The Direct Detect system employs a hydrophilic polytetrafluoroethylene (PTFE) membrane designed to be transparent in

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most of the infrared spectral region and enables application of biomolecular solutions directly onto the membrane. The system relies on infrared-based detection of biomolecules, so that the users can obtain accurate and reproducible protein quantitation in the presence of reducing agents and detergents. As a result, the Direct Detect (EMD Millipore; Billerica, MA, USA; <u>www.emd.us</u>) system can measure protein concentrations from 0.2 mg/mL to 5 mg/mL within seconds, without any bio- or immunochemical staining, directly from samples, including buffered solutions.

Blood Test Predicts Impending Heart Attack

A blood test was devised that identifies specific cells that flake off when the blood vessel walls weaken and signal the initial stages of acute myocardial infarction (MI). Scientists at Scripps Translational Science Institute (La Jolla, CA, USA, <u>www.scripps.org</u>) enrolled patients who presented to the emergency room with STsegment elevation MI (STEMI) and had blood drawn for circulating endothelial cells (CECs) characterization. The CEC blood levels among those who had had a heart attack were over four times higher when compared to those in the healthy control group. In addition, the patients' CECs had changed: they had either become larger, misshapen, and/or many had multiple nuclei. The study was published on March 21, 2012, in the journal *Science Translational Medicine*.

Lung Biopsies Reduced by Panel of Serum Biomarkers

A panel of serum biomarkers could help predict the level of lung cancer risk in high-risk patients, offering physicians an option before proceeding with a biopsy. A multicenter team identified a panel of 10 serum biomarkers including prolactin, transthyretin, thrombospondin-1, E-selectin, C-C motif chemokine 5, macrophage migration inhibitory factor, plasminogen activator inhibitor, receptor tyrosine-protein kinase, cytokeratin fragment 21.1, and serum amyloid A, which distinguished lung cancer patients from controls. The authors concluded that although the biomarker model they described could not detect every lung cancer, it offers a significant clinical improvement over computed tomography (CT) imaging alone. The study was published in the April 2012 issue of the *Journal of Thoracic Oncology*.

APRIL

Novel Biomarker Facilitates Diagnosis of Alzheimer's Disease

A method has been developed to measure aggregated beta-amyloid in cerebrospinal fluid that may well facilitate diagnosis and detection of Alzheimer's disease (AD). Scientists used a novel method to quantify soluble variants of aggregated beta-amyloid (A β oligomers) in cerebrospinal fluid by flow cytometry. They analyzed the cerebrospinal fluid of neurological patients, including Alzheimer's patients. They found that patients had a more pronounced disease when they had greater number of A β oligomers in the cerebrospinal fluid. Conversely, a decline in the number of A β oligomers in cerebrospinal fluids could be a hint for the effectiveness of new drug therapies. The study was published in the March 2012, issue of *Journal of Alzheimer's Disease*.

Complimentary Reflex Test Determines Drug Resistance in Trichomoniasis

A drug resistance-reflex assay for *Trichomonas vaginalis* is currently only available from commercial laboratories but will be performed at no additional charge when *T. vaginalis* is detected in a patient's specimen. This new assay will provide another tool for clinicians to make appropriate decisions pertaining to treatment regimens to achieve an effective cure for *T. vaginalis*, a flagellated protozoan parasite. The reflex test can now detect metronidazole resistance in a subset of *T. vaginalis* positive specimens by real-time polymerase chain reaction (rt-PCR). The new assay detects a *T. vaginalis* gene mutation highly associated with metronidazole resistance with a 91% positive predictive value (PPV). The assay was developed by Medical Diagnostic Laboratories, (Hamilton, NJ, USA; <u>www.mdlab.com</u>).

New Diagnostic Hepatitis C Assay Extends Effectiveness of Serology Panel

serological assay for hepatitis C (HCV) provides A serological assay for hepatitic contract, for the service of the tion and patient-oriented decision-making. Clinical diagnosis of HCV is difficult largely due to the high rate of asymptomatic infections, making improved screening assays of major importance. The generation Elecsys anti-HCV II assay, developed by Roche (Basel, Switzerland; www.roche.com), has been added to the Roche serology panel, which includes assays for Hepatitis A, Hepatitis B, Hepatitis C, HIV, TORCH, Herpes, Syphilis, and other infectious diseases. Elecsys anti-HCV II provides 100% clinical sensitivity for all known genotypes. The assay can play an effective role in strategies for addressing public health concern as it is used to demonstrate the presence of antibodies against HCV during acute and chronic stages of disease, and after a passed infection.

Noninvasive Stool Test Biased by Patient's Age

DNA methylation test for colorectal cancer (CRC) A is influenced by the clinical variable age and not by drug choice or other variables. Stool assays of carefully selected methylated gene-marker candidates yield highdetection rates of both CRC and large adenomas, as aberrantly methylated genes represent attractive and broadly informative markers for these forms of malignancy. The only patient characteristic that significantly influenced all methylated marker levels in stool was age. Standardized relative change was greatest with Tissue Factor Pathway Inhibitor 2 gene at +91.3, least with Bone Morphogenetic Protein 3 gene at +29.7, and intermediate with vimentin at +46.0 and N-Myc Downstream-Regulated gene 4 at +45.1. The study was presented at the American Association for Cancer Research (www.aacr.org) Annual Meeting, held March 31 - April 4, 2012, in Chicago (IL, USA).

Urinary Test Score Unchanged by Chronic Prostatitis

The influence of chronic prostatitis on the potential new biomarkers of prostate cancer (PCa) found in male urinary samples have been determined. The authors of the study, which was published in the April 2012 edition of the journal *Prostate* concluded that prostate massage included within the Meares–Stamey four-glass localization test allows informative samples for urinary Prostate cancer gene 3 (PCA3) test. The PCA3 score was found to be negative with less than the usual cutoff of 35, in all tested patients, suggesting that PCA3 test can be used as a valuable tool in patients with raised PSA and suspicion of chronic prostatitis to distinguish those patients who will really benefit from prostate biopsy.

Method Detects Hypervirulent Bacterial Strains

The discovery of hypervirulent *Salmonella* bacteria has given doctors the means to potentially prevent food poisoning outbreaks from these particularly potent

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strains. A team of scientists examined human clinical *Salmonella* isolates obtained from fecal and blood samples derived from patients with gastroenteritis or bacteremia, respectively; and animal isolates derived from different outbreaks, individual cases, or surveillance submissions to diagnostic laboratories. The results of the study indicated that the 14 hyperinfectious Salmonella strains were considerably more virulent than *other* animal-passaged clinical isolates and the display of increased virulence traits by bacterial strains after murine passage does not necessarily equate to hypervirulence. The study was published online in April 2012 in the journal *Public Library of Science Pathogens.*

Next Generation Digital PCR System Launched

 ${f T}$ he system, which is designed for advanced stan-dards in sensitivity, multiplexing, and absolute quantitation in polymerase chain reaction (PCR) analysis, is capable of generating more than a billion reactions in a single day, and transforms the performance of molecular assays by enabling digital answers across a number of applications. Based on RainStorm picodroplet technology, the RainDrop System generates up to 10 million picoliter-sized droplets per lane. The RainDrop System (RainDance Technologies; Lexington MA, USA; www.raindancetechnologies.com) also shifts the current digital PCR (dPCR) paradigm from a single-color-permarker approach to a two color and varying probe intensity method that is capable of multiplexing up to 10 markers. It will be particularly useful for detecting lowfrequency tumor alleles, gene expressions, copy number variations, and single-nucleotide polymorphism (SNP) measurements.

Nonsurgical Test Developed for Brain Cancer

S pecific microribonucleic acids (miRNAs) that are present in cerebrospinal fluid (CSF) can serve as biomarkers for particular brain malignancies and disease activity. Scientists studied patients with different types of brain cancers and showed that miRNA profiling of CSF can be used to determine the presence of glioblastomas. In the study published on April 4, 2012, in the journal *Neuro-Oncology*, the investigators concluded that are several advantages of using miRNAs as biomarkers for brain cancer compared with other biomarkers. MiRNAs are highly stable, and their detection by qRT-PCR is quantitative, extremely sensitive, requiring only nanograms of starting RNA material, highly specific, and reproducible. The same process can be used to detect the presence of cancer that started in another part of the body and spread to the brain.

MAY

Bartonella Infection Linked with Rheumatoid Illnesses

bacterium associated with cat scratch fever and A bacterium associated with cut octains transmitted predominately by fleas may also play a role in human rheumatoid illnesses. Antibody assays and polymerase chain reaction tests (PCR) were used to identify Bartonella species in patients suffering from rheumatoid diseases. From such patients examined by a rheumatologist blood samples were taken and analyzed by immunofluorescence antibody assay (IFA). Each sample was tested by PCR amplification of Bartonella species DNA. Sixty-two percent had Bartonella antibodies, which supported prior exposure to these bacteria. Bacterial DNA was found in 41% of patient samples, allowing investigators to narrow the species of Bartonella present, with B. henselae, B. koehlerae, and B. vinsonii subsp. berkhoffii the most prevalent. The study was published online in the May 2012 issue of the journal Emerging Infectious Diseases.

Immunosignaturing Provides Accurate Diagnoses

technique known as immunosignaturing harnesses A the human immune system as an early warning system, which is acutely sensitive to changes in the body that may be indicative of disease. These immunosignatures are not only strong indicators of presymptomatic illness but also those samples from serum, plasma, saliva and dried blood can yield reliable and highly stable diagnostic results under a variety of conditions. In a study published in the March 2012 issue of the journal Clinical and Vaccine Immunology, a team of scientists report on the immunosignaturing technique that uses random sequence arrays of peptides to trawl for antibodies to disease. They demonstrated that a glass slide containing an array of some 10,000 such random sequences can be used to screen the body's full complement of antibodies.

Simple Blood Test Identifies Cancer from Asbestos

A small protein molecule has been identified that is more prevalent in the blood of people with mesothelioma than in healthy people. Scientists working on asbestos cancer at Concord Hospital (Sydney, Australia; <u>www.adri.org.au</u>) studied patients with pleural mesothelioma to explore whether micro ribonucleic acids (microRNAs) could serve as markers for the cancer. They identified 17 microRNAs that appeared in significantly different levels in the blood of healthy patients and mesothelioma patients. They found that the levels of a particular microRNA, identified as miR-625-3p, were four-fold higher in the blood of mesothelioma patients. The study was presented at the 3rd European Lung Cancer Conference held April 18-21, 2012 in Geneva (Switzerland).

Simple Sedimentation Technique Diagnoses Intestinal Parasites

The sedimentation technique for intestinal parasites is applicable for poor healthcare settings and under fieldwork conditions. The advantages of the spontaneous sedimentation technique in tube (SSTT) are its ability to detect the majority of intestinal parasites, including eggs, larvae, cysts, and trophozoites, its USD 0.03 cost, and its simplicity of use in poor healthcare settings. The initial technique uses a 50 mL shaped plastic tube and surgical gauze to filter the homogenized stools of patients infected by intestinal parasites. The authors concluded that the potential of the SSTT as a diagnostic tool for intestinal parasites in endemic areas is promising, but further studies are required. The study was published online on April 10, 2012, in the *International Journal of Infectious Diseases.*

Stable Isotope Labeling Detects Mutated Viral Strains

bank of molecular signatures has been constructed A bank of molecular signatures has seen the severity of virus infection from characteristic changes seen in cells. Changes in lung cells infected with swine flu from the 2009 outbreak compared with seasonal flu have been investigated using a technique called stable isotope labeling by amino acids in cell culture (SILAC) to measure and compare thousands of different proteins in a sample. A team used the SILAC alongside mass spectrometry to identify the proteins most affected by viral infection and used these as molecular signatures to provide the "barcode" of disease. The study revealed how several processes in the cell were affected by the virus, with most changes seen in proteins involved in cell replication. The study was published on May 14, 2012, in the iournal Proteomics.

Urine Dipstick Accurately Predicts Renal Failure

The presence of excess protein in a common urine test is an effective prognostic marker of acute renal failure in patients with severe sepsis. Scientists analyzed data from sepsis patients with no previous history of protein in the urine. After a urine sample was taken, a specially treated chemical strip was placed into the sample. The presence of white blood cells, protein, or glucose in the urine is indicated by patches on the dipstick, which change color. They found that the urine dipstick test predicted the presence of renal failure in 55% of these patients. The results of the study were presented at the National Kidney Foundation's annual meeting, May 9-13, 2012, held in Washington DC (USA; www.kidney.org).

Liquid Control System Simplifies Urine Chemistry Testing

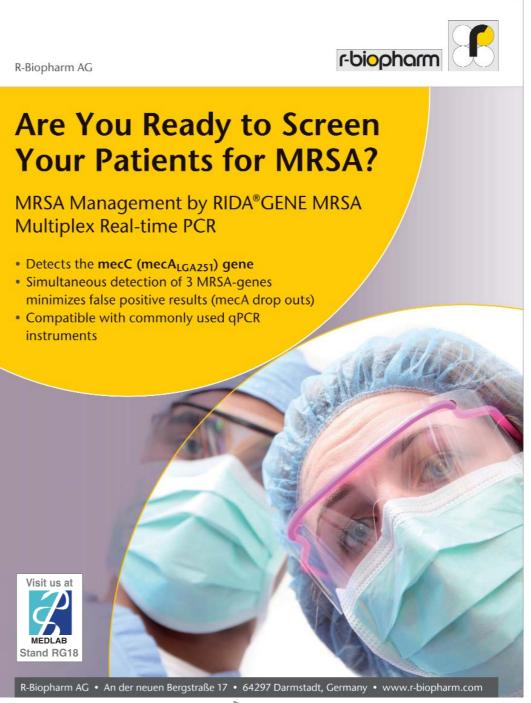
A liquid urine control includes fully assayed target values for 18 commonly performed urine chemistry tests including microalbumin and the hormone human chorionic gonadotropin (hCG), and enables consolida-

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tion and cost savings. The Acusera liquid urine control is manufactured by Randox (Crumlin, United Kingdom; <u>www.randox.com</u>) from 100% human urine, not only providing a matrix similar to the patient sample but also reducing antibody interference and the possibility of control values shifting after the reagent batch is changed. A 10 mL vial size and an open vial stability of 30 days at 2-8 °C for all parameters ensure that both waste and costs are kept to a minimum.

Interferon-Gamma Release Assays Preferred for Latent TB

Interferon-gamma release assays (IGRAs) are significantly better than tuberculin skin tests (TST) at predicting progression from latent tuberculosis (TB). Scientists carried out a meta-analysis to qualitatively evaluate the positive predictive value (PPV) and negative predictive value (NPV) for progression of commercial and "in-house" IGRAs and the TST for persons not receiving preventive treatment. The authors concluded that progression rates for commercial IGRA blood tests are remarkably higher than those for the TST, but remain low in absolute numbers. The data suggests that IGRAs provide significant benefits over the TST, but that



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the use of IGRAs, and testing for LTBI in general, should be targeted at high-risk groups. The study was published online on April 5, 2012, in the journal *Chest*.

Single Test Detects All Existing Strains of H5N1

n advanced kit enables the rapid detection of all existing strains of H5N1 viruses in a single test with almost 100% accuracy. The H5N1 real-time Reverse Transcription Polymerase Chain Reaction (RT-PCR) assay is the only detection kit currently available on the market that can accurately and rapidly detect all known strains of the H5N1 avian Influenza A virus. Codeveloped by Dr. Masafumi Inoue, a senior research scientist and project director of technology development from the Experimental Therapeutics Centre (ETC) under the Agency for Science and Technology Research (A*STAR; Singapore; www.etc.a-star.edu.sg) and Dr. Timothy Barkham, a senior consultant of Laboratory Medicine from Tan Tock Seng Hospital (TTSH; Singapore; www.ttsh.com.sg), the newly launched H5N1 test kit has been clinically validated by several hospitals in Southeast Asia.

JUNE

Antigen Test Designed for Point-of-Care Detection

n antigen-detection test shows efficacy in rapidly An antigen-detection test shows children in the automated point of care in a pediatric setting. The automated, MultiAnalyte system, is capable of detecting from a single nasopharyngeal swab specimen eight respiratory viruses. Scientists evaluated the technology's efficacy in a pediatric emergency setting. Results with the MariPOC (ArcDia; Turku, Finland; www.arcdia.fi) test showed sensitivities and specificities for viral detection as follows: for the children with RSV, 83% and 99%, with influenza B, 85% and 96%, with influenza A, 50% and 99%, with adenovirus, 25% and 97%, with Metapneumovirus, 50% and 100%. The study was presented on May 10, 2012, at the European Society for Pediatric Infectious Diseases (ESPID) 30th Annual Meeting, held in Thessalonica (Greece).

Biomarkers Discovered for Bowel Cancer Blood Test

Genes have been discovered that show identifiable Genanges in the blood of people with bowel cancer and has the potential to be used in a blood test. The test is the result of collaboration between the biotechnology company Clinical Genomics (North Ryde, NSW, Australia; <u>www.clinicalgenomics.com</u>) and Flinders University (Adelaide, SA, Australia; <u>www.flinders.edu.au</u>). One new gene identified was particularly sensitive to cancer. This gene is called *colon adenocarcinoma hypermethylated* or CAHM. In 120 blood samples observed, a high 68% positivity for cancers, while still being accurate in 97% of normal patients. The scientists have also shown that a threegene test including CAHM was able to detect cancer 76% of the time with 93% accuracy in normal patients.

Identification of Abnormal Oocyte Should Improve IVF Success Rates

Scientists have identified the chromosomal make-up of a human egg, a discovery that should avoid using abnormal eggs during infertility treatments, and pick eggs healthy enough for a successful in vitro fertilization (IVF) cycle. Oocytes are surrounded by cumulus cells, which regulate and assist the process of egg maturation. In the study published in the May 2012 issue of the journal *Human Reproduction*, scientists studied genes expressed in the cumulus cells. They were able to identify a set of genes that are less active in cells that are associated with abnormal eggs. They characterized two genes–SPSB2 and TP5313–and found that the expression of these genes was consistently underrepresented in cumulus cells that surrounded abnormal eggs.

Glucose Levels May Predict Pneumonia Death Risk

 ${\bf N}$ ondiabetic patients who have high blood glucose on admission for community-acquired pneumonia (CAP) are at significantly elevated risk for death and may benefit from intensified care. At the University Hospital of Saarland (Homburg, Germany; www. uniklinikum-saarland.de) scientists carried out a prospective multicenter study on 6,891 patients from 12 clinical centers. Higher serum glucose levels were associated with increased mortality in all patients. The authors concluded that patients with increased serum glucose levels or diabetes at the time of CAP was diagnosed were at significantly increased risk of death from the disease. Oral glucose tolerance test and close glucose monitoring after discharge are necessary to diagnose overt diabetes and to prevent subacute or longterm complications. The study was published on May 29, 2012, in the British Medical Journal (BMJ).

Liquid Stable Kit Determines Homocysteine in Serum and Plasma

liquid stable homocysteine kit provides a conven-A liquid stable nonnocysteme for the determination of homocysteine in human serum and plasma. The Randox (Crumlin, United Kingdom; www.randox.com) kit can aid in the diagnosis of both elevated and depleted levels of homocysteine and the diverse range of potential health problems associated with these. The kit has liquid ready-to-use reagents requiring no preparation, and good on-board stability of 28 days minimizes reagent waste. The measuring range of 1.74 µmol/L to 47.9 µmol/L, allows both normal and abnormal values to be accurately measured. There is limited interference from bilirubin, hemoglobin, intralipids, and triglycerides, enabling optimum performance and the generation of precise, reliable results. A correlation coefficient of 0.98 was obtained against another commercially available kit.

Urine Test Detects Changes in Bone Mineral Balance

A technique has been introduced that is more sensitive in detecting bone loss than the X-ray method used today, and with less risk to patients. The technique makes use of a fact that different isotopes of a chemical element can react at slightly different rates. When bones form, the lighter isotopes of calcium enter bone a little faster than the heavier isotopes. That difference, called isotope fractionation, is the key. Analysis of the subjects' urine samples revealed that the technique can detect bone loss after as little as one week of bed rest, long before changes in bone density are detectable by dualenergy X-ray absorptiometry (DEXA). The study was published on May 31, 2012, in the *Proceedings of the National Academy of Science of the United States* (*PNAS*).

Neutrophil Cell Population Indicates Postsurgical Infection

The modern hematology analyzer can determine white blood cell counts (WBC) with differentials and determine their intrinsic biophysical properties, known as cell population data (CPD). Hematologists at the Nantong University (China; <u>www.ntu,edu.cn</u>) investigated the clinical usefulness of mean neutrophil volume (MNV) and neutrophil volume distribution width

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(NDW) to differentiate postoperative infection. There were no significant differences in MNV and NDW observed before surgery between infected and uninfected patients when compared with controls. The MNV and NDW in infected patients were significantly increased after surgery when compared with uninfected patients. The authors concluded that the parameters generated during automated differential analysis, without additional specimen requirements, are quantitative, more objective, and more accurate than manual differential counts. The study was published in the June 2012 issue of the *International Journal of Laboratory Hematology*.

Diabetic Blood Tests Affected by Elevated Liver Enzymes

Measurement of glycated hemoglobin (HbA1c) has several advantages over glucose, but there are also potential disadvantages, with falsely low results in patients with increased liver enzyme concentrations in general, but also in severe liver disease and liver failure. Clinical biochemists at the Odense University Hospital (Denmark; <u>www.ouh.dk</u>) investigated the correlation between HbA1c and venous fasting plasma glucose. In the study published on May 16, 2012, in the journal Diabetic Medicine, the authors concluded that the study strongly indicates that increased liver enzyme concentrations in general do not bias the correlation between glycated hemoglobin and fasting plasma glucose. However, men with increased concentrations of both liver enzymes do have a slightly decreased HbA1c and, if the clinical suspicion is strong enough, oné should consider supplementary testing.

Image Analysis Algorithms Integrated into Digital Pathology Solution

range of image analysis algorithms provides solu-A range of fillage analysis angentation proapplications. Indica Labs (Albuquerque, NM, USA; http://indicalab.com) image analysis algorithms for molecular assay and morphological feature detection and quantification in whole slide images, coupled with Leica Microsystems (Wetzlar, Germany; www.leicamicrosystems.com) Tissue image analysis (IA), provides a solution for complex image analysis problems in digital pathology. Leica Microsystems Tissue IA software is a key component of the total digital pathology portfolio and enables the analysis of whole slide images. The Indica Labs range, including algorithms for neurobiology, toxicological pathology, and brightfield in situ hybridization (ISH), can now be integrated with Leica's Tissue IA, providing a powerful solution for a broad range of targeted applications.

JULY

Real-Time Thermocycler Offers More Flexibility

real-time polymerase chain-reaction system has A feal-unite polymerase chain reactive and chemistry format. The system, called the PrimeQ, gives users the freedom to choose their preferred chemistry, consumables, and data analysis methods using intercalating dyes or probes, and it provides a wide dynamic range and high sensitivity for absolute and relative quantification. The Techne Prime Q (Bibby Scientific Limited; Stone, UK; www.techne.com) has been designed with a single white light-emitting diode (LED) light source, a photomultiplier tube (PMT) detector providing raw data for analysis and a scanning mechanism allowing both partial and full plate reads. The five paired excitation and emission filters covers the wavelengths 470-710 nm and housed in an individual cartridge system. The system is supported by Quansoft software.

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Protein Indicator Identified for Breast Cancer Relapse

I dentifying the mechanisms involved in the survival of breast cancer cells and their ability to colonize other tissues are crucial issues for improving treatment. Scientists at the Hospital Del Mar Research Institute (IMIM; Barcelona, Spair; <u>www.imim.es</u>) studied analyzed the possible usefulness of determining the lack of the 14-3-3 σ and/or the activation of NF-κB in tumor cells as a factor in prognosis and diagnosis, as well as for future clinical and therapeutic applications. The authors concluded that they had identified 14-3-3σ as a negative regulator of NF-κB in breast cancer and demonstrated that loss of 14-3-3 expression is directly associated with the capacity of breast cancer cells to metastasize. The study was published on May 31, 2012, in the *Public Library of Science One (PLoS One).*

Genetic Test Improves Noonan Syndrome Diagnosis

one-step test provides large-scale parallel screen-A one-step test provides large search particular disor-ing of all 12 genes associated with Noonan disorders in one panel. This includes all coding exons of 11 genes plus exon 2 of SHOC2. Molecular testing company NewGene (Newcastle-Upon-Tyne, United Kingdom; www.newgene.org.uk) developed the new test in collaboration with the South West Thames Regional Genetics Service at St George's Healthcare NHS Trust (Tooting, United Kingdom; www. southwestthamesgenetics.nhs.uk). A positive test result will provide a definite diagnosis of the syndrome in question as the mutation spectrum has been well defined and no cases of nonpenetrance have been identified. Importantly, as a positive result will also determine which disorder is applicable, medical interventions appropriate for that specific disorder can be highlighted more quickly.

Molecular Assay Approved for Dengue Diagnosis

A molecular diagnostic test has been developed and officially approved to detect the dengue virus in people with symptoms of dengue or dengue hemorrhagic fever. The DENV-1-4 Real Time Polymerase Chain Reaction (RT-PCR) Assay was developed by the US Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA; <u>www.cdc.gov</u>) for use in the USA and can be conducted by using equipment and supplies that are already performed in many public health laboratories to diagnose influenza. With the RT-PCR test, laboratories are now able to diagnose all four dengue virus types within the first seven days after the appearance of any dengue-related symptoms.

Laboratory Testing Platform for Vitamin D Assay Validated

The quality of Vitamin D assays was demonstrated based on performance metrics. With a simple blood test, the Architect 25-OH Vitamin D assay can measure the stable form of Vitamin D. The Architect 25-OH Vitamin D assay by Abbott (Abbott Park, IL, USA; <u>www.abbott.com</u>) is a chemiluminescent microparticle immunoassay (CMIA), for the quantitative determination of 25-hydroxyvitamin D (25-OH vitamin D) in human serum and plasma. The Architect 25-OH Vitamin D assay is to be used as an aid in the assessment of vitamin D sufficiency. It is recommended that each laboratory establish its own reference range, and results should be used in conjunction with other data such as symptoms, results of other tests, clinical impressions.

Scanning Platform Provides Management and Analysis of Digital Pathology Images

A scanning platform processes batches of slides using both brightfield and multichannel fluorescence, providing a solution for digital pathology scanning. The platform offers monochrome detectors for fluorescence, which provide excellent separation of individual fluorophores that may be close in wavelength, while color detectors for brightfield provide exceptional digital slide capture quality. The SCN400 2.2 by Leica Microsystems (Wetzlar, Germany; www.leica-microsystems.com) can handle up to five fluorescence channels per slide, providing a flexible whole slide scanning solution. The advanced tissue finding system automatically identifies areas for capture for brightfield imaging. Leica's Dynamic Focus saves the overhead cost of slide premapping, rapidly scanning high quality whole slide images. The addition of the SL801 autoloader with capacity for 384 slides makes the SCN400 2.2 a fully automated, high-throughput system.

Assay Accurately Differentiates Between 4 Main Lung Cancers

lung assay based on the expression levels of A microRNAs has been validated. The assay can differentiate between the four main types of lung cancer. Rosetta Genomics (Rehovot, Israel; www.rosetta genomics.com) announced that data from the study validating the company's miRview lung assay was published in the June 29, 2012, online edition of the Journal of Molecular Diagnostics. The miRview lung assay is based on the expression levels of eight microRNAs, measured using a sensitive quantitative real-time polymerase chain reaction (RT-PCR) platform. In the study, more than 90% of the samples were successfully processed with an overall accuracy of 94%. Similar performance was observed in both pathologic and cytologic samples, demonstrating the assays' ability to differentiate among squamous cell carcinoma, non-squamous non-small-cell lung cancer, carcinoid, and small-cell carcinoma.

Monitoring Test Helps Guide Inflammatory Bowel Disease Management

new generation test measures drug (infliximab) and drug antibody levels in one sample among inflammatory bowel disease (IBD) patients who use infliximab. The test is called Anser IFX and is a product of Prometheus Laboratories Inc., (San Diego, CA, USA; www.prometheuslabs.com). The Anser IFX test was verified with more than 3,000 IBD clinical patient samples. The test uses Prometheus' nonradiolabeled homogeneous mobility-shift assay (HMSA) to measure the antibodies-to-infliximab (ATI) and IFX levels in serum samples. Approximately 50% of IBD patients using infliximab may eventually experience a loss of treatment response. If the loss of treatment response is due to the development of ATI, increasing the infliximab dose-the most common first step for physicians-may be less effective than switching to another treatment agent.

AUGUST

Rapid PCR Immunoassay Developed for Malaria Diagnosis

A polymerase chain reaction (PCR) immunoassay has been developed that detects the different malaria



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species and differentiates between *Plasmodium falciparum* and *P. vivax.* The test, which combines PCR with a nucleic acid lateral flow immunoassay (PCR-NALFIA) for amplicon detection, was thoroughly evaluated for the analytical sensitivity and specificity in the laboratory, the robustness, and reproducibility in a ring trial and accuracy and predictive value in a field trial. Scientists at the Royal Tropical Institute (Amsterdam, The Netherlands; <u>www.kit.nl</u>) developed the PCR-NALFIA and tested its validity. The study was published on August 17, 2012, in the *Malaria Journal*.

Clinical Diagnostic Test Validated for Bacterial Vaginosis

clinical study supports validation of a new diagnos-A tic test for bacterial vaginosis (BV). Laboratory Corporation of America Holdings (LabCorp; Burlington, NC, USA; <u>www.labcorp.com</u>) announced publication of the clinical study in the July 2012 Journal of Clinical *Microbiology*. During the study, quantitative polymerase chain reaction (PCR) assays were developed for four organisms reported previously to be indicators for the diagnosis of bacterial vaginosis (BV) and a single organism that had been implicated as a negative indicator for BV. The new test called Bacterial Vaginosis is currently available as part of the NuSwabsm series of tests. LabCorp introduced NuSwab in 2011 as a single collection device that improves the convenience and efficacy of sample collection for clinically validated test profiles for targeted women's health clinical conditions.

Prognostic Molecular Panel Launched for Chronic Lymphocytic Leukemia

A molecular assay for clinical use is offered as a stand-alone test in the USA, in conjunction with a new comprehensive prognostic profiling panel for patients with chronic lymphocytic leukemia (CLL). The standalone test detects mutations in the splicing factor 3b, subunit 1 (SF3B1) gene. The CLL Profile panel also includes assays for IgVH mutation analysis, ZAP-70 expression measured by flow cytometry, and fluorescence in situ hybridization (FISH) tests targeting abnormalities of certain genes associated with CLL. NeoGenomics (Fort Myers, FL, USA; www.neogenomics.com) a provider of cancer-focused genetic testing services, launched the new prognostic molecular panel for CLL. The company is a high-complexity Clinical Laboratory Improvement Amendments (CLIA)certified clinical laboratory that specializes in cancer genetics testing.

Forgotten Vital Stain Identifies Resistant TB

Vital staining with fluorescein diacetate (FDA) stains only living *Mycobacterium tuberculosis* bacilli so that those bacilli resistant to treatment alone are seen. Scientists improved the detection of the luminous bacilli by replacing the classical fluorescence microscope with its light-emitting diode (LED) counterpart. Together with colleagues in Bangladesh, scientists at the Antwerp Institute of Tropical Medicine (Belgium; <u>www.itg.be/itg/</u>) tested the approach in the field for four years. If after treatment the FDA-test was negative, in 95% of cases more elaborate tests did not find active bacilli in the patient's sputum; if the test was positive, a resistant bacillus had been found.

Positive HPV Test Predicts Cervical Precancer for 18 Years

Testing for human papillomavirus (HPV) can predict which women will develop cervical precancers for 10 to 18 years after the test is conducted. A large study examined the long-term benefits of HPV DNA testing alone, cytology (Pap testing), and combinations of the two, to predict cervical precancerous disease and invasive cervical cancer risk. Results of the study showed that while both a positive HPV test and an abnormal Pap test predicted which women would develop precancers within two years of testing, the positive HPV test continued to predict which women were at risk for the entire 18-year follow-up of the study. An initial negative HPV test, on the other hand, provided greater reassurance against cervical precancer and cancer over 18 years than a one-time normal Pap test. The results of the study were published in the July 30, 2012, online issue of the *Journal of Clinical Oncology*.

Pathology Checklist a First for Next Generation Sequencing Laboratory Standards

A gold standard molecular pathology checklist has been revised to include a dedicated section on next generation sequencing (NGS) — the first published laboratory accreditation checklist that addresses

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NGS— advancing standardized practice in genomic testing. The College of American Pathologists (CAP; Northfield, IL, USA; <u>http://cap.org</u>), the largest association of board-certified pathologists and a global leader in laboratory quality assurance, published the new edition of the CAP Laboratory Accreditation Program checklists, released July 31, 2012. CAP checklists are used to guide accreditation of more than 7,000 laboratories worldwide. The CAP's efforts to further advance clinical testing using NGS go beyond accreditation and will include development of NGS proficiency testing products in the near future.

Blood Type May Affect Heart Disease Risk

The blood type of an individual may affect their risk of coronary heart disease (CHD). Studies have indicated that ABO blood group might influence plasma lipid level and recently, several genome-wide association studies found that variants at ABO locus were associated with plasma lipid levels and inflammatory markers associated with CHD risk. Blood type AB, the rarest type, occurs in around 7% of Americans, while type O,

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the most common, occurs in around 43%. Those with blood type AB had a 23% increased risk for heart disease, those with type B had an 11% increased risk, and those with type A had a 5% increased risk compared to people with type O. The study was published on August 14, 2012, in the journal *Arteriosclerosis, Thrombosis and Vascular Biology*.

Patients Colonized with MRSA Rapidly Identified

A molecular test rapidly and accurately identifies patients colonized with methicillin-resistant *Staphylococcus aureus* (MRSA). Performed on the fullyautomated BD Diagnostics' MAX System, the MRSA molecular test received a Moderate Complexity rating under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88, a US regulatory standard). Moderate Complexity rating allows the test to be performed by a qualified technician. BD MAX is a fully automated, bench-top molecular system designed to perform a broad range of molecular tests. This includes in vitro diagnostic assays, as well as user-defined protocols and life science research applications.

SEPTEMBER

Assay Measures Low Levels of Testosterone

A chemiluminescent, microparticle immunoassay has been developed for the quantitative determination of testosterone in human serum and plasma. In 2010, the Endocrine Society published a consensus statement calling for improved testosterone assays and noted that the availability of highly accurate testosterone assays would result "in improved diagnosis, treatment, and prevention of disease." With a simple blood test, the ARCHITECT 2nd Generation Testosterone Assay accurately measures the wide range of testosterone levels observed in a number of different patient populations and clinical settings. The assay, which has improved sensitivity and clinical utility, is a product of Abbott (Abbott Park, IL, USA; <u>www.abbottdiagnostics.com</u>) and it has received the CE marking.

Assay Released for Free Protein S Antigen Testing

n assay for specific and stable free protein S antigen A n assay for specific and static field particles coat-(PS Ag) testing employs polystyrene particles coated with monoclonal antibodies for specific determination of free protein S (PS). Siemens Healthcare Diagnostics (Tarrytown, NY, USA; www.siemens.com/ healthcare) unveiled its INNOVANCE Free PS Ag assay, which will help labs complete their thrombophilia testing portfolio on the company's automated hemostasis systems. The INNOVANCE Free PS Ag assay demonstrates linearity and precision over the calibrated measuring range, as well as specificity for free protein S antigens with no major interference, including those commonly incurred from rheumatoid factors and heterophilic antibodies. The new test complements Siemens' existing protein S activity assay (Protein S Ac) and enables the company to provide a complete protein S testing menu to labs.

Clot Protection Benefits Evaluated for New Blood Gas Testing System

The clot protection capabilities of a new blood gas testing system have been highlighted in an evaluation undertaken at a hospital intensive care unit. Blood sample clotting is a main concern in point-of-care (POC) testing systems, particularly in neonates for whom blood gases are the most common test performed. At the intensive care unit, patient samples, including "high risk" samples were analyzed in an evaluation of the new "Roche cobas b 123 POC" system from Roche Diagnostics (Basel, Switzerland; <u>www.roche.com</u>), specifically designed to eliminate risk of clot blockages. A new clot clearance feature prevents movement of clots from the syringe or capillary into the analyzer. In both internal and external ongoing evaluations, no downtime owing to clots were reported.

Tests Combined for Early Diagnosis of Liver Disease

test could be used in primary care to diagnose liver A fibrosis and cirrhosis in high-risk populations more easily than current tests. Known as the Southampton traffic light test (STL), it combines the fibrosis markers procollagen-3 N-terminal peptide (P3NP) and hyaluronic acid, along with routine liver function tests in a clinical algorithm that can be used in an outpatient clinic. Scientists studied patients with suspected liver disease whose progress was tracked. The results of the study published in September 2012 in the online edition of the British Journal of General Practice (BJGP) show that the test proved to be accurate in severe liver disease. and while not a substitute for clinical judgment or other liver function tests, it can provide physicians with objective means to accurately assess the potential severity of liver fibrosis in high-risk patients.

Nutrient Agar Substituted for Blood in Antibiograms

In resource poor laboratories, testing antibiotic sensitivity of bacteria on blood agar plates may not be feasible. Beta-hemolytic *Streptococcus* species also grow on Standard Nutrient Agar 1 (StNA1) and it has been suggested this type of nutrient medium could be used for running agar diffusion tests. The results of the study published on August 29, 2012, in the *European Journal of Clinical Microbiology & Infectious Diseases* conclude that although blood agar is always the better choice, the reading of the zone of inhibition is often easier on StNA1 than on Müller–Hinton agar because StNA1 is more transparent and, therefore, the edges between bacterial growth and the inhibition zone can be discerned more easily. In places where no blood agar is available for conducting antibiograms, StNA1 is an appropriate substitute for blood-supplemented Müller–Hinton agar.

Specialized Tubes Selected to Optimize Biofluids Sample Storage

 ${\displaystyle S}$ pecialized sample tubes chosen by a biorepository sinstitute have successfully supported the development of an optimized automated workflow to secure the long-term storage of serum, plasma, and urine samples. In improving the long-term storage of samples and the efficiency of its facility, the Karolinska Institute Biobank (KI Biobank; Stockholm, Sweden; http:// ki.se/ki) now uses the single-use heat-sealed REMP sample tubes from Brooks Life Science Systems, a division of the automated sample storage and management pioneer Brooks Automation, Inc. (Poway, CA, USA; www.brooks.com). The format avoids repeat freezethaw and minimizes risk of contamination. The heat seal, available on all tubes (40 to 900 μ L), provides the highest integrity of any available sealing system at low temperatures, reducing potential interference of the sample caused by adhesives.

"Labs for Life" Program to Strengthen Laboratories in Developing Regions

A new collaboration, valued at USD 20 Million, between global medical technology leader Becton, Dickinson and Company (BD; Franklin Lakes, NJ, USA;

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<u>www.bd.com</u>) and the US President's Emergency Plan for AIDS Relief (PEPFAR; Washington DC, USA; <u>www.PEPFAR.gov</u>) through the US Department of Health and Human Services' Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA; <u>www.cdc.gov</u>) has now launched "Labs for Life" to help strengthen healthcare and laboratory systems in resource-limited regions heavily burdened by disease. The new five-year program, announced at the 2012 International AIDS Conference, will continue efforts in Africa as well as increase scope to include additional regions and diseases. It builds on a successful prior fiveyear public-private partnership (PPP) between BD and PEPFAR that focused on regions severely affected by HIV/AIDS and tuberculosis.

High Glucose Levels Predict Mortality in Pneumonia

cute hyperglycemia associated with community-A cute nypergrycenna associated man end acquired pneumonia (CAP) can identify at-risk patients who need additional care to reduce their risk for mortality. Scientists evaluated whether acute dysglycemia could predict a poor outcome in patients with CAP who had not been diagnosed with diabetes. At the time of hospital admission, patients who had glucose levels from 6 to 11 mmol/L (108-198 mg/dL) were considered to have mild acute hyperglycemia and patients who had glucose levels of 14 mmol/L (252 mg/dL) or more were considered to have acute hyperglycemia. In all, 40% of CAP patients presented with hyperglycemia. An elevated glucose level at hospital admission corresponded to increasing risk for death from CAP. The study was presented on September 2, 2012, at the European Respiratory Society (ERS) 2012 Annual Congress held in Vienna (Austria).

OCTOBER

Novel Coronavirus Detected by Molecular Technique

Scientists developed diagnostic real-time reverse-transcription polymerase chain reaction (RT-PCR) assays suitable for qualitative and quantitative detection of the novel human coronavirus (hCoV) that causes an illness similar to the severe acute respiratory syndrome (SARS) virus. Upon scanning of a provisional genome assembly, a region upstream of the putative E gene was identified as a particularly suitable target region for a real-time RT-PCR assay. The assay designed for this region is referred to as the upE-assay. A confirmatory test was designed in the open reading frame 1b, termed the ORF1b assay. This target gene did not overlap with those of known pan-CoV assays including the SARS. If laboratories find patient samples positive by the upE assay and control, they can conduct confirmatory testing using the ORF1b assay. The study was published on September 27, 2012, in the journal Eurosurveillance.

Whole Genome Test Pinpoints Mutations in Neonates

S cientists used STAT-Seq, a whole genome sequencwith a sequencing machine, to cast a broad net over the 3,500 or so known genetic diseases and achieve results in time for physicians to make clinical decisions. The prototype was tested by doing retrospective 50-hour WGS on two children whose molecular diagnoses had already been done the conventional way. Then the scientists did tests on children not tested before, and confirmed the results by sequencing genomes of parents and siblings. The authors of the study, which was published on October 3, 2012, in the journal *Science Translational Medicine* concluded that rapid WGS can potentially broaden and foreshorten differential diagnosis, resulting in fewer empirical treatments and faster progression to genetic and prognostic counseling.

Lactate Concentrations Evaluated in Suspected Infections

The prognostic significance of incremental blood lactate concentrations among emergency department (ED) patients with suspected infection has been evaluated and categorized into low, intermediate, and high groups. The median initial lactate concentration was 2.1 mmol/L, and 459 out of 2596 (17.6%) subjects had an initial lactate greater than 4 mmol/L. Mortality continued to rise across the continuum of incremental elevations, from 6% for lactate greater than 1.0 mmol/L up to 39% for lactate 19-20 mmol/L. In the study published on August 20, 2012, in the journal *Academic Emergency Medicine*, the authors concluded that in ED patients with suspected infection, incremental elevations in whole blood lactate values up to 20 mmol/L are associated with progressive increases in mortality.

Gene Test Detects Early Mouth Cancer

A gene test that can detect precancerous cells in patients with benign-looking mouth lesions could potentially allow at-risk patients to receive earlier treatment. The test is less invasive than the standard histopathology methods, as it requires only a 1-2 mm piece of tissue and it takes less than three hours to get the results, compared to up to a week for standard histopathology. The test is based on a cancer gene encoding the Forkhead box protein (*FOXM1*) - (isoform B). The 14 associated genes are implicated in the regulation of the cell cycle, differentiation, aging, genomic stability, epigenetic and stem cell renewal. Two reference genes are included in the test. The study was published on October 4, 2012, in the journal *International Journal of Cancer*.

Serological Assays Assessed for Q Fever

 ${f T}$ he indirect immunofluorescence assay (IFA) is considered the reference method for diagnosing Q fever, but serology is also performed by complement fixation assay (CFA) or enzyme-linked immunosorbent assay (ELISA), however, comparability between these assays is not clear. The Q fever cases were confirmed either by a positive polymerase chain reaction (PCR) or by seroconversion. For the diagnosis of Q fever, all assays reached a specificity of 95% to 100% in the samples with an intended negative outcome. However, there were differences in sensitivity between the methods. The IFA (Focus Diagnostics, Cypress, CA, USA; www.focusdx.com) appears to be the method of choice when high sensitivity is required, for example, identifying chronic Q fever. The study was published on October 5, 2012, in the journal Diagnostic Microbiology and Infectious Disease.

Exosomes Infected with Prions Diagnostic for vCJD

Genetic sequencing enables scientists to discover cells infected with prions, the infectious agent responsible Creutzfeldt-Jakob disease (vCJD) and Bovine Spongiform Encephalopathy (BSE). Circulating exosomes released during prion infection have a distinct miRNA signature that can be utilized for diagnosis and understanding pathogenic mechanisms in prion disease. Exosomes are shed into blood, urine, and cerebrospinal fluid, forming a highly enriched source of intact, disease-specific nucleic acids. If the exosomes are infected with prions, they also carry a specific signature of miRNAs. The research was published in the September 2012 issue of Oxford University Press *Nucleic Acids Research*. The lead author of the study, Dr. Shayne Bellingham, said that the breakthrough might also help detect other human neurodegenerative diseases, such as Alzheimer's and Parkinson's.

Routine Blood Tests Gauge Liver Cancer Risk

E levated levels of two enzymes, alanine transaminase (ALT) and aspartate transaminase (AST), which are involved in producing amino acids, are an indicator of liver damage. A team of scientists divided study participants into two groups: the 130,533 who had known Hepatitis C (HCV) test results and the other 298,051. They found 1,668 cases of liver cancer. The researchers developed their risk prediction models by dividing each cohort in half, which allowed them to base the model on one set and then validate the model in the second set. The model that relied only on levels of the enzymes alanine transaminase (ALT) and aspar-

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tate transaminase (AST) predicted 91.2% of cancer cases. The study was published on October 16, 2012, in the *Journal of the National Cancer Institute*.

Molecular Assay Used to Diagnose Buruli Ulcer

quick and inexpensive diagnostic test can identify Mycobacterium ulcerans, the bacterium responsible for Buruli Ulcer (BU), and could replace the current laboratory diagnosis based on microscopy, which requires confirmation. Scientists employed the methodology based on the loop mediated isothermal amplification (LAMP) technique. The BU-LAMP assay was developed and tested on five M. ulcerans strains and two reference isolates. The assay was tested on other closely related, mycolactone-producing mycobacterial strains M. marinum, M. liflandii and M. pseudoshotsii, as well as experimentally infected laboratory animal and clinical samples. The results revealed a high specificity of the BU-LAMP assay for selectively detecting M. ulcerans. Compared to the conventional PCR, the new assay is cheaper, simpler, and ten times more sensitive. The study was first published online on January 12, 2012, in the journal BMC Infectious Diseases.



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NOVEMBER

Rare Cell Isolation Technique Improved

A technique, which does not rely on antibodies, allows an entire blood draw to be processed quickly. Scientists at the University of Cincinnati (OH, USA; <u>www.uc.edu</u>) used inertial microfluidics to continuously and selectively collect rare cells, such as circulating tumor cells, based on their size versus other biomarkers. The advantage of inertial microfluidics in cell separation is that it can be done easily, without cumbersome equipment. This type of work is leading to an entirely new generation of testing capabilities that lend themselves to direct use in the field and in physicians' offices in just about any country and economic setting. The study was reported at the Sixteenth International Conference on Miniaturized Systems for Chemistry and Life Sciences (microTAS) held October 28 to November 1, 2012, in Okinawa (Japan).

Shiga Toxin-Producing E. coli Directly Detected from Stool

A rapid diagnostic test, which combines the accuracy of an enzyme immunoassay with the speed and ease of use of a cassette, can detect Shiga toxin-producing *Escherichia coli* (STEC) directly from a stool specimen. The test offers significant advantages over other rapid cassette assays in that it removes the need for overnight bacterial culture preparation. Alere Inc., (Waltham, MA, USA; <u>www.alere.com</u>) received confirmation that the US Food and Drug Administration has cleared the TECHLAB (Blacksburg, VA, USA; <u>www.techlab.com</u>) Shiga Toxin Quik Chek test for the US market. The Shiga Toxin Quik Chek detects toxins from both O157 and non-O157 strains of *E.coli*.

Immunoassay Developed for Rapid Leptospirosis Diagnosis

rapid assay has been developed using immunodom-A rapid assay has been developed allog Dual Path Platform (DPP) for the diagnosis of leptospirosis. The assay was developed by Chembio Diagnostic Systems (Medford, NY, USA; www.chembio.com). The overall sensitivity for paired sera was 100% for severe and 73% for mild disease. In the acute phase of the infection, the assay achieved a sensitivity of 85% for severe and 64% for mild leptospirosis. The authors of the study published on November 1, 2012, in the journal Public Library of Science Neglected Tropical Diseases (PLoSNTD) concluded that the DPP assay performed acceptably well for diagnosis of severe acute clinical leptospirosis and can be easily implemented in hospitals and health posts where leptospirosis is a major public health problem.

Molecular Assay Diagnoses Neoehrlichiosis

A molecular assay has been developed to diagnose Neoehrlichiosis caused by *Candidatus* Neoehrlichia mikurensis, which is an emerging zoonotic disease. Scientists at the University of Zurich (Switzerland; <u>www.uzh.ch</u>) developed assay based on the signature sequence of a 282-bp fragment of the *Candidatus* N. mikurensis 16S ribosomal ribonucleic acid (rRNA) gene and incorporates a *Candidatus* N. mikurensis species, a *Neoehrlichia* genus and an *Anaplasmataceae* family probe for simultaneous screening. The assay was found to be suitable for the direct detection of *Candidatus* N. mikurensis DNA in clinical samples like blood and bone marrow. In addition, it allows for monitoring treatment response during antibiotic therapy. The study was published on October 31, 2012, in the *Journal of Clinical Microbiology*.

Exome Sequencing Detects Intellectual Disability

E xome sequencing can be used as a diagnostic assay to determine the genetic mutations that may explain why some patients suffer from significant limitations both in intellectual functioning and in adaptive behavior. A team of scientists at Radboud University (Nijmegen, The Netherlands; <u>www.ru.nl</u>) performed exome sequencing of patients with unexplained cognitive impairment, and uncovered 79 genes with unique de novo mutations. These de novo mutations were present in the DNA of the patients but not in that of their parents whose exomes also were sequenced. The diagnostic interpretation revealed that 16 of the 100 mutations were causative, or pathogenic. The results of this study were presented on November 8, 2012, at the American Society of Human Genetics meeting (<u>www.ashg.org</u>) held in San Francisco (CA, USA).

Improved Detection of Polyomavirus in Merkel Cell Carcinoma

 $T^{
m he}$ sensitivity of detection of Merkel polyomavirus (MCPyV) in Merkel cell carcinomas (MCC) has been improved, enabling high-confidence discrimination between virus-positive and virus-negative tumors. A team of scientists analyzed archival FFPE tissue samples of MCC tumor specimens obtained from patients. The newly developed monoclonal antibody Ab3 showed markedly increased sensitivity in detecting MCPyV large T antigen in 97% of MCC tumors tested. Additionally mutations in the gene tumor protein (TP53) were identified in the two tumors that lacked detectable MCPyV. The authors concluded that that the presence of MCPyV in MCC is more common than previously reported and that improved detection methods may reveal that all MCC specimens contain viral DNA. The study was published on November 1, 2012, in the Journal of Clinical Investigation.

Cervical Cancer Test Can Improve Early Detection

Immunological methods have been used to detect an oncoprotein associated with human papillomaviruses (HPV) that cause cervical cancer. Scientists at the University of Gothenburg (Sweden; <u>www.gu.se</u>) raised monoclonal antibodies against the E7 oncoprotein, which is an absolute prerequisite of malignant transformation and the protein is expressed at increasing levels during cancer development. Antibodies specific for the E7 protein of oncogenic HPV types were selected using immunological methods. Phage display was used to identify antibody epitopes thereby predicting and verifying antibody specificity. Two of the antibodies, recognizing HPV16 and HPV18 E7 demonstrated strong staining of dysplastic cell

DECEMBER

Serum Cortisol Predicts Death and Critical Disease

B iomarkers and prognostic scores were evaluated to predict prognosis in community-acquired pneumonia (CAP). Scientists measured the serum cortisol concentrations of hospitalized CAP patients and compared its prognostic accuracy to the leucocyte count, C-reactive protein levels, and the clinical prediction CRB-65 score. Serum cortisol levels on admission were significantly higher in nonsurvivors at a median of 870 nmol/L when compared to survivors at 602 nmol/L. In patients with critical pneumonia the median was 972 nmol/L compared with a median 598 nmol/L in patients with noncritical pneumonia. The authors of the study originally published in April 2012 in the Biomedical Central Journal *BMC Infectious Diseases* concluded that cortisol predicts mortality and critical disease in hospitalized CAP-patients independently of clinical scores and inflammatory biomarkers.

Molecular Test Detects Transrenal Cancer Mutations

The first molecular diagnostic test capable of detecting genetic mutations from a urine specimen has been successfully developed. The initial oncogene mutation tests will include V-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog (*KRAS*), V-raf murine sarcoma viral oncogene homolog B1 (*BRAF*) and phosphatidylinositol 3kinase (*PIK3CA*). Potential uses of this noninvasive technology include monitoring for recurrence of disease, determining response to therapy, and disease detection. The transrenal molecular diagnostic tests have been developed by Trovagene, Inc. (San Diego, CA, USA; <u>www.trovagene.com</u>). Transfer of the transrenal *KRAS* test to the company's Clinical Laboratory Improvement Amendments (CLIA) certified laboratory is expected soon and commercial availability foreseen shortly thereafter.

Blood Test Improves Prostate Cancer Detection

A simple blood test that is 2.5 times more specific in detecting prostate cancer than prostate-specific antigen test (PSA) has been officially approved. The Prostate Health Index (*phi*) noninvasive blood test is designed specifically for patients with PSA values in the 4–10 ng/mL range and is proven to reduce the number of prostate biopsies. The test provides an answer to the current PSA testing controversy, where prostate cancer screening to save lives has been weighed against over-diagnosis and over-treatment. The Prostate Health Index (Beckman Coulter, Brea, CA, USA; <u>www.beckmancoulter.com</u>) helps physicians distinguish prostate cancer from benign conditions. The results of *phis* multicenter clinical study showed a 31% percent reduction in unnecessary biopsies.

Serum Procalcitonin as Interstitial Pneumonia Diagnostic Marker

T he diagnostic and prognostic role of serum procalcitonin in patients with acute exacerbation of interstitial pneumonia has been appraised. Acute exacerbation of interstitial pneumonia (AE-IP) is defined as a lifethreatening deterioration of IP without identifiable cause and $\ensuremath{\bar{\text{the}}}$ role of serum procalcitonin has been evaluated for discriminating AE-IP from other lung diseases. Scientists evaluated the levels of serum procalcitonin (PCT) in consecutive patients admitted for AE-IP. Serum PCT levels in AE-IP were significantly lower with a mean of 0.62 ng/mL than in Acute Respiratory Distress Syndrome due to bacterial pneumonia (BP-ARDS) patients whose mean was 30.14 ng/mL or for patients BP with IP, where the mean was 8.31ng/mL. The authors concluded that serum PCT is a useful marker for discriminating between AE-IP and bacterial pneumonia, but not useful as a prognostic marker for survival. The study was published on December 5, 2012, in the journal Respirology.

Biofluid Ribonucleic Acid Isolation Kit Launched

A n isolation kit for the extraction of small ribonucleic acid (RNA) from serum, plasma, urine and other biofluids has been specifically optimized for such applications. The new biofluids kit allows scientists to obtain high quality microRNA from virtually all types of biofluids in just 45 minutes and the workflow is completed in six simple steps without the use of hazardous chemicals such as phenol and chloroform. The miRCURY RNA Isolation Kit – Biofluids (Exiqon; Vedbaek, Denmark; <u>www.exiqon.com</u>) is optimized to work with company's highly sensitive miRCURY LNA Universal real-time microRNA polymerase chain reaction (qPCR) platform. The Isolation Kit is ideal for use with urine samples together with Exiqon's Toxicology Focus microRNA PCR Panels, and for serum and plasma samples with the Serum/Plasma Focus microRNA PCR Panels.

Vitamin B12 Assays Could Be Missing Anemia

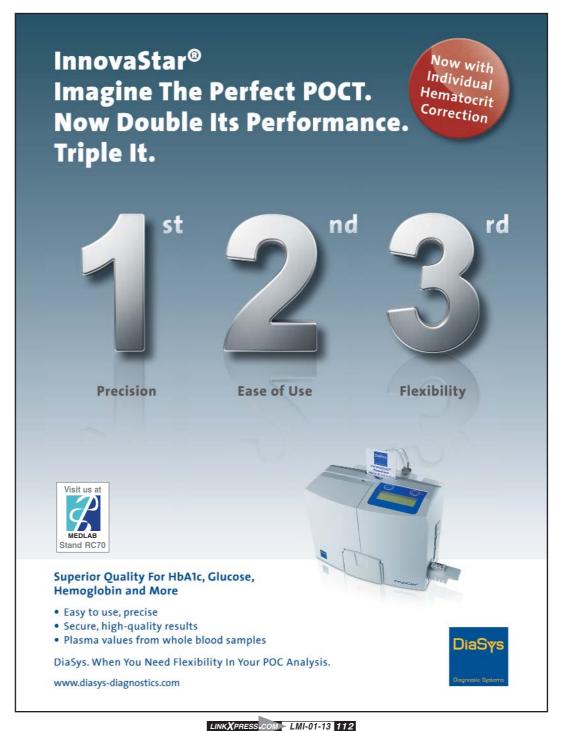
A new study suggests that newer competitive-binding luminescence assay (CBLA) tests for measuring cobalamin (vitamin B12) levels may miss over a third of pernicious anemia cases. Researchers used frozen serum samples obtained from 23 untreated pernicious anemia patients (15 with anti-intrinsic factor antibodies and 8 without). The results showed that the CBLAs showed false normal values in 6 of 23 (26%), 5 of 23 (22%), and 8 of 23 (35%) serum samples, respectively, as compared with a radioisotope-dilution assay; 5 of the serum samples failed with all three CBLAs. False normal results affected 33%–53% of positive serum samples for anti-intrinsic factor antibodies, but no serum samples that were negative

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for anti-intrinsic factor antibodies. The study was published on September 6, 2012, as a letter to the editor in the *New England Journal of Medicine (NEJM)*.

Immune Protein Levels Predict Hodgkin Disease Risk

 ${f T}$ he amount of an immunity-related protein in the blood of patients with newly diagnosed Hodgkin lymphoma reflected the extent of their cancer and correlated with other predictors of outcome. Antibodies have been developed that recognize the galectin-1 protein and were used in creating a sandwich enzymelinked immunosorbent assay (ELISA) as serum galectin-1 levels are significantly associated with tumor burden and additional adverse clinical characteristics in newly diagnosed Hodgkin lymphoma (HL) patients. Scientists tested the blood levels of galactin-1 in 315 patients, and found that by using the sandwich ELISA, the blood galectin-1 levels in Hodgkin lymphoma patients were significantly higher than in normal control patients. The study was presented at the 54th Annual Meeting of the American Society of Hematology held December 8-11, 2012, in Atlanta (GA, USA; www.hematology.org).



Industry News of 2012

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Signal Genetics Expands Oncology Pipeline

Signal Genetics (New York, NY, USA; <u>www.signal</u> <u>genetics.com</u>), a company focused on personalized medicine for cancer patients, purchased all the assets of ChipDX (New York, NY, USA; <u>www.chipdx.com</u>). As part of the transaction, Signal Genetics acquired BreastGeneDX, ColonGeneDX, and LungGeneDX, all diagnostic and prognostic tests in development by ChipDX. Ryan VanLaar, PhD, CEO, and founder of ChipDX, joined Signal as head of bioinformatics. Financial details of the transaction were not disclosed. The genetic tests represent novel products or improvements over other products currently on the market for lung, breast, and colon cancers.

BD Diagnostics Widens Microbiology Portfolio

B^D Diagnostics (Franklin Lakes, NJ, USA; <u>www.</u> <u>bd.com</u>) has acquired Kiestra (Drachtan, The Netherlands; <u>www.kiestra.nl</u>), expanding the company microbiology portfolio to include new automated instrumentation technologies, which will enable it to offer total lab automation solutions worldwide. Kiestra Lab Automation BV, which designs, develops, manufactures, and markets lab automation solutions for the microbiology lab, complements BD's microbiology portfolio of instruments, reagents, and supplies. Kiestra offers two lines of automated solutions: Total Lab Automation (TLA) and Work Cell Automation (WCA). Total Lab Automation is designed to significantly increase overall microbiology lab productivity, streamline workflow, and shorten the time to results. Kiestra's Work Cell solution offers customers a modular and scalable approach to automate their lab within current space and budget constraints.

Beckman Coulter Acquires Flow Cytometry Developer

Beckman Coulter Life Sciences (Indianapolis, IN, USA; <u>www.beckmancoulter.com</u>) has acquired Blue



Ocean Biomedical, LLC (Pembroke Pines, FL, USA; http://blueoceanbio.com), manufacturer of automated flow cytometry systems and reagents. The acquisition provides Beckman Coulter Life Sciences with low-complexity analyzers that integrate automated sample preparation and directly address emerging flow cytometrymarket trends. Driving growth through internal product development and through acquisition of differentiated businesses and technologies is a core strategy for Beckman Coulter Life Sciences. The transaction expands the company's flow cytometry line and targets routine clinical analyses. Blue Ocean Biomedical products complement the company's existing cytometry portfolio with instruments based on a "sample in, result out" (SIRO) approach that represents a fundamental change in the routine clinical analysis sector.

Beckman Parent Acquires IRIS International for USD 338 Million

Danaher Corp. (Washington DC, USA; <u>www.</u> <u>danaher.com</u>) acquired IRIS International, Inc. (Chatsworth, CA, USA; <u>www.proiris.com</u>) for about USD 338 million. The transaction was completed on October 31, 2012. Upon closing, IRIS became part of Danaher's Beckman Coulter Diagnostics business unit. Other life sciences brands of Danaher Corp. include Radiometer, Molecular Devices, and AB Sciex. IRIS is a manufacturer of automated in vitro diagnostics systems and consumables. IRIS is focused on products that analyze particles and living cell forms and structures, or morphology of a variety of body fluids. IRIS is expanding its core imaging and morphology expertise into related markets, including applications in hematology and body fluids.

Sysmex and Roche Extend Hematology Alliance

Sysmex Corporation (Kobe, Japan; <u>www.sysmex.co.</u> <u>ip/en</u>) and Roche (Basel, Switzerland; <u>www.roche.</u> <u>com</u>) signed a restated 10-year distribution, sales, and services agreement (DSS Agreement). Roche will continue to distribute Sysmex hematology products, including instruments, reagents, and data management solutions in selected countries and regions. These include Spain, Turkey, Greece, South Africa, Russia, Finland, Baltic Territory, Brazil, Mexico, Chile, Argentina, Uruguay, Colombia, Peru, Ecuador, Venezuela, Central America, Australia, and New Zealand. Since entering into the DSS Agreement in 1999, Sysmex and Roche have combined their mutual strengths to expand market share while building a positive relationship.

Distribution Agreement Between IL and Beckman Comes to an End

A fter over 20 years of successful collaboration, Instrumentation Laboratory (IL; Bedford, MA, USA; <u>www.instrumentationlaboratory.com</u>) announced the termination of the Strategic Alliance Cross-Distribution agreement of their Hemostasis product line with Beckman Coulter, Inc. (Brea, CA, USA; <u>www. beckmancoulter.com</u>). On June 23, 2012, IL initiated direct sale and support services in the USA and Canada for their own Hemostasis product line in order to improve the quality of their products and services and simplify lab operations. Ramon Benet, CEO, IL, said, "Now is the ideal time for us to apply our expertise, resources, and world-class service organization to working directly with our Hemostasis customers in North America, and focus on ensuring a smooth transition for our customers."

Thermo Fisher Acquires Transplant Diagnostics Leader

Thermo Fisher Scientific (Waltham, MA, USA; www.thermofisher.com) has completed on September 13, 2012, a previously announced agreement to acquire One Lambda (Canoga Park, CA, USA; www.onelambda.com) for USD 925 million in cash. One Lambda, a pioneer and global leader in transplant diagnostics, whose business generated revenues of USD 182 million in 2011, became part of Thermo Fisher's Specialty Diagnostics Segment. One Lambda develops its own transplant diagnostic tests utilizing serological, molecular, ELISA, flow, and Luminex xMAP technologies. The company also manufactures laboratory instrumentation and computer software that are used to simplify and automate testing procedures and final test evaluations. The transaction enhances Thermo Fisher's presence in specialty in vitro diagnostics as growth in transplant diagnostics is being driven by global demand.

Fresenius Kabi Buys Fenwal Holdings

Fresenius Kabi (Bad Homburg, Germany; <u>www.</u> <u>fresenius.com</u>) acquired Fenwal Holdings, Inc., (Lake Zurich, IL, USA; <u>www.fenwalinc.com</u>), a USbased provider of transfusion technology products for blood collection, separation, and processing from TPG (formally Texas Pacific Group) and Maverick Capital. The acquisition announced on July 20, 2012, was consolidated as of December 2012. The acquisition marks another major step in Fresenius Kabi's previous statement that expanding its medical devices/transfusion technology segment is a priority. Combining the two businesses will lead to a comprehensive product portfolio in transfusion medicine. Fresenius Kabi will now become a global leader in transfusion technology.

Hologic Completes Acquisition of Gen-Probe

Hologic (Bedford, MA, USA; <u>www.hologic.</u> <u>com</u>) has completed the acquisition of Gen-Probe (San Diego, CA, USA; <u>www.gen-probe.com</u>) for a net purchase price of USD 3.72 billion. Gen-Probe is a molecular diagnostics company with services used to diagnose human diseases, screen donated human blood, ensure transplant compatibility, and aid biomedical research. The acquisition will allow Hologic to expand its growing diagnostics products and services business. Hologic, Inc. is a developer, manufacturer, and supplier of diagnostic products, medical imaging systems, and surgical products. The company operates four core business units focused on breast health, diagnostics, GYN surgical, and skeletal health.

Leica Biosystems Acquires ePathology Systems Provider

Leica Biosystems (Nussloch, Germany; <u>www.</u> <u>leicabiosystems.com</u>) completed the acquisition of Aperio (Vista, CA, USA; <u>www.aperio.com</u>) a provider of ePathology solutions, finalizing on October 24, 2012, the agreement originally announced in August 2012. Aperio will be integrated into Leica Biosystems and the two businesses will leverage each other's strengths to grow and expand digital pathology into the global Life Science and Healthcare markets. The integrated business will provide solutions in each step of the anatomical pathology workflow, from sample preparation and staining, to imaging and reporting. The company will continue to offer both the Aperio and the existing Leica portfolio of Digital Pathology solutions.

ALPHABETICAL LISTING OF COMPANIES



77 Elektronika

Hungary • Budapest Tel: (36) 1-481-0139 Web: www.e77.hu E-mail: sales@e77.hu

Develops, manufactures, and markets fully automated and semiautomated urine test strip readers and microscopic urine sediment analyzers, blood glucose meters and their consumables under own brand name, as well as OEM products for market-leading multinational companies.

AADEE

Argentina • Buenos Aires Tel: (54) 11 45234848 Web: www.aadee.com

Manufactures, exports/imports medicine and biochemistry items. Products include the Automatic pH Blood Gas Analyzer, the AADEE-ZEN model and a fully automatic selective ION analyzer "AADEE-ZEN" ISE that has the capability to measure Na, K, Cl, and Ca.



AB Sciex

USA • Foster City, CA Tel: (1) 877-740-2129 Web: www.absciex.com E-mail: support@absciex.com Develops scientific instrumentation, software, and services used to discover new drugs, and advance medical science. ► SEE AD ON PAGE 35

Abaxis

USA • Union City, CA Tel: (1) 510-675-6500 Web: www.abaxis.com E-mail: abaxis@abaxis.com

Produces point-of-care blood analyzers for both humans and animals. The analyzers are designed to be portable, require minimal training, provide on-the-spot results and offer built-in quality control and calibration. Abaxis markets the system under the name Piccolo in the human medical market and under the name VetScan in the veterinary market.

Abbott Diagnostics

USA • Abbott Park, IL Tel: (1) 847-937-6100 Web: www.abbott.com Provides in vitro diagnostics, instrument systems, and tests. Products offer diagnostic solutions in immunochemistry, hematology, automation, molecular and remote diagnostics.

AbD Serotec

UK • Oxford Tel: (44) 1865-852-700 Web: www.abdserotec.com

Labhedica World's IN VITRO DIAGNOSTICS COMPANIES

E-mail: sales.uk@abdserotec.com Develops and manufactures antibodies, immunological reagents, and custom monoclonal antibodies, as well as offering largeand small-scale antibody production and conjugation services.

ABS Advanced Biomedical Systems

Italy • Milan Tel: (39) 2-925-904-41 Web: www.absdiag.com E-mail: info@absdiag.com Focuses mainly on supplying diagnostic products, rapid test (IVD) kits and instruments to pediatric offices.

AccuBio Tech

China • Beijing Tel: (86) 10-6205-8220 Web: www.accubiotech.com E-mail: sales@accubiotech.com Develops and manufactures in vitro rapid diagnostic tests. Products include tests for pregnancy, infectious diseases, sexually transmitted diseases, fecal occult blood, tumor markers, drugs of abuse, blood glucose, and urine reagent strips.

Acon Laboratories

USA • San Diego, CA Tel: (1) 858-875-8000 Web: www.aconlabs.com E-mail: info@aconlabs.com Provides rapid diagnostic products. The product line includes items for fertility, urine drugs of abuse, multidrug tests, oral fluid drugs of abuse, cotinine, urine adulteration, infectious disease, cardiac and tumor markers. Recently added products include a blood glucose monitoring system, urinalysis reagent strips, thermometers, and blood pressure monitors.

Adaltis

Italy • Rome Tel: (39) 0774-5791 Web: www.adaltis.net E-mail: info@adaltis.net Develops, manufactures, and markets in vitro diagnostic systems and reagent products to detect viral infections, diagnose

ucts to detect viral infections, diagnose immune system diseases, and measure human hormone responses.

Adam Equipment

UK • Milton Keynes, Buckinghamshire Tel: (44) 1908-274-545 Web: www.adamequipment.com E-mail: sales@adamequipment.co.uk Manufactures and distributes a complete range of balances and scales for medical, laboratory, education, and industrial markets.

Advanced Biotechnologies

USA • Columbia, MD Tel: (1) 410-792-9779 Web: www.abionline.com Specializes in the manufacture and development of products and services for the

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Advanced

Instruments USA • Norwood, MA Tel: (1) 781-320-9000 Web: www.aicompanies.com E-mail: info@aicompanies.com Supplies instrumentation for clinical, pharmaceutical, biotechnology, microbiology, and food laboratories. Primarily known for the application of freezing-point depression technology, current products have expanded to also include cytology, infrared, and image analysis.

SEE AD ON PAGE 32

Aeon Technology China · Shenzhen Tel: (86) 755-8618-2140 Web: www.aeon-med.com E-mail: raymond@aeon-med.com Designs and produces clinical diagnostic equipment, as well as containers and disposables.

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mail@globescientific.com

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www.aeschemunex.com E-mail: contact@

aeschemunex.com

Manufactures and markets a comprehensive range of tests, rapid analyzers, and lab automation equipment for microbiology laboratories, including culture media, and media preparation equipment.

AESKU Diagnostics

Germany • Wendelsheim Tel: (49) 6734-9627-0 Web: www.aesku.com E-mail: info@aesku.com Distributes ELISA kits for diagnostics of autoimmune diseases, including the AESKULISA product line. The main indications are rheumatology, antiphospholipid syndrome (APS), vasculitis, gastroenterology, hepatology, and diabetes.

Affinity Biologicals

Canada • Ancaster, ON Tel: (1) 905-304-9896 Web: www.affinitybiologicals.com E-mail: info@affinitybiologicals.com

Manufactures antibodies, purified proteins, control plasmas, calibrator plasmas, ELISA kits, and factor-deficient plasmas prepared by immunoaffinity chromatography.

Agappe Diagnostics Switzerland

Switzerland • Cham Tel: (41) 41-780-60-10 Web:

www.agappeswiss.com E-mail:

info@agappeswiss.com Manufactures products and immunoturbidimetry reagents for clinical chemistry, serology, serum protein, coagulation, and HbA1c analyzer.

Alere

USA • Waltham, MA Tel: (44) 1234-759900 Web: www.alere.com Develops rapid point-of-care diagnostics that focus on infectious disease, cardiology, oncology, drugs of abuse, and women's health.

Alfa Scientific Designs

USA • Poway, CA Tel: (1) 858-513-3888 Web:

www.alfascientific.com E-mail:

info@alfascientific.com Develops and manufactures rapid in vitro diagnostic devices to serve the pointof-care marketplace. The company focuses on rapid immunoassays including those for the detection of drugs of abuse, fertility hormones, infectious diseases, cardiac and cancer markers.

Alfa Wassermann

Netherlands • Woerden Tel: (31) 348-487-300 Web:

www.alfawassermann.com E-mail: office@alfawassermann.nl

Develops and manufactures instruments and products designed for use in diagnostic applications in clinical chemistry laboratories.

Alifax

Italy • Padua Tel: (39) 49-099-2000 Web: www.alifax.com E-mail: info@alifax.com Specializes in diagnostics, and offers the biotechnology field a diagnostic as well as a medical line, along with laboratory equipment and disposables.

All.Diag

France • Strasbourg Tel: (33) 3 88 78 80 88 Web: www.alldiag.com E-mail: info@alldiag.com Specializes in the development and the distribution of rapid diagnostic tests, both in the human and veterinary fields.

American Biochemical & Pharmaceuticals

UK • London Tel: (1) 856-988-5492 Web: www.abpcorp.com E-mail: pbyrne@abpcorp.com Develops, manufactures, and markets products necessary for hemostasis, thrombosis, and platelet function.



Ameritek USA

USA · Everett, WA Tel: (1) 425-379-2580 Web: www.ameritek.org E-mail: info@ameritek.org Develops and manufactures rapid test kits for point-ofcare markets and ELISA kits for laboratories. The test kits are used to detect a number of conditions such as pregnancy, ovulation, various infectious diseases, tumors, allergies, drugs of abuse, heart, kidney, and liver functions. SEE AD ON PAGE 19

AMS

Italy • Rome Tel: (39) 0774-354441 Web:

www.ams-analyzers.com E-mail:

info@ams-analyzers.com Produces and exports automatic analyzers for clinical chemistry and nephelometric assays, with a wide range of products that fully adapts to the needs of different sized laboratories.

Analyticon Biotechnologies Germany • Lichtenfels

Tel: (49) 6454-7991-0 Web: www.analyticon-diagnostics.com E-mail:

info@analyticon-diagnostics.com Specializes in complete system solutions for small- to medium-sized labs, including analyzers, reagents, controls, and calibrators. Product lines focus on clinical chemistry, hematology, coagulation, and urinalysis.

Ani Labsystems Finland • Vantaa

Tel: (358) 20-155-7530 Web: www.anilabsystems.com E-mail: sales@anilabsystems.com Develops and manufactures diagnostic kits for clinical and research laboratories including high-quality EIA kits for various infectious diseases, neonatal screening, and other disorders.



Apel

Apex Biotechnology

Taiwan • Hsinchu Tel: (886) 3-564-1952

Web: www.apexbio.com

Manufactures surgical and medical instruments, as well as being involved in the development and production of testing products for blood glucose, cholesterol, hemoglobin, and blood uric acid.

Argutus Medical

An EKF Diagnostics Company Dublin • Ireland Tel: (353) 1-670-8576 Web: www.argutusmed.com E-mail: info@argutusmed.com Develops and manufactures ELISAs and rapid tests for detection of acute injury to the kidney and liver, as well as offering a range of additional assays and antibodies.

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Arista Biologicals

USA • Allentown, PA Tel: (1) 484-223-0309 Web: www.aristabiologicals.com E-mail: info@aristabiologicals.com Designs, develops, manufactures and markets reagents for the rapid diagnostic test industry. Reagents produced are used in rapid tests for pregnancy, drug abuse, infectious diseases, etc. Custom applications include tumor markers and other disease state applications.

Artel

USA • Westbrook, ME Tel: (1) 888-406-3463 Web: www.artel-usa.com E-mail: info@artel-usa.com Focuses on improving process productivity and quality by providing easy-touse systems for validating liquid delivery performance.

Astech

Japan • Tokyo Tel: (81) 03-3366-0811 Web: www.astechcorp.co.jp Designs and produces scientific instruments such as generators and microprocessor-controlled matching network products.

Astra Biotech

Germany • Luckenwalde Tel: (49) 3371-681-450

Web: www.astrabiotech.de E-mail: info@astrabiotech.de Offers a wide range of reagents and diagnostic kits for detection of human hormones, genetic diseases, tumor markers, and allergens.

Atlas Link

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USA • Manassas, VA Tel: (1) 703-366-3851 Web: www.atlaslink-inc.com E-mail: info@atlaslink-inc.com Manufactures IVD test kits and supplies generic and branded pharmaceuticals, medical disposables, medical and laboratory equipment, and blood glucose and cholesterol monitoring products.

LabMedica 300

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E-mail:

Pharmaceutical

Tel: (82) 70-8250-7839

www.asanpharm.co.kr

global@asanpharm.co.kr

Offers diagnostic products

such as DNA chip and protein chip. The company

plans to develop vaccines for HBV, HCV, and also new

drugs for hepatitis.

Audit Diagnostics

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Tel: (353) 21-453-3652

www.auditdiagnostics.ie

info@auditdiagnostics.ie

Provides clinical chemistry

reagents and analyzers.

Products include a range of

liquid ready-to-use reagents for all types of routine analyzers from semiautomated

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Express range of Analyzers.

Autobio

Autobio Diagnostics

Tel: (86) 371-6798-5313

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Develops and manufactures

clinical diagnostic products

including ELISA, chemiluminescence immunoassays,

microbiology, and POCT.

SEE AD ON PAGE 5

AutoGenomics

Tel: (1) 760-477-2251

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Provides automated micro-

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that can be used to assess disease signatures with ge-

nomic and proteomic markers in the area of genetic disor-

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analyzers, microplate readers and washers, along with the ChemWell automated

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UK • Dundee Tel: (44) 1382-422-000 Web: www.axis-shield.com E-mail: shield@axis-shield.com

Develops and manufactures in vitro tests. Recent attention was given to more effective testing at point-of-care, along with existing products for risk assessment of cardiovascular and neurological disease.

BBInternational

UK • Cardiff Tel: (44) 2920-747232 Web: www.bbigold.com E-mail: info@bbigold.com Supplies diagnostic and therapeutic reagents and conjugates, gold and silver labeling of proteins and oligonucleotides, as well as quality control sera for molecular diagnostic tests.

BD Diagnostics

USA • Franklin Lakes, NJ Tel: (1) 201-847-6800 Web: www.bd.com Manufactures and sells medical supplies, devices, laboratory equipment, and diagnostic products.

Beckman Coulter

USA • Brea, CA Tel: (1) 714-993-5321 Web:

www.beckmancoulter.com Manufactures biomedical testing instrument systems, tests and supplies that simplify and automate laboratory processes.

Bel-Art Products

USA • Wayne, NJ Tel: (1) 800-423-5278 Web: www.belart.com E-mail:

salesdept@belart.com Manufactures and distributes a wide variety of labware items. Manufacturing capabilities include injection, blow, vacuum and rotomolding, plastic and metal machining and fabrication, wire forming, and custom coating.

Berthold Technologies

Germany • Bad Wildbad Tel: (49) 7081-177-0 Web: www.berthold.com E-mail: info@berthold.com Offers a broad line of bioanalytical instruments including gamma counters, luminometers, flurometers, imaging systems, and HPLC detectors.

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France • Paris Tel: (33) 1 39 30 60 00 Web: www.bertin.fr Focuses on laboratory instrumentation and equipment including sample preparation, PLC for clinical diagnosis and food safety, and medical devices.

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I KM-DU53Y1E (526 pared to MDF-U53V at value -80°C, 23°C no load, 230V 50Hz, n. Actual energy use rings will depend on perating conditions.



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Korea • Uiwang Tel: (82) 70-7791-3034 Web: www.biofocus.co.kr E-mail: info@biofocus.co.kr Manufactures products for IVD and point-ofcare testing.



Bio-Rad Laboratories

USA • Hercules, CA Tel: (1) 510-724-7000 Web: www.bio-rad.com E-mail: diagcs@bio-rad.com Provides a full range of instrumentation, reagent kits, software and quality control systems to clinical laboratories. Areas of expertise include autoimmune, infectious disease, diabetes monitoring, hemoglobin screening, quality control, HIV, and hepatitis testing. ► SEE AD ON PAGE 17

Bio-Tek Instruments

USA • Winooski, VT Tel: (1) 802-655-4740 Web: www.biotek.com E-mail: sales@biotek.com Developer and supplier of microplate instrumentation and software solutions used in drug discovery, genomics and proteomics, and life science research.

BioAssay Works

USA • Ijamsville, MD Tel: (1) 301-874-8888 Web: www.bioassayworks.com E-mail: sales@bioassayworks.com Offers gold sol nanoparticles (10 to 50 OD), gold conjugates, and rapid assay development services, including custom conjugation.

Bioer Technology

China • Hangzhou Tel: (86) 571-8777-4575 Web: www.bioer.com.cn E-mail: overseas@bioer.com.cn Focuses on researching and manufacturing high-tech products for life science applications including instrumentation, related reagents, disposables, general lab equipment, and temperature baths.

Biohit HealthCare

Finland • Helsinki Tel: (358) 9-773-861 Web: www.biohithealthcare.com

E-mail: cs@biohit.fi

Develops, manufactures, and markets liquid handling products and accessories, as well as diagnostic test systems. Products include test kits based on the enzyme immunoassay (EIA) method and monoclonal antibodies for the screening of diseases; and microplate readers and washers.

Biokit

Spain • Barcelona Tel: (34) 93-860-9000 Web: www.biokit.com E-mail: biokit@biokit.com *Researches, manufactures and distributes clinical diagnostics reagents. Products include coagulation, and blood gas reagents.*

Biolabo

France • Maizy Tel: (33) 323 25 15 50 Web: www.biolabo.fr E-mail: info-societe_@_biolabo.fr Produces reagents and offers a comprehensive range of kits for biochemistry, coagulation and specific proteins. The company also produces polyvalent QC Sera and multicalibrators for biochemistry.

Biologix Research Company

USA • Lenexa, KS Tel: (1) 913-648-8575 Web: www.biologixgroup.com E-mail: ellen@biologixgroup.com Manufactures and supplies high-quality plastic laboratory supplies including containers, disposables, pipettes, and liquid handling systems.



Biomat

Italy • Rovereto Tel: (39) 0464 443320 Web: www.immunosurface.com E-mail: biomat@tin.it Manufactures microplates for immunoassays and research, with a wide range of surfaces. The company also offers surface modification services for biomedical applications.

Biomedical Polymers

USA • Gardner, MA Tel: (1) 978-632-2555 Web: www.biomedicalpolymers.com E-mail: sales@biomedicalpolymers.com Manufactures plastic consumables for research and medical diagnostic laboratories.

Biomerica

USA • Irvine, CA Tel: (1) 949-645-2111 Web: www.biomerica.com E-mail: bmra@biomerica.com Develops, manufactures, and sells products designed to detect diseases in the areas of cancer, cardiology, fertility, gastroenterology, diabetes, allergy, and infectious diseases.

BioMerieux

France • Marcy l'Etoile Tel: (33) 4-7887-2000 Web: www.biomerieux.com Designs, develops, manufactures and markets in vitro diagnostics systems used in clinical and industrial applications.

BioPorto Diagnostics

Denmark • Gentofte Tel: (45) 4529-0000 Web: www.bioporto.com E-mail: info@bioporto.com Focuses on diagnosis and monitoring of critically ill patients by means of analyses suitable for point-of-care (POC) testing.

BioSampling Systems

France • Paris Tel: (33) 1-34-30-42-00 Web: www.biosamplingsystems.com E-mail: marketing@biosamplingsystems.com *Provides full sample management solutions such as software, automates, readers, accessories, and consumables for pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, and research institutions.*

Biosearch Technologies

USA • Novato, CA Tel: (1) 415-883-8400 Web: www.biosearchtech.com E-mail: info@biosearchtech.com Designs and manufactures nucleic acidbased products that accelerate the discovery and application of genomic information.

Biosigma

Italy • Cantarana Di Cona Tel: (39) 4-2630-2224 Web: www.biosigma.com E-mail: magazzino@biosigma.com Specializes in the production of optical multisample cuvettes and cups, as well as a wide range of disposable labware.

Biosino Bio-Technology & Science

China • Beijing Tel: (86) 10-6972-2840 Web: www.zhongsheng.com.cn E-mail: biosino@zhongsheng.com.cn Develops, manufactures, and markets clinical chemistry reagents. Products include one-step rapid test kits, clinical chemistry reagent kits, as well as immunology reagent kits.



BioSystems

Spain • Barcelona Tel: (34) 93-311-0811 Web: www.biosystems-sa.com Develops and manufactures reagents and instruments for clinical analysis.

Biotech Company of China

China • Nanchang Tel: (86) 791-8816-8999 Web: www.biotech.com.cn E-mail: overseas@biotech.com.cn *Provides a range of diagnostic instruments and reagents for medical and clinical applications.*

Biotecnica Instruments

Italy • Rome Tel: (39) 6-411-2316 Web: www.biotecnica.it E-mail: bt@biotecnica.it

Designs and manufactures standard and OEM clinical chemistry equipment and relevant reagent products intended for private and state clinical laboratories including photometers, automatic analyzers, and ion selective analyzers.

Biotrin International

Ireland • Dublin Tel: (353) 1 283 1166 Web: www.biotrin.com E-mail: info@biotrin.ie

Develops and manufactures biomarker assays used in drug development, toxicology, clinical trials, diabetes, hepatitis monitoring, and transplantation. The Smartassays range enables renal and hepatic effects to be identified earlier and at lower doses of test substance.

Biotron Diagnostics

USA • Hemet, CA Tel: (1) 951-658-7766 Web: www.biotrondiagnostics.com E-mail: sales@biotrondiagnostics.com Develops and manufactures a complete line of kits and reagents for IVD.

Block Scientific

USA • Bohemia, NY Tel: (1) 631-589-1118 Web: www.blockscientific.com E-mail: info@blockscientific.com Provides reconditioned laboratory equipment as an alternative to purchasing new. Areas of specialty include blood gas, electrolyte, chemistry and hematology, with products such as consumables, parts, reagents, and technical service also available.

Blue Cross Bio-Medical

China • Beijing Tel: (86) 10-6975-6015 Web: www.bcbmcn.com E-mail: export@bcbmcn.com Manufactures in vitro rapid test kits. Main products include the test strips and cassettes for fertility, hepatitis B&C, drugs of abuse, infectious diseases, tumor marker, and sexually transmitted diseases.

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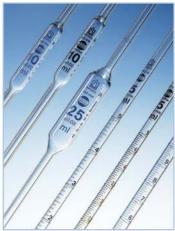
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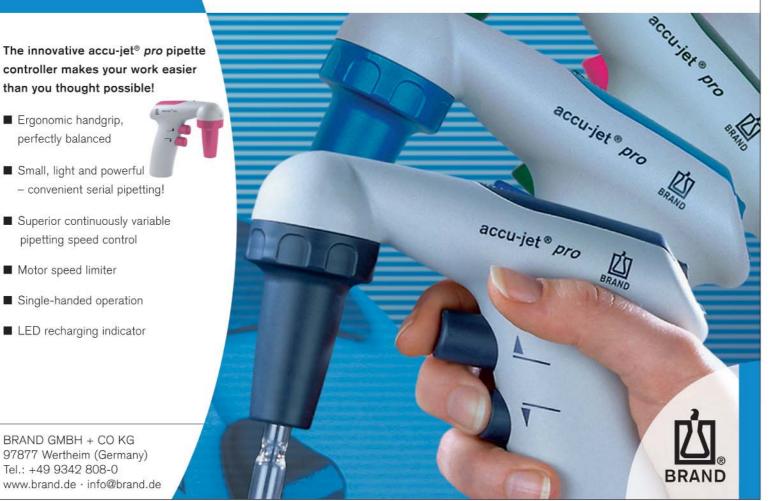
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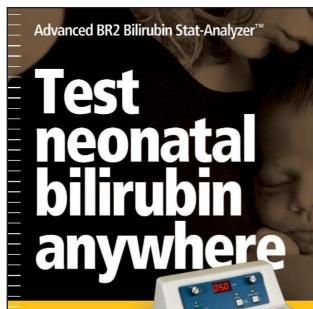
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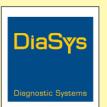


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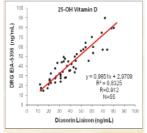
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USA · Cypress, CA Tel: (1) 562-240-6500 Web: www.focusdx.com Develops and provides specialized testing services, diagnostic products and anti-infective surveillance and consultative services for the diagnosis, treatment and management of infectious diseases.

Fosun Diagnostics

China · Shanghai Tel: (86) 21-6076-5718 Web: www.fosun-diagnostics.com E-mail: shengli@fosunpharma.com Develops and markets in vitro diagnostic products including real-time quantitative PCR detection systems, microbiology ID and AST systems, clinical chemistry reagents and analyzers, and urine strips and analyzers

Fujirebio Diagnostics

USA · Malvern. PA Tel: (1) 610-240-3800 Web: www.fdi.com E-mail: customerservice@fdi.com Manufactures monoclonal antibodies designed to detect a variety of tumor markers. These antibodies have also been used to help develop a menu of in vitro diagnostic tests.

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Taiwan • Taipei Tel: (886) 2-2553-1456 Web: www.gemmy.com.tw E-mail: gemmy888@gemmy.com.tw Manufactures laboratory equipment, suction units, autoclaves/sterilizers, and ENT treatment units.

GeneReach Biotechnology

Taiwan • Taichung City Tel: (886) 4-2463-9869 Web: www.genereach.com E-mail: sales@genereach.com Manufactures and markets products for applied nucleic acid detection technology, including equipment and reagents, as well as diagnostic kits for the point-of-care market.

Genius Electronics

China · Shenzhen Tel: (86) 755-2683-5560 Web: www.geniusmedica.com E-mail: international@geniusmedica.com Designs and produces medical instruments focused on medicine inspection.

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USA · Carlsbad, CA Tel: (1) 760-448-4300 Web: www.genmarkdx.com E-mail: info@genmarkdx.com Provides cost-effective molecular diagnostic technologies and tools that enable a broader range of hospitals and laboratories to offer molecular diagnostic services for improved patient care.

GenoID

Hungary • Budapest Tel: (36) 1-465-01-24 Web: www.genoid.net E-mail: info@genoid.hu Focuses on HPV diagnostics research, offering a real-time PCR test that detects all 14 high-risk HPV types in one reaction.

Getein Biotechnology

China • Nanjing Tel: (86) 25-6856-9011 Web: www.bio-gp.com.cn E-mail: biogetein.overseas@hotmail.com Develops and manufactures a range of rapid test kits for disease detection, as well as quantitative immunoassay analyzers.



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USA · Paramus, NJ Tel: (1) 201-599-1400 Web: www.globescientific.com E-mail: mail@globescientific.com Specializes in laboratory plasticware, glassware, and benchtop equipment. The company also offers a complete line of pipette tips, cen-trifuge tubes, serological pipettes and pipettors for the biotechnology market. The newest product lines include one-piece plastic serological pipettes, lot-certified cryogenic tubes with leak-proof caps, borosilicate glass culture tubes, and white glass microscope slides. SEE AD ON PAGE 25

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Italy • Arcore Tel: (39) 039 6882252 Web: www.glysby.com E-mail: bidoli@glysby.com Offers OTC diagnostic tests for home- and self-testing. Products also include tests for professional use including ELISA tests, biochemistry kits, and instruments.



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Web: www.goldsite.com.cn E-mail: marketing@goldsite.com.cn Specializes in producing serum protein assaying instruments and reagents, including Nephstar and Nephstar Plus protein analysis system, along with up to 30 kits for determining specific proteins.

Gongdong Medical Technology

China • Taizhou Tel: (86) 576-8408-2905 Web: www.chinagongdong.com E-mail: jim@chinagongdong.com Manufactures and distributes disposable medical and lab consumables.

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test.

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USA • Pompano Beach, FL Tel: (1) 954-979-3845 Web: www.healthchemdiagnostics.com E-mail: info@ healthchemdiagnostics.com Manufactures diagnostic tests for clinical chemistry, POC, immunology, microbiology,

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Humasis

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Hycor Biomedical

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Immuno Concepts

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Immunodiagnostic Systems

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Inova Diagnostics

USA • San Diego, CA Tel: (1) 858-586-9900 Web: www.inovadx.com Focuses on autoimmune disease diagnostics and offers autoimmune testing reagents. The autoimmune product groups include kits and components for testing for connective tissue disease, coagulation, gastrointestina disorders, vasculitis, endocrine, autoimmune liver disease, and related infectious disease.

Institute of Isotopes

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Instrumentation Laboratory USA • Bedford, MA Tel: (1) 781-861-0710

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E-mail: customerservice@ilww.com Offers a complete line of systems, instruments, reagents and specialty kits for critical care, blood gas, and coagulation testing.

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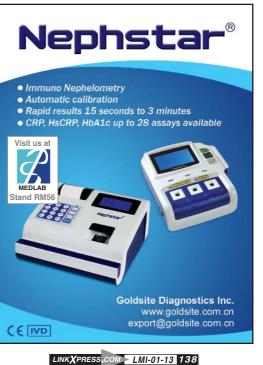
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nostic reagents, the production of laboratory information software, and the import and distribution of in vitro diagnostics and automated analytical systems.

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Finland • Kauniainen Tel: (358) 9-547-680 Web: www. medixbiochemica.com E-mail: medix@ medixbiochemica.com Develops, produces, and markets in vitro immunodiagnostic raw materials. as well as point-of-care tests for human healthcare. The product line is the Medix-MAB line that includes monoclonal antibodies (e.g., infertility, tumor marker, thyroid, cardiac, serology, and infectious fields).

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relassay@relassay.com Designs and distributes medical and laboratory disposable equipment.

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Italy • Florence Tel: (39) 55-56801 Web: www.menarini.com Focuses on the research and development of diagnostic drugs that target cardiovascular diseases, oncology, and pain/inflammation, asthma.

Meridian Bioscience

USA • Cincinnati, OH Tel: (1) 513-271-3700 Web: www.meridianbioscience.com E-mail: mbi@ meridianbioscience.com

Develops, manufactures, and markets immunodiagnostic kits for the diagnosis of infectious diseases.

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Micro Lab Instruments

India • Ahmedabad, Gujarat Tel: (91) 79-2658-5919 Web: www.microlab.co.in E-mail: info@microlab.co.in

Manufactures clinical chemistry analyzers, ELISA readers and plate washers, dry bath incubators, blood mixers, and single- and dualchannel coagulometers.

MicrobioLogics

USA • St. Cloud, MN Phone: (1) 320-253-1640 Web:

www.microbiologics.com Email:

info@microbiologics.com Produces lyophilized microorganisms for quality control in microbiology laboratories worldwide. The company specializes in clinical, industrial, food quality, environmental and educational markets, and offers over 3,000 items in the product line with more than 500 different lyophilized microorganism strains.

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Provides clinical laboratory equipment, clinical chemistry analyzers, hematology analyzers, coagulation analyzers, analytical lab equipment, biotechnology equipment, and diagnostic imaging equipment.

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UK • Alva, Scotland Tel: (44) 1259-763-030 Web: www.omegadiagnostics.com E-mail: odl@omegadiagnostics.com Develops and manufactures IVD products, specializing in the areas of allergy, food intolerance, autoimmune disease, and infectious disease.



Operon

Spain • Cuarte de Huerva Tel: (34) 976-50-3597 Web: www.operon.es E-mail: sales@operon.es Focuses on research, development, manufacturing and sales of in vitro diagnostics products.

SEE AD ON PAGE 43

OraSure Technologies

USA • Bethlehem, PA Tel: (1) 610-882-1820 Web: www.orasure.com Develops, manufactures and markets oral fluid specimen collection devices, as well as diagnostic products including immunoassays and in vitro diagnostic tests.

Orgentec Diagnostika

Germany • Mainz Tel: (49) 6131-9258-0 Web: www.orgentec.com E-mail: orgentec@orgentec.com Focuses on the development and production of autoimmune ELISA test systems.

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Finland • Espoo Tel: (358) 10-4261 Web: www.oriondiagnostica.fi Specializes in rapid and easy-to-use clinical diagnostic and hygiene-monitoring products.

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Switzerland • Plan-les-Ouates Tel: (41) 22-884-90-90 Web: www.orphee-medical.com E-mail: contact@orphee-medical.com Develops and markets instrumentation for the hematology diagnostic market, addressing the needs of small and mid-sized laboratories, as well as physician offices.

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USA • Auburn, WA Tel: (1) 800-728-4146 Web: www.peripheralvisions.com E-mail: orders@peripheralvisions.com Manufactures Perphormax replacement parts for clinical chemical analyzers and rebuilds or refurbishes Hitachi and Beckman clinical chemistry analyzers.



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USA • Charlottesville, VA Tel: (1) 434-293-8180 Web: phthisisdiagnostics.com E-mail: overseas@perlong.com.cn Develops and manufactures a wide range of diagnostic products and reagents for use in molecular-based diagnostic assays, point-ofcare tests, and environmental pathogen testing applications.

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Quantimetrix

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R-Biopharm

Germany • Darmstadt Tel: (49) 6151-8102-0 Web: www.r-biopharm.com E-mail: info@r-biopharm.de Develops, produces and markets enzyme immunoassays for the detection of human infectious diseases. The product line contains test systems in the field of stool diagnostics, infectious disease, serology, and allergy testing.

Radim

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E-mail: info@rayto.com

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USA • San Antonio, TX Tel: (1) 210-699-8800 Web: www.sascientific.com E-mail: sales@sascientific.com Focuses on rapid diagnostic tests for infectious and bacterial diseases, as well as food microbiology, veterinary testing, and environmental testing.

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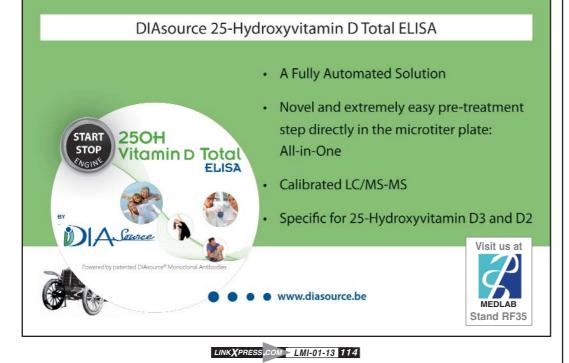
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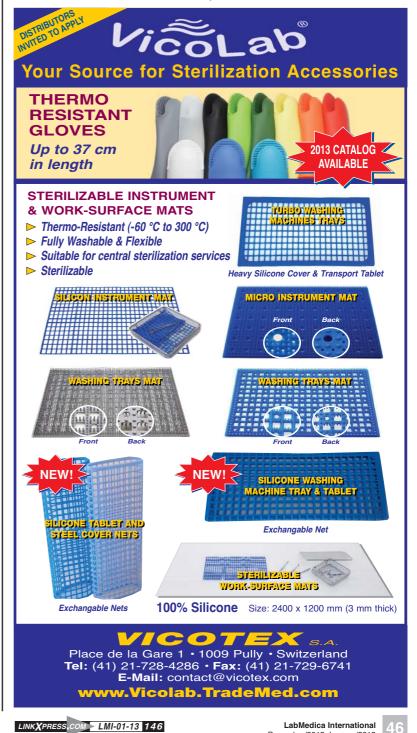
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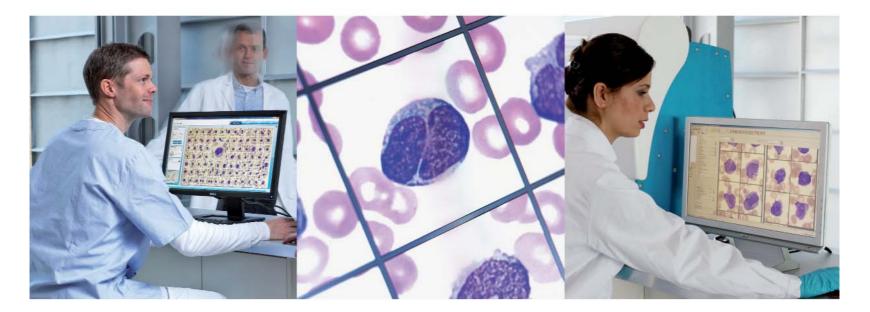
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