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LabMedica INTERNATIONAL

Blood Test for Early Detection of Lung Cancer

A blood test has been made available for the early detection of lung cancer, addressing the need for a widely useable early detection protocol for asymptomatic patients. The test detects a panel of protein biomarkers in the blood that are associated with early lung cancer and will be initially

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Fresh Guidelines Issued for Red Blood Cell Transfusion

Wide variability in the use of transfusions in the United States indicates that in many settings patients are receiving unnecessary transfusions.

Evidence shows no difference in mortality, ability to walk independently, or length of hospital stay between patients on a liberal transfusion strategy or a restrictive strategy of red blood cell transfusions.

The AABB (formerly known as the American Association of Blood Banks, Bethesda, MD, USA; www.aabb.org), has recently updated its guidelines for a red blood cell transfusion strategy for

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Simple Test Predicts Sickle Cell Severity

A simple blood test has been devised that can predict whether sickle cell patients are at high risk for painful complications of the disease.

The device measures how well blood samples flow through a microfluidic device, which could help doctors monitor sickle cell

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Scientists Call for Obstetrical Screening for Toxoplasmosis

A new blood test detects the presence of strain-specific antibodies to pinpoint *Toxoplasma gondii* strains that children acquire from their acutely-infected mothers while in the womb.

See article on page 8

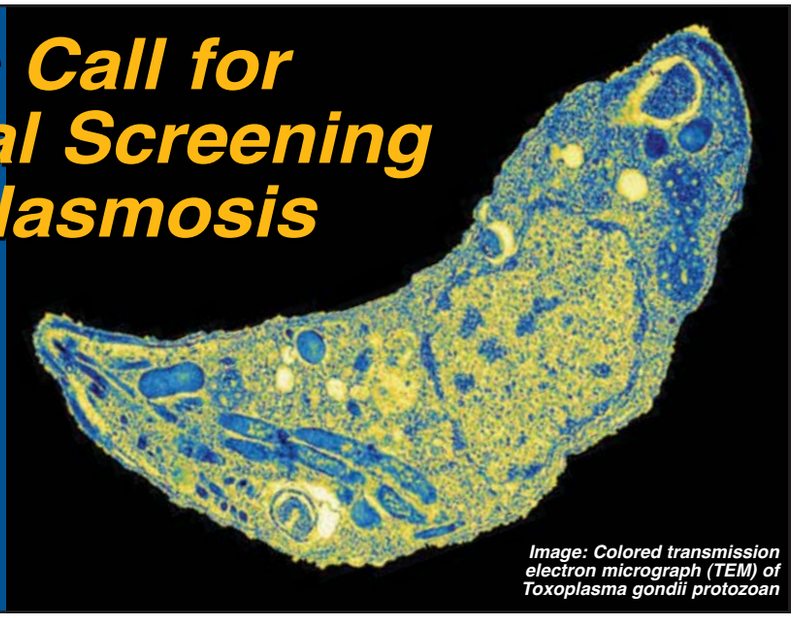

Image: Colored transmission electron micrograph (TEM) of Toxoplasma gondii protozoan

Optical Technique Offers Rapid Malaria Diagnosis

A promising new optical imaging system may make the diagnosis of malaria much easier, faster, and more accurate.

The new system uses speckle imaging, an optical sensing technique that measures the differences in how laser light bounces off the membranes of healthy and

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INSIDE

High-Throughput PLEX-ID System Introduced in Europe

The rapid, high-throughput PLEX-ID instrument, along with three assays for use on the system, has obtained Conformité Européene (CE) marking for the European Economic Area.

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Oral Cancer Detection Improved with Saliva Test

A simple saliva test has been created which could identify the presence of biomarkers that are associated with oral cancer.

The easy, cost-effective saliva test to detect oral cancer would be a breakthrough that would drastically improve screening and result in

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Novel miRNA Assay Assesses Pancreatic Masses

A 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

Cont'd on page 12

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Automated System Exceeds Laboratory's Expectations

by Karen Appold, LabMedica Contributing Writer

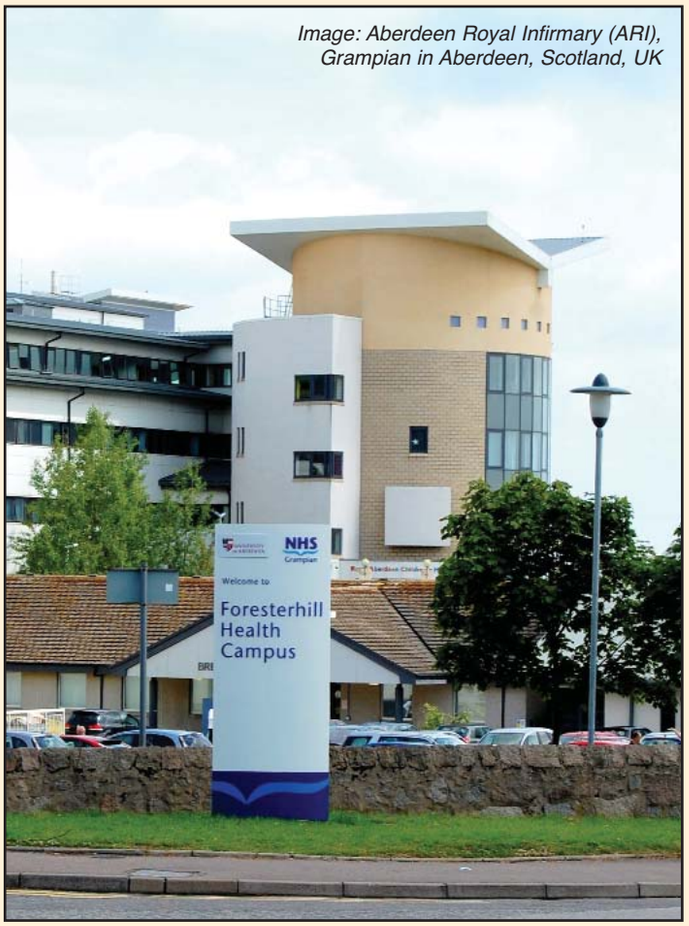


Image: Aberdeen Royal Infirmary (ARI), Grampian in Aberdeen, Scotland, UK

The biochemistry department at Aberdeen Royal Infirmary (ARI), part of National Health Service (NHS) Grampian in Aberdeen, Scotland, United Kingdom, was struggling to keep up with sample processing. Demands were increasing for faster turnaround times (TATs) and better patient flow due to new patient protocols designed to expedite patient triaging.

NHS Grampian serves more than 500,000 people, covers 3,000 square miles and has more than 16,000 employees. Laboratories serving all disciplines have a total of 250 employees; there are 58 employees in the biochemistry department specifically. Biochemistry receives a combined 3,500 patient samples per day from ARI, other city hospitals and 92 general practitioner (GP) practices from all types of specialties. Inpatient samples arrive around the clock, peaking in the middle of the afternoon, while GP samples predominantly come in late afternoon and early evening. The biochemistry department offers 24/7 service, with core services from 9 a.m. to 10 p.m. and selected services from 10 p.m. to 9 a.m.

An insufficient number of platforms were crippling the lab's workflow. Aging equipment used 24/7 was improperly maintained and often broke down. This resulted in huge backlogs in processing specimens, often delaying sample analysis until the following day. Retiring staff were being replaced with inexperienced employees who weren't up to speed on practices and procedures.

Additionally, many pre-analytical procedures were manually driven and required a significant number of employees to manage them. These positions were often vacant because of low salaries. "This became the bottleneck of the whole process," says Jim Allison, consultant clinical scientist for biochemistry at ARI.

In order to overcome these challenges, the department looked to ensure its success long into the future by installing scalable track-linked analyzers and incorporating Lean and Six Sigma processes.

ARI adopted an automated system by Siemens, installing its first-generation ADVIA WorkCell® solution in 2001. The track system allowed sample monitors and multiple analyzers to be connected onto one track. "This was quite a leap forward," Allison says. "Prior to this we only had stand-alone analyzers, which required a lot of staff to man multiple platforms." Even with a high-throughput system, however, the large quantity of samples from primary care continued to be problematic at times.

Opportunities to Innovate, Streamline and Automate

In 2007, NHS Grampian began searching for a partner that would deliver a sustainable laboratory service to Grampian's population. Its main goal was to find an automated system that offered resilience, higher capacity and even more automation. The lab wanted to redesign pre-analytical processes to make them more robust, and less prone to bottlenecks and the negativities of staff absences.

Laboratory management and staff communicated the following specific objectives for a new automated system to suppliers during the procurement process:

- include due diligence and proof of concept
- provide fast TAT for inpatient requests as workloads increased
- have the potential to upgrade equipment and the flexibility to deal with unpredictable changes and workload increases
- incorporate the new solution into a multi-service contract, with the ability to work with third parties
- have flexibility to work with information technology (IT) for multiple systems
- have the ability to provide sample centrifugation, decapping and recapping
- maintain cost efficiency
- deliver same-day results to GPs
- maximize the return on investment (ROI) with effective resource utilization (i.e., staff, financial information and real estate)
- ensure that service quality is maintained by addressing accreditation requirements
- give staff career ladder paths
- assist in staff retention, including a pleasant work environment
- address gaps in staff vacancies
- deliver consistent service even when staff resources change
- manage the attrition of skilled staff throughout their tenure

The Best Automated Solution

Siemens' Managed Pathology Services (MPS), which included an ADVIA® LabCell® configuration, was determined to be the best system to meet the biochemistry lab's needs. Globally, the lab was an early adopter of this system. ADVIA LabCell, which would future-proof the lab's service for seven to nine years, would replace the lab's ADVIA WorkCell system.

Prior to signing a long-term contract in 2007, simulation modeling was performed at ARI to prove that Siemens' system could meet all of the biochemistry lab's objectives. In order to fulfill its end of the agreement, Siemens required the lab to significantly change some of its processes and procedures as well as to adopt Lean and Six Sigma principles.

ADVIA LabCell allows for many more high-throughput chemistry systems to be connected than the ADVIA WorkCell solution. Equipment can accommodate all pre-analytical, analytical and post-analytical steps. Specifically, the biochemistry lab has three ADVIA Centaur® XPs, three ADVIA® 2400 systems and one 1800 system, as well as one IMMULITE® 2000 immunoassay system for esoteric testing and online and offline decapping.

The lab uses Siemens' ADVIA CentraLink® Data Management System as the interface between the lab information system (LIS) and the analyzers. This allows operators to view quality control results, confirming that analyzers are performing satisfactorily. Previous patient results can also be viewed. This is particularly useful when obtaining an abnormal result; patients can be checked for previous abnormal results.

By upgrading ADVIA CentraLink Data Management System last year, the lab was able to establish some disease specific protocols for different patient groups in primary care. This is an example of the lab using ADVIA CentraLink Data Management System's customizable IT capabilities. Messages seamlessly pass from the ward (which has disease specific protocols), to LIS to ADVIA CentraLink Data Management System via interfaces. "It's a very efficient way of communication," Allison says. "We don't have to manually enter different tests. It allows us to report results as soon as they are available and upload results into the patient record."

The lab's ADVIA pilot system is a software system that allows access to all of the instruments and analyzers on a track from one position. Quality control, performance and reagents can all be viewed from one PC. Staff no longer have to walk around the system to view all of the analyzers. This has saved a significant amount of time.

Managing the Lab-Transformation Change Process

As part of the agreement, Siemens' provided onsite engineers who oversaw the new equipment's installation and coordinated the entire project with the hospital's support services in terms of IT, electricians and other essential staff. The project spanned two floors and took 27 weeks, just one week over the estimated time. "This was a remarkable achievement," Allison says.

Lab administrators met with Siemens' implementation staff and their third party support team, who helped them to design a project plan for the workflow redesign. "Our users weren't aware of any disruption because we were able to maintain a high level of service while the lab was repurposed," Allison says. "We could stagger work on certain areas at different times. This allowed us to dismantle ADVIA WorkCell and stand alone stations, partition off parts of the lab at different times and to install the new track and refurbish areas. Eventually, we installed the track and equipment in the main part of the lab while we used stand alone analyzers in another part of the lab."

Embedding Lean, Six Sigma Provides Continuous Process Improvements

According to the multi-service contract, Siemens provided basic Lean training to all staff and trained staff (up to a yellow belt) in Six Sigma. As part of the Lean program, the lab's sample processing system was analyzed from start to finish.

The specimen receipt area was redesigned by doing a process flow analysis. "We consolidated processes and eliminated unnecessary delays between processes, which sped up the whole specimen receipt process," Allison says.

Staff roles were redefined. Specimen receipt staff

(data entry) and sample handling staff (label samples, put samples on analyzers, etc.) were cross-trained. These groups had the most absences and vacancies. Afterwards, outages were no longer problematic. This resulted in maximizing pre-analytical processes and saving staff time, since the lab required fewer staff to process the same amount of samples.

In January 2011, the lab introduced electronic order communications into primary care and set up demand management procedures to avoid duplicate requests and ensure that time intervals between certain investigations were appropriate. "This avoids unnecessary duplications of expensive investigations," Allison says. In order to implement this change and handle samples from primary care, job processes in the specimen receipt room changed again, as well as employees' job duties. "Because staff had been trained in Lean, they had the skills and confidence to make an additional change on top of the previous changes," Allison says.

"Due to Lean processes, employees think differently and have more time to think," Allison says. "This has facilitated a culture of continuous service improvement. Lean continues to drive service improvement."

The lab did a Six Sigma project with the accident and emergency (A&E) department, mapping the entire specimen process from obtaining a sample to delivering results to clinicians. Siemens helped to plan and lead the project. The objective was to help A&E triage patients to the appropriate medical discipline or discharge them within four hours. Staff with Six Sigma training undertook the project. They submitted data to Siemens' Six Sigma black belt personnel, who did a data analysis and provided a Six Sigma score. They identified areas of significant deviation. Improvement was significant after a six-month evaluation.

The Six Sigma project is still in operation because the lab will soon implement a pneumatic tube delivery system to deliver samples from locations such A&E to the lab, and therefore remove the requirement for portering samples.

Expectations Exceeded

In addition to its original objectives, the biochemistry department has realized other benefits, including:

- the flexibility to monitor multiple systems from one master control due to IT solutions.
- on-site engineer support ensures that daily equipment maintenance is performed, which increases reliability of analyzers.
- the ability to prioritize samples while dealing with a high routine workload, and still provide a fast TAT.
- having the time to evaluate processes and procedures and make improvements accordingly.
- employees can be removed from certain areas and assigned to other tasks, saving a significant amount of time.

Measuring Success

The lab has realized faster turnaround times, can process more samples per hour and has had a reduction of errors as a result of installing the ADVIA LabCell system.

Previously, 60 percent of inpatient samples had a TAT of two hours; now 80 percent of these samples are completed in two hours. For fast track requests from A&E and acute units, the lab reduced TAT from one hour and 50 minutes to one hour and seven minutes.

The number of samples that core chemistry analyzes has doubled, from 450 specimens per hour to 900. Immunoassay sample testing has increased from 450 to 650 samples per hour. Consequently, fewer samples are delayed until the next day.

The lab is also able to save 15 staff working hours every day by relieving staff of pre-analytical processes. By not having to perform manual procedures, staff can be more involved in added-value steps. For example, they can examine processes and employ Lean training to make processes even more efficient.

ADVIA LabCell can accommodate increases in sample growth each year. "There has been an increase every year, but it has not been as bad as expected," Allison says. The lab had a 7 percent increase in samples the first two years and a 2 percent increase the last two years.

Despite an increased workload, the lab continues to realize savings every year. Expenditure are predictable. "We don't have any anxieties about unforeseen costs, especially because we incorporated subcontracted suppliers into the contract." The contract transfers the financial risk of owning equipment to Siemens, and includes flexibility for equipment upgrades and replacements.

Because Lean has helped the lab to make processes more simplified and efficient, the number of errors has decreased. Automation has eliminated the manual processes of centrifugation, decapping and recapping. Staff had often become stressed while doing these manual processes due to time constraints, resulting in errors.

The lab can investigate errors more easily because staff is trained to troubleshoot errors. "Now we always know where samples are," Allison says. In addition, there are reliable performance and external quality controls across all platforms.

Ultimately, ADVIA LabCell provides the lab with the analytical power to help it handle unexpected occurrences, such as vacant positions or unforeseen breakdowns, and the ability to recover much more quickly.

ADVIA LabCell is Valued Hospital-Wide

NHS management appreciates the lab's ability to provide effective TAT, meet changing needs and offer its Lean and Six Sigma experience to projects hospital-wide.

By improving quality and reliability of services, patient care has gotten better. Staff now have more time to dedicate to tasks that enhance the quality of results. "We have more confidence as time goes by that we are improving the quality of our services as a result of Lean and Six Sigma," Allison says.

Clinicians, including in-hospital and community GPs, recognize that lab personnel understand what is going on throughout the hospital, not just within the lab's four walls. "We are able to influence the entire sample process from uplift to delivering results because we interact with IT and other staff groups," Allison says. Clinicians, most notably GPs, particularly appreciate the speed and accuracy of results.

Lab staff view their work lives are much less stressful and more manageable. "Consequently, they are more accepting of changes," Allison says. "They are not too apprehensive about future changes." They realize the value of opportunities to advance their careers and a good working environment.

Next Steps

ADVIA LabCell allows for the addition of new lab tests. The biochemistry lab would like to introduce an in-house blood test for B-type natriuretic peptide (BNP) for heart failure patients. Presently, the test is only available for GP surgeries via point-of-care testing. "The money has been available in primary care to do this, but it is not available in secondary care like hospitals due to budgetary restrictions," Allison says. "We would have to purchase additional reagents."

The lab would also like to add a blood test for procalcitonin (PCT). Evidence suggests that measuring the levels of this hormone can be useful to discriminate patients who should receive antibiotic therapy as well as when they can discontinue therapy. PCT can also be used along with a host of other hormone tests to help determine other conditions. "We are optimistic that we will be able to add these tests in the future," Allison says.

The lab, which has maintained chemical pathology accreditation since 2000, has an ongoing commitment to make improvements, such as provide additional tests. "We always want to continuously improve, even taking small steps with daily improvements," Allison says.

"The level of our communication with Siemens is at a level where we believe they are an active partner in whatever situation we face," Allison concludes. "We tackle challenges together."

ADVIA LabCell was definitely the right choice, Allison says. The various multi-service contract components, technical innovation, excellent maintenance service with onsite engineer support, user training and the potential for future updates all work together to enable the lab to reach its greatest potential.

Image: Jim Allison, Consultant Clinical Scientist for Biochemistry at Aberdeen Royal Infirmary.

Five Powerful Principles for Lab Automation Success

Siemens offers proven techniques used to maximize laboratory performance

A perfect storm of continuing budget pressure, expanding test volumes, and a shortage of qualified laboratory personnel is driving the migration of laboratory processes to automation. For labs to ensure the successful implementation of new workflows, they should consider these principles when choosing an automation solution.

1 Flexibility and adaptability

Consider a lab automation system that adapts easily to higher test volumes. For most labs, it is difficult to accurately anticipate its future needs, but most will agree that as the population ages and assays are developed, volumes will grow and menus will expand. Look for a solution that can be customized to: configure your unique floor space; add optional operational modules such as centrifuges; and connect analyzers from various clinical disciplines as they are needed.

2 Efficient tube management

Ascertain how well the platform facilitates both total tube management—from the time a tube arrives until it is archived—and primary tube efficiency. An inefficient pre- and post-analytical workflow will be greatly magnified as testing volume grows. For example, by implementing automated post-analytical tube management, a hospital in California reduced the time to retrieve a sample for add-on testing from hours to 60 seconds.[1]

3 Integrated IT

Utilize information technology as the cornerstone of total lab process management. As an illustration, after automation, a Chicago hospital's TAT for routine chemistries dropped from 96 to 73 minutes. By implementing key IT features like auto-verification, QC review, and instrument flagging, they reduced TAT another 30%.[2] With integrated information technology, a lab's information flow can become routine by building in total process management.

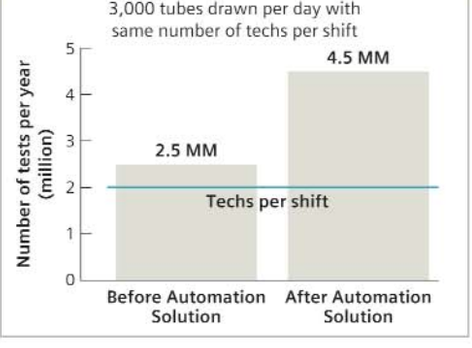
4 Sustainability

Evaluate how much waste your lab currently produces. A sustainable lab automation solution can dramatically reduce costs by improving staff efficiency, streamlining process variations, and reducing consumable usage. For example, by cutting the number of tubes collected for each patient in half, a major Portuguese hospital reduced overall lab costs by 30%, producing 30 fewer tons of waste each year. (Solid waste volume was cut 61% and liquid waste by 74%).[3]

5 Improved staff utilization

Assess the overall level of workflow automation. When repetitive, manual tasks are greatly reduced, staff can be placed in roles, which better utilize their training and enable them to make a larger contribution. As an example, a large UK hospital saved 15 hours/day by taking staff away from offline centrifugation and redeploying them to focus on service to clinicians, quality management, and continuous lab process improvement with their automation solution.[4]

Greater Efficiency with Lab Automation[5]



Choose a partner you can trust

An automation solution decision creates a long-term relationship with the products and the people who support it. Choose a partner with deep automation experience, expertise in Lean and Six Sigma process improvements, and a commitment to ongoing customer success. Select a company that provides vision, excellent service, and analytical horsepower—all working together as one unified solution for your lab's future growth.

Contact your Siemens Healthcare Diagnostics representative for more information, or please visit **www.siemens.com/automate.**

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Fresh Guidelines Issued for Red Blood Cell Transfusion

Image: Colored scanning electron micrograph (SEM) of normal human blood. The majority of the cells are red blood cells, but white blood cells (yellow) and platelets (pink) are also seen (Photo courtesy of Steve Gschmeissner / SPL).

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stable adults and children. A 20-member panel of experts based their assessment on a systematic review of research published from 1950 to 2011 to determine optimal use of red blood cells to maximize clinical outcomes and avoid the harms and costs of unnecessary transfusions.

The panel examined the proportion of patients who received any red cell transfusion and the number of red cell units transfused to describe the impact of restrictive transfusion strategies on red blood cell usage. To determine the clinical consequences of a restrictive strategy, the scientists examined overall mortality, nonfatal myocardial infarction, cardiac events, pulmonary edema, stroke, thromboembolism, renal failure, infection, hemorrhage, mental confusion, functional recovery, and length of hospital stay.

They recommended that physicians should consider transfusing at a hemoglobin threshold of 7 to 8 g/dL. Physicians should also consider transfusion for patients with symptoms of anemia or a hemoglobin of less than or equal to 8 g/dL. However, the researchers caution that there was some uncertainty about risk for perioperative myocardial infarction associated with this approach. The panel found insufficient evidence to recommend a liberal or restrictive transfusion strategy for patients with acute coronary syndrome. While physicians most commonly use hemoglobin concentration to decide when to transfuse, the panel suggests that physicians also consider symptoms of anemia in their decision-making.

Jeffrey L. Carson, MD, from the Robert Wood Johnson Medical School, (New Brunswick, NJ, USA; www.rwjms.umdnj.edu), and lead author of the guidelines, said, "Our recommendation is based on the evidence that restrictive transfusion is safe and associated with less blood use. Of course, clinical judgment is critical. Physicians may choose to transfuse above or below the specified hemoglobin threshold based on individual patient characteristics." Darrell J. Triulzi, MD, the president of AABB, added, "AABB believes that hospitals and clinicians can reduce the number of unnecessary transfusions. Implementing evidence-based transfusion is perhaps the most important step hospitals can take to achieve this goal." The guidelines were published in the March 26, 2012, online edition of the *Annals of Internal Medicine*.

High-Throughput PLEX-ID System Introduced in Europe

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The PLEX-ID apparatus, which is based on molecular diagnostic technologies, addresses a significant unmet need for rapid detection and identification of a broad range of microbes that cause infections in patients combining the high levels of sensitivity and specificity of polymerase chain reaction (PCR) technology with the precision and accuracy of mass spectrometry. The instrument provides results in less than eight hours instead of the days or even weeks required for traditional culture methods. The unique advantage of the system is the ability to characterize a very wide range of microorganisms directly from clinical specimens, thus minimizing both the amount of time and laboratory work required to provide physicians important information they can use to best tailor treatment for the patient. The three assays that are available for the PLEX-ID are the PLEX-ID Viral IC Spectrum, PLEX-ID BAC Spectrum BC and PLEX-ID Flu.

The PLEX-ID Viral IC Spectrum assay is designed to detect and identify 11 viral families with more than 250 species of important systemic viral pathogens, including herpes simplex virus (HSV), *Cytomegalovirus* (CMV), Epstein-Barr virus (EBV), human adenovirus, human *Enterovirus*, BK and JC polyomaviruses, and parvovirus B19, directly from plasma specimens. The PLEX-ID BAC Spectrum BC assay can detect and identify nearly 400 species of bacteria, and also can detect the presence of genetic markers that determine bacterial resistance to certain antibiotics. In addition, the test can identify and classify species of *Candida*, a fungus that is an increasingly common cause of serious systemic infections. The assay performs this analysis on blood culture positive specimens. The PLEX-ID Flu assay is intended for detection and identification of known influenza A viruses, newly emerging influenza A strains, and influenza B. The PLEX-ID system is a product of Abbot Ibis Biosciences (Wiesbaden-Delkenheim, Germany; www.ibisbiosciences.com).

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Simple Test Predicts Sickle Cell Severity

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patients and determine the best course of treatment. Scientists at Massachusetts Institute of Technology (MIT; Cambridge, MA, USA; web.mit.edu), collaborating with 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 many parameters that mimic physiological conditions during vaso-occlusion, including channel size, blood pressure, and oxygen concentration.

The investigators compared blood samples taken from sickle cell patients who had or had not made an emergency trip to the hospital or received a blood transfusion within the previous 12 months. Tests were carried out with blood samples from 23 patients with severe disease and 6 patients with benign disease. They directed blood through a microchannel and lowered its oxygen concentration, which triggers sickle cells to jam and block blood flow. These conditions can produce a vaso-occlusive crisis.

Blood samples from patients with more benign disease showed a significantly slower decrease in the conductance after deoxygenation. Oxygen concentration of the gas phase was measured with a fiber optic sensor (Ocean Optics; Dunedin, FL, USA; www.oceanoptics.com) connected to the outlet of the gas reservoir. No other existing measures of blood properties, including concentration of red blood cells, fraction of altered hemoglobin or white blood cell count, can make this kind of prediction of severe disease.

The authors concluded that the strong correlation between blood rheodynamics and the clinical outcomes in the study population provides a valuable tool for scientific discovery, drug development, and possibly for patient monitoring and clinical decision-making in sickle cell disease. The scientists have applied for a patent on the technology and are now working on developing it as a diagnostic tool. The study was published on February 29, 2012, in the journal *Science Translational Medicine*.

Image: Female patient with sickle cell anemia undergoing a blood transfusion (Photo courtesy of Faye Norman / SPL).

Scientists Call for Obstetrical Screening for Toxoplasmosis

Strains of the *Toxoplasma gondii* parasite have been identified that are most strongly associated with premature births and severe birth defects. A new blood test has been developed detect the presence of strain-specific antibodies to pinpoint *T. gondii* strains that children acquire from their acutely infected mothers while in the womb.

Scientists at the US National Institute of Allergy and Infectious Diseases (NIAID; Bethesda, MD, USA; www.niaid.nih.gov) applied the test to blood samples collected between 1981 and 2009 as part of the National Collaborative Chicago-Based Congenital Toxoplasmosis Study. Sera were obtained from 183 mothers who transmitted *T. gondii* to their fetuses and 151 infants, most diagnosed with substantial disease as newborns.

Studies performed included the Sabin-Feldman Dye test; immunoglobulin G (IgG) and immunoglobulin M (IgM) enzyme linked immunosorbent assays (ELISA) on maternal serum; IgM immunosorbent agglutination assay on newborn samples; immunoglobulin A (IgA) ELISA on mother and child sera; differential agglutination tests and avidity assays on maternal samples. Presence of strain-specific antibodies in people infected by parasites with type II or non-II alleles was determined in an ELISA using polymorphic peptides derived from two *T. gondii* dense granule proteins (GRA6 and GRA7) and two control peptides coupled to keyhole limpet hemocyanin (Biosource; Camarillo, CA, USA; www.invitrogen.com).

The scientists found evidence of either type II or not exclusively type II strains (NE-II) infections in 183 of the mother-child pairs in the national congenital toxoplasmosis study. The NE-II parasites were more likely to be associated with premature birth, and infants infected with these strains were more likely to have severe manifestations of disease than infants infected by type II parasites. Severe eye damage was seen in 59 out of 88 (67%) of NE-II cases, while such eye damage was present in only 18 out of 46 (39%) of type II cases.

Rima McLeod, MD, from the University of Chicago (IL, USA; www.uchicago.edu) and principal author of the study, said, "In the United States, obstetrical screening for *Toxoplasma* infection is rarely practiced. This new study underscores the value of identifying all patients who will benefit from treatment and suggests that widespread screening and treatment of pregnant women who are infected could prevent infants from suffering eye and brain damage due to congenital toxoplasmosis." The study was published on April 11, 2012, in the journal *Clinical Infectious Diseases*.

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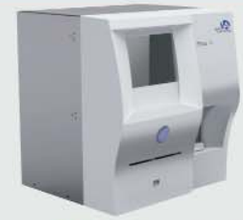

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Blood Test for Early Detection of Lung Cancer

cont'd from cover

offered to area primary care physicians to help them identify patients at the highest risk of having lung cancer. The PAULA's blood test was developed over a period of five years and has been tested using over 1,500 different patient samples. The test has been analytically validated under rigorous scientific and regulatory controls and will be performed in a Clinical Laboratory Improvement Amendments (CLIA)-approved laboratory. A larger national roll out is anticipated in about 18-24 months. PAULA is an acronym that stands for "protein assays using lung cancer antigens."

The PAULA's Test, a product of Genesys BioLabs (Rockville MD, USA; http://genesysbiolabs.com), is a simple blood test which looks at a panel of six proteins in the blood which are known to be associated with lung cancer. By comparison, another commonly given test, prostate specific antigen (PSA), is a blood test for prostate cancer, but only looks at a single protein. The test was introduced to several dozen physicians over the past several weeks including a group of lung cancer specialists who attended the Lung Cancer 2012 conference held during March 2012, in Washington DC (USA).

According to the US National Cancer Institute (Bethesda, MD, USA; www.cancer.gov), 160,000 people die each year from lung cancer, making it the number one cause of cancer death in the United States. Currently, lung cancer is most often detected in the late stages when patients develop symptoms and is associated with poor prognosis. John Gillespie, MD, Genesys BioLabs' Medical Director, said, "This blood test will allow physicians to greatly improve detection of early-stage lung cancer in asymptomatic patients where treatment will dramatically improve survival. Physicians know that patients have an 80% five years survival rate if lung cancer is caught in the early stages. We're fortunate to now have a test that physicians can use to test for lung cancer."

Oral Cancer Detection Improved with Saliva Test

cont'd from cover

fewer people dying of the world's sixth most common cancer. A surgical team at Michigan State University (East Lansing, MI, USA; www.msu.edu) is teaming up with a local area dental benefits firm for a clinical trial of the saliva test that will aid physicians and dentists to know which patients need treatment and which ones could avoid needless and invasive biopsies. The scientists will be looking for certain biomarkers previously identified by researchers at the University of California (UCLA; Los Angeles, CA, USA; www.ucla.edu). The biomarkers have been shown in studies to confirm the presence of oral cancer.

Barry Lloyd Wenig, MD, MPH, PhD, a professor of otolaryngology and lead investigator said, "Most white lesions are benign, so a majority of people who develop them are getting biopsies that are not needed. Conversely, a simple test would allow us to identify those patients with malignant lesions and get them into treatment quicker. These tests are as non-invasive as it gets; patients simply need to spit into a cup. The ease of the test will greatly expand our ability to effectively screen for the cancerous lesions. Right now, there are no early screenings available for most head and neck cancers."

Prof. Wenig is teaming up with Delta Dental (Okemos, MI, USA; www.deltadentalmi.com) which works with scientists from leading universities to monitor advances in science. Their chief science officer, Jed J. Jacobson, DDS, MPH, said, "The results of this trial could be life changing for many people. It is a tremendous opportunity for the dental community to participate in what could be a groundbreaking project." Oral cancer has a poor survival rate linked to late detection; only 60% of patients live beyond five years after diagnosis. The survival rate is less than 38% among black males.

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 at the University of Michigan (Ann Arbor, MI, USA; www.umich.edu) conducted a cross-sectional study of 254 overweight or obese children aged 10-17 years. Subjects came for two visits to a clinical research unit. They arrived fasting on the first visit and a glucose tolerance test and HbA1c and fructosamine testing were performed. For the second visit, they arrived nonfasting and had a random plasma glucose, a one hour 50-gram nonfasting glucose challenge test (1-h GCT), and urine dipstick performed. The primary end point was dysglycemia, that is a fasting plasma glucose of greater than 99 mg/dL or a two-hour postglucose greater than139 mg/dL. Approximately 50% of the children were female, 59% were white, and 30% were black.

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.

Glucose, fructosamine, and HbAlc were all measured using the Cobas Mira Plus Chemistry Analyzer (Roche; Basle, Switzerland; www.roche.com). The urine dipstick test was performed using Chemstrip 10 strips also manufactured by Roche.

The authors concluded that they found reasonable test performance for the 1-h GCT and the random glucose, having systematically evaluated a variety of nonfasting screening tests used in the clinical setting for identifying dysglycemia in a population of overweight and obese adolescents, In contrast, test performance for HbAlc, fructosamine, and urinalysis was poor. Their findings have direct relevance for future recommendations for screening and diagnosis of dysglycemia among overweight and obese children and adolescents. The study was published the December 2011 issue of the journal *Diabetes Care*.

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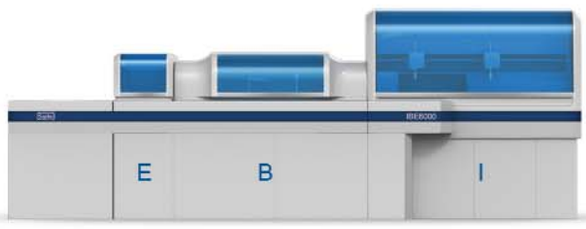

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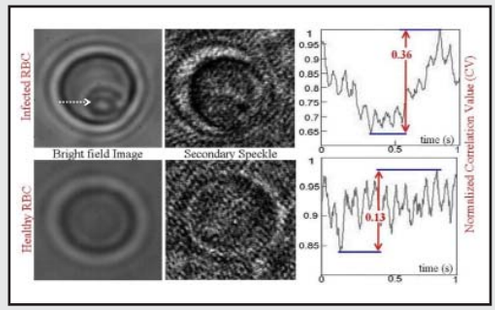
Optical Technique Offers Rapid Malaria Diagnosis

cont'd from cover

infected red blood cells. An international team of scientists led by those at Materials Technology Institute (Trieste, Italy; www.iom.cnr.it) compared the apparently random scattering, called speckling of light as it builds up from multiple images. A clear statistical pattern emerges that identifies cells that harbor the parasite responsible for malaria. The team has preliminary results involving 25 cell samples of which 12 were healthy and 13 infected with malaria.

The specific technique the scientists used is called Secondary Speckle Sensing Microscopy. By applying this imaging technique to an automated high-throughput system, the scientists were able to deliver results in as little as 30 minutes. They did so with a high rate of accuracy and without the need for highly trained technicians and a well-equipped hospital laboratory. The current time to diagnosis in most African medical centers is typically between 8-10 hours.

Secondary Speckle Sensing Microscopy consists of a custom inverted microscope in which the sample of red blood cells is illuminated by a tilted laser beam (Laser Physics; Milton Green, UK; www.laserphysics.co.uk). This produces a time-varied speckle pattern field based on the cells' thermal vibration and the movement of their membranes, traits that differ in healthy and diseased states. The speckle patterns are inspected under the microscope and recorded on a camera at a high frame rate. Using two automated analytical methods called fuzzy logic and principal component analysis; scientists scour a set of speckle



parameters to extract statistical information about changes in red blood cells' membranes and their flickering movements. Scientists then make a diagnosis based on statistical correlations in speckle patterns between healthy and diseased cells.

Dan Cojoc, PhD, lead author of the study, said, "A new diagnostic tool is urgently needed. With a fast, portable, low-cost, and accurate diagnostic tool, physicians can confidently and quickly administer the correct therapy." The current diagnostic gold standard for malaria is a Giemsa-stained blood smear, which uses optical microscopy to identify different species of the malaria parasite, *Plasmodium*, in blood samples. This technique requires skilled medical professionals trained to identify the telltale signs of the parasite throughout its life cycle and its population density in the bloodstream. The study was published in the April 2012 issue of *Biomedical Optics Express.*

Image: Secondary Speckle Sensing Microscopy (S3M). The difference between an infected red blood cell (top) and a healthy cell (bottom) is revealed by S3M, in part, by considering the dynamics of the correlation value (CV). CV indicates the similarity between two patterns. 1,000 CVs are calculated from pairs of consecutive speckles acquired in 1 second. As shown in the chart at right, the CV oscillation range for the infected cell (top, 0.36) is almost three times larger than that of the healthy red blood cell (bottom, 0.13). In the top left image of the infected cell a parasitic life-cycle stage of malaria, called "trophozoite" can be seen (arrow) (Photo courtesy of Dan Cojoc, Materials Technology Institute, National Research Council, Italy).

Novel miRNA Assay Assesses Pancreatic Masses

cont'd from cover

as microRNA's (miRNA). An algorithm calculates a score between 0 and 1 by measuring the expression levels of seven miRNAs, and this determines whether or not PDAC has been identified.

The Asuragen, Inc. (Austin, TX, USA; www.asuragen.com) miRNA assay, called the miRInform pancreas test, is immediately 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.

"The development and commercialization of miRInform Pancreas for FNA specimens represents another breakthrough for Asuragen and capitalizes on our deep molecular expertise and unsurpassed foundation in using miRNAs for diagnostic and therapeutic applications," commented Matt Winkler, PhD, CEO of Asuragen. "We believe miRNAs will prove to be highly relevant for many additional cancer diagnostic applications.

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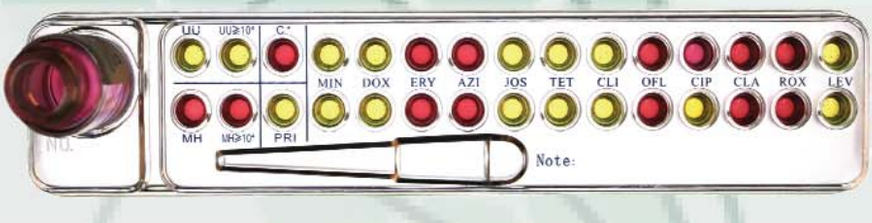

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Rare Blood Types Due to Genetic Variation

Blood group typing is a routine procedure before blood transfusion, but some blood types, such as Langereis and Junior, are exceedingly rare worldwide.

While blood transfusion problems due to Langereis and Junior blood types are uncommon, several ethnic populations, such as certain Japanese populations and European Gypsies, are at risk.

An international team working with the University of Vermont (Burlington, VT, USA; www.uvm.edu) used a multiplicity of analytical techniques including flow cytometry, immunofluorescence microscopy, mass spectrometry, and sequencing to identify the genetic basis of the Langereis blood group.

The scientists identified the human adenosine triphosphate (ATP)-binding cassette (ABC) transporter *ABCB6* as the genetic basis of the Langereis blood group antigen expressed on red blood cells, but also at the plasma membrane of hepatocellular carcinoma (HCC) cells, and established that *ABCB6* encodes a new blood group system (Langereis, Lan). Targeted sequencing of *ABCB6* in 12 unrelated individuals of the Lan(–) blood type identified 10 different *ABCB6* null mutations.

A Lan-specific monoclonal antibody has been developed and will greatly facilitate the identification of Lan(–) blood donors. In elucidating the genetic basis of the Lan(–) blood type, the scientists have uncovered ten null mutations of *ABCB6*. It will be necessary to closely monitor Lan(–) (*ABCB6*+/–) individuals, especially those treated with drugs potentially transported by *ABCB6*, because this deficiency may alter the pharmacokinetics of these drugs or result in adverse effects such as hepatotoxity. The authors concluded that transfusion support of individuals with an anti-Lan antibody is highly challenging partly because of the scarcity of compatible blood donors, but mainly because of the lack of reliable reagents for blood screening.

Junior-negative blood donors are extremely rare too, but that may soon change. Bryan Ballif, PhD, an assistant professor at the University of Vermont and an author of the study said, "We're following up on more unknown blood types. There are probably on the order of 10 to 15 more of these unknown blood type systems, where we know there is a problem but we don't know what the protein is that is causing the problem. More than 50,000 Japanese are thought to be Junior negative and may encounter blood transfusion problems or mother-fetus incompatibility." The study was published in the February 2012 issue of *Nature Genetics*.

Image: In addition to A, B, AB or O, two new blood groups - the Langereis blood type and Junior blood type, positive or negative - have been discovered (Photo courtesy of GPSN).

HPV Testing to Be More Widely Available in China

Free HPV testing will be given to underprivileged women in China, especially in less populated and remote regions.

Qiagen (Hilden, Germany; www.qiagen.com) is expanding access to *Human papillomavirus* (HPV) screening in China through a comarketing agreement with KingMed Diagnostics (Guangzhou, China; www.kingmed.com.cn), China's largest independent laboratory network.

The "gold standard" in testing for high-risk types of HPV, the primary cause of cervical cancer, is Qiagen's digene HPV Test

KingMed Diagnostics will function as a centralized lab, allowing smaller hospitals and those in less-populated areas to offer the digene HPV Test and send samples to KingMed Diagnostics for processing and analysis.

The agreement is a landmark for Qiagen's molecular diagnostics franchise in China and its focus on driving growth in emerging markets. The digene HPV test was first registered in China in 2000 and is now widely available in many of the country's hospitals and private labs.

Cervical cancer affects approximately 500,000 women annually worldwide and causes about 275,000 deaths each year. After breast cancer, it is the second most common malignancy found in women. In China, there are 80,000-100,000 new cases of cervical cancer each year and 30,000 to 50,000 deaths.

Cervical cancer is caused by high-risk types of HPV. An estimated 80 % of women will get an HPV infection at some point in their lives. However, in most cases, the infection goes away or is suppressed by the body without causing problems. If infections persist abnormal cells are formed, which may develop into cervical cancer if not detected and treated early.

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Improved Diagnostic MRSA Screening Kit Enhances Sensitivity, Simplifies Processing

Sensitivity of an already high sensitivity, high specificity PCR assay for MRSA (methicillin-resistant *Staphylococcus aureus*) screening and diagnosis is further strengthened by inclusion of additional MRSA strains. The new kit also shortens sample preparation and minimizes required hands-on time.

The Detect-Ready MRSA Panel is a qualitative real-time PCR in vitro diagnostic test. It is CE-marked for the detection of MRSA and MSSA (methicillin-sensitive *S. aureus*), and it is the only marketed PCR-based MRSA screening test with the proven ability to discriminate accurately between these pathogens and other related bacteria.

In the new Detect-Ready MRSA Panel, performance has been further enhanced by covering additional MRSA strains known to be missed by at least one other market-leading assay to the set of known common MRSA strains that were already included.

A comparative study examining the accuracy of the Detect-Ready MRSA panel was conducted at St. Thomas' Hospital in London. The researchers compared the performance of Detect-Ready and the GeneOhm MRSA PCR tests and concluded that the Detect-Ready assay is superior to the GeneOhm panel in terms of specificity, while still providing a more rapid screening service compared to traditional microbiology culture methods.

Developed by Molecular Detection Inc. (MDI; Wayne, PA, USA; www.detect-ready.com), this new version of the kit was launched at the 2012, 22nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID; London, UK; www.congrex.ch/eccmid2012/home.html). "We are delighted to offer this improved version of the Detect-Ready MRSA Panel to our growing customer base," commented David Wilson, MDI's Vice President for Commercial Operations, Europe. "The inclusion of additional covered MRSA strains reinforces the superior performance of our existing test, which was recently reconfirmed in an independent comparative study with a market leading competitor. In addition, the simplicity and ease-of-use of Detect-Ready MRSA is further enhanced with our new streamlined protocol for sample prep."

The Detect-Ready MRSA Panel is currently available in Australia, Austria, Belgium, Germany, Ireland, Israel, Luxembourg, the Netherlands, Spain, Switzerland, the UK, and is in late-stage development in the US.

Image: The Detect-Ready MRSA panel (Photo courtesy of Molecular Detection).

Companion Diagnostic to Help Development of Cancer Therapy

A companion diagnostic test is to be created to aid in the development of an investigational cancer therapy.

Abbott (Abbott Park, Il, USA; www.abbott.com) will collaborate with Merck (Whitehouse Station, NJ, USA; www.merck.com) to evaluate the use of a fluorescence in situ hybridization (FISH)-based companion diagnostic test to aid in the development of a Merck investigational cancer therapy.

FISH-based companion diagnostic tests are designed to identify specific DNA sequences to help determine which patients are likely to benefit from a particular therapy. FISH technology can identify whether too many, or too few, copies of a particular gene are present in the body's cells, or whether certain genes have rearrangements that play an active role in disease progression. Cancer diagnostics is one of its fastest growing applications.

Abbott will develop a test based on its FISH technology, intended to identify deletions of the TP53 gene in cancer patients. The Abbott FISH assay will be evaluated in clinical trials to help identify patients more likely to respond favorably to Merck's investigational cancer therapy.

Abbott Molecular is a leader in molecular diagnostics. The company analyses DNA and RNA at the molecular level. "Our goal through this collaboration, and others like it, is to ensure that the right medicine gets to the right patient," said Stafford O'Kelly, head of Abbott's molecular diagnostics business. "As one of the early pioneers in companion diagnostics, we believe that linking genetic testing with drug development at the earliest stages can increase the effectiveness and predictability of medicines and help physicians make more informed treatment decisions."

Abbott's portfolio of companion diagnostic tests includes the PathVysion HER-2 DNA probe kit, which represents one of the first examples of innovations in the field of personalized medicine. The test is approved for use in selecting breast cancer patients for whom Herceptin (trastuzumab) therapy is being considered. In addition, Abbott's Vysis ALK Break Apart FISH probe kit was approved in 2011 for use in identifying non-small-cell lung cancer patients for Xalkori (crizotinib) treatment.

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Spinal Fluid Tests Differentiate Concurrent Brain Diseases

Alzheimer's disease (AD) can be distinguished from frontotemporal lobar degeneration (FTLD) by looking at the levels of two specific biomarkers in the spinal fluid.

By using different platforms and assaying the concentration of a neuronal protein and peptide amino acids in cerebral spinal fluid (CSF) it is possible to make a definitive differentiation between the two brain diseases.

Scientists at the University of Pennsylvania (Philadelphia, PA, USA; www.upenn.edu) studied 142 neuropathologically diagnosed neurodegenerative dementia patients, including 71 with AD, 29 with FTLD, three with amyotrophic lateral sclerosis, seven with dementia with Lewy bodies, and 32 with mixed diagnosis. For 136 patients there was enzyme linked immunosorbent assay (ELISA) CSF data for comparison to 43 controls and for 110 patients there was Luminex CSF data for comparison with 46 controls. Amyloid beta (Aβ42), total, and phosphorylated tau181 were measured.

The investigators determined that values from the two platforms could effectively be transformed into equivalent units, and these values accurately distinguished AD from FTLD. A cutoff of 0.34 for the t-tau: Aβ1-42 ratio had 90% to 100% sensitivity and 91% to 96.7% specificity to differentiate FTLD cases, respectively. Clinical and neuropathological diagnoses showed an 81.3% overall agreement. ELISA and Luminex showed high sensitivity and specificity to classify AD subjects against FTLD subjects and controls and moderate sensitivity and specificity for classifying FTLD subjects against controls. The ELISA platform revealed 69.4% and the Luminex (Austin, TX, USA; www.luminexcorp.com) platform 96.4% of the cases with mixed neuropathological diagnoses including a diagnosis AD (which was 24.8% of the sample), were classified as AD. Probabilities obtained by models based on clinical and neuropathological diagnoses differed and underestimated the true diagnostic accuracy.

John Q. Trojanowski, MD, PhD, professor of Pathology and Laboratory Medicine and co-director of the Center for Neurodegenerative Disease Research, said, "With the emergence of disease-modifying treatments for AD and other neurodegenerative diseases, it will be of utmost importance to accurately identify the underlying neuropathology in patients." Murray Grossman, MD, professor of Neurology, and senior author of the study added, "We need to develop better CSF diagnostic panels for the early diagnosis of neurodegenerative dementias, including those due to mixed neurodegenerative disease pathologies that commonly co-occur with Alzheimer's." The studies were presented at the American Academy of Neurology's 64th Annual Meeting, held April 21 to April 28, 2012, in New Orleans (LA, USA; www.aan.com).

Image: A doctor taking a sample of cerebrospinal fluid by means of a lumbar puncture procedure (Photo courtesy of Simon Fraser / SPL).

Genetic Abnormality Linked to Brain Cancer

A chromosomal abnormality in children with a deadly form of brain cancer has been discovered, and is linked with a poorer chance of survival.

The discovery could potentially lead to a new diagnostic test to allow doctors to identify youngsters who are at the highest risk associated with an ependymoma tumor and may need aggressive life-saving treatments.

A study led by experts at University of Nottingham (UK; www.nottingham.ac.uk) as part of a European collaboration focused on looking at abnormal copies of chromosomes in the cells of ependymoma tumors and aimed to establish whether it was associated with a worse outlook for children suffering from the disease. The scientists assessed the results from 147 brain ependymomas in young UK and French children who received tumor surgery followed by chemotherapy and older European children who received tumor surgery followed by radiotherapy.

In tumor cells, the number of chromosomes can vary significantly from the normal cell numbers and in ependymoma a frequent finding from biological studies is increased copies of chromosome number 1, specifically increased numbers of the long arm of chromosome 1. This abnormality is termed 1q copy number gain. Copy number gain of 1q in the ependymoma cells from each of the 147 patients was assessed using a technique called fluorescence in situ hybridization (FISH) in which pieces of DNA called probes are made in the laboratory containing a fluorescent dye. This enables the tumor cells to be seen down a fluorescent microscope. In the project, the scientists used a green probe (Vysis; Des Plaines, IL, USA; www.vysis.com) that bound to a region within chromosome 1q of the tumor cells, called 1q25.

The team then linked which of the ependymomas had increased copies of the 1q25 probe in their cells to corresponding patient data to work out whether increased copy number gain was associated with a worse survival rate. The authors advocate the prospective evaluation of 1q25 gain as a prognostic marker in forthcoming large international clinical trials of pediatric intracranial ependymoma, both independently and integrated with tumor resectability. Upon successful validation, 1q25 gain could be incorporated into future clinical trial design in order to improve risk stratification for children diagnosed with this tumor.

Richard Grundy MBChB, PhD, professor of Pediatric Neuro-oncology and Cancer Biology at Nottingham said, "We are now hoping that these findings are reproduced in other studies currently underway in other countries, including the USA. If their results match ours, then the presence of 1q25 copy gain in childhood ependymoma could be introduced into future international treatment planning as a new marker of poor outcome which will in turn define treatment." The study was published in the April 1, 2012, edition of the journal *Clinical Cancer Research*

Molecular Assay Employed for Extrapulmonary TB Specimens

The laboratory diagnosis of tuberculosis (TB) on extrapulmonary specimens is particularly challenging, as invasive procedures are often required in order to obtain samples for culture.

A number of commercial nucleic acid amplification tests able to detect and identify *Mycobacterium tuberculosis* (MTB) complex directly from respiratory secretions have been developed, but their use on extrapulmonary samples still calls for validation.

Scientists at the United Hospitals (Ancona, Italy; www.ospedaliriuniti.marche.it) performed a retrospective analysis aiming to evaluate the diagnostic accuracy of a Complex Direct Detection Assay (DTB) on 918 nonrespiratory specimens collected from 863 patients investigated for TB based on different levels of clinical suspicion, between January 2006 and December 2009. The specimens included 84 gastric aspirates, 145 urine, 136 sterile body fluids, 83 cerebrospinal (CSF) fluids, 237 fine-needle aspirates, 175 pus, 56 biopsies, and 2 stool specimens.

The results were compared with those of acid-fast staining and culture, solid plus liquid media, setting the combination of culture and clinical diagnosis as the gold standard. Ninety-two specimens yielded culture positive for MTB and 24 who were smear and culture negative were from patients with TB clinical diagnosis. Of these patients, 96 were positive with the BDProbeTec ET *Mycobacterium tuberculosis* Complex Direct Detection Assay (DTB, Becton, Dickinson and Company, Franklin Lakes, NJ, USA; www.bd.com) including all of those from culture-negative TB cases. From 26 specimens, nontuberculous mycobacteria were grown and two of these specimens were positive by the DTB assay.

The authors concluded that the overall sensitivity, specificity, and positive and negative predictive values of the DTB assay for extrapulmonary TB were high. A reduced sensitivity of 73.5% was observed among smear-negative specimens when compared with 91.7% for smear-positives specimens. Although amplification assays cannot replace culture techniques, DTB proved to be rapid and specific for the detection of MTB in extrapulmonary samples. The study was published in the March 2012 issue of the *European Journal of Clinical Microbiology & Infectious Diseases*.

Blood Test Approved For Viruses Linked to Leukemia

A test has been approved that will detect antibodies to viruses in donors of human blood and blood components that are associated with several diseases.

The test can be used to both screen the blood supply for antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and Human T-Lymphotropic Virus Type II (HTLV-II), and help diagnose infection with these viruses, which are associated with some forms of leukemia and neurologic diseases.

The HTLV-I/II Microelisa System is intended for screening living individual human donors, including volunteer donors of whole blood and blood components for the presence of HTLV antibodies. It is also approved for testing serum and plasma specimens to screen potential organ donors when specimens are obtained while the donor's heart is still beating. It is not intended to be used to screen cord blood specimens or cadaveric blood specimens.

Developed as a standard two-step indirect microelisa system assay, the HTLV-I/II Microelisa System contains coated 96-well microwell plates, color-coded, liquid negative and positive control. Derived from purified and inactivated HTLV-I viral lysate, a purified HTLV-II viral lysate, and a recombinant HTLV-I p21E antigen, the HTLV-I/II Microelisa System is an enzyme-linked immunosorbent assay (ELISA). The HTLV-I/II Microelisa System is manufactured by Avioq Inc., (Research Triangle Park, NC, USA; www.avioq.com). This Avioq test has received approval from the US Food and Drug Administration (FDA; Silver Spring, MD, USA; www.fda.gov).

The Avioq HTLV-I/II assay features a user-friendly microplate design suitable for various testing volumes and automation. In addition to being used as a manual assay, the assay is also intended for use with the ORTHO Summit System (Ortho Clinical Diagnostics, Rochester, NY, USA; www.orthoclinical.com) in the screening of blood donors. Both HTLV-I and HTLV-II can be transmitted through transfusion, reuse of syringes, and by breast-feeding from infected mothers.

Karen Midthun, MD, director of the FDA's Center for Biologics Evaluation and Research, said, "Since 2008, there has been only one FDA-licensed donor screening test available for detection of antibodies to HTLV. This approval provides an additional test for HTLV, providing greater flexibility to blood establishments and helping to assure the safety of the blood supply." Screening of all blood donors in the USA for evidence of HTLV infections is required to assure the safety of blood transfusions.

Method Detects Hypervirulent Bacterial Strains

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

Previous efforts to find hypervirulent strains were unsuccessful since bacteria behave much like their less-virulent cousins after environmental exposure and it is difficult to assess their virulence during infection, before they switch back to a less-virulent state in the laboratory.

An international team of scientists led by those at the University of California, Santa Barbara (UCSB; USA; www.ucsb.edu) 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 team screened 184 isolates for hyper-infectious strains and performed virulence assays, and bacterial cytocidal activity assays.

Real-time polymerase chain reaction (qPCR) and transcriptome analysis was used to further characterize the isolates. 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 strategy to identify hypervirulence was aided by a special medium utilized by the scientists that forces the bacteria to reveal their weapons in the laboratory, which is the first step in the design of therapeutics to combat them.

Douglas Heithoff, PhD, the lead author of the study, said, "These strains exhibit this behavior in the extreme, essentially having a '5th gear' they can switch to during infection. Now that we have identified the problem - and potential solutions - we just need to get to work." Humans usually get *Salmonella* food poisoning from eating contaminated beef, chicken, or eggs. However, animal waste can contaminate fields where fruits, nuts, and vegetables are grown, thus posing a particular health concern for vegetarians. The study was published online in April 2012, in the journal *Public Library of Science Pathogens.*

Image: Colored scanning electron micrograph (SEM) of Salmonella typhimurium bacteria, a major cause of food poisoning (salmonellosis) in humans, most commonly caught from infected pork, poultry and eggs (Photo courtesy of Steve Gschmeissner / SPL).

Immunological Assays Correlated for Lupus Diagnosis

Two immunoassays have been used to detect autoantibodies to the ribosomal P proteins (Rib-P) that are a serologic marker for systemic lupus erythematosus (SLE). Enzyme immunoassays and an indirect immunofluorescence test have been tested and compared in their ability to diagnose SLE and to see whether the results are interrelated.

Scientists at Dong-A University College of Medicine (Busan, Republic of Korea; www.donga.ac.kr) collected serum samples from 91 SLE patients, 50 rheumatoid arthritis patients and 43 healthy subjects, between March 2009 and May 2010. A total of 184 samples were analyzed for anti-Rib-P antibodies using two immunoassays and an indirect immunofluorescence test (IIF) simultaneously. The IIF on HEp-2 cells was assayed using HEP-ANA test system (Medical & Biological Laboratories, MBL, Naka-ku, Japan; www.mbl.co.jp) and anti-Rib-P antibodies by IIF were determined by the pattern with cytoplasmic and nucleolar staining.

Of 91 SLE patients, the positive rates of two immunoassays for anti-Rib-P antibodies were significantly higher than that of IIF. Eleven of 91 SLE patients showed simultaneous positivity in two immunoassays, but negativity in IIF. None of 93 control group subjects was positive for anti-Rib-P antibodies in two immunoassays and IIF. The two immunoassays used were the Quanta Lite Ribosome P enzyme-linked immunosorbent assay (ELISA) (Inova Diagnostics, San Diego, CA, USA; www.inovadx.com) that uses synthetic ribosome P antigen and the EliA Rib-P (Phadia AB; Uppsala, Sweden; www.phadia.com) which uses human recombinant ribosomal P-proteins P0, P1, and P2.

The authors concluded that the sensitivity of immunofluorescence antibody tests (IFA) on HEp-2 cells is not optimal as a first-line screening test for detection of anti-Rib-P in SLE patients. Therefore, additional immunoassays are required to determine the presence of anti-Rib-P antibodies. The high titer of anti-Rib-P antibodies determined using immunoassays could also be demonstrated by IIF on HEp-2 cells. The discrepancy between immunoassays and IIF on HEp-2 cells for detection of anti-Rib-P antibodies may be explained by their titer. The study was published on March 15, 2012, in the journal *Clinica Chimica Acta.*

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Gene Variants Indicate Increased Susceptibility to Colon Cancer

The imbalance observed in the human tumor tissues appears to be the result of a complex, multistep process by the enzyme sarcoma tyrosine kinase (SRC).

Some tissues, like liver, have just one type of variant of the nuclear receptor hepatocyte nuclear factor 4α (HNF4α), but the colon has both P1 and P2 variants. The P1 variant is found in the nuclei of cells in the normal colon, but in the human colon cancer samples this variant is frequently either absent or located outside of the nucleus and, presumably, no longer functional.

An international team led by cell biologists at the University of California, (Riverside, CA, USA; www.ucr.edu) has uncovered a new insight into colon cancer. The team analyzed about 450 human colon cancer specimens and found that in nearly 80% of them, the variants of the *HNF4A* gene are out of balance. The team used both SRC kinase assays and human colonic adenocarcinoma tissue staining. Tissue microarrays (TMAs) were constructed with 1.0 mm cores from morphologically representative areas of the original archived paraffin blocks, the central region of the tumor, deep advancing tumor front, and adjacent non-neoplastic mucosa using an Advanced Tissue Arrayer, ATA-100.

SRC kinase has been known to be activated in colon cancer but, until now, it was not known to act on the HNF4α protein. The cell biologists found that activated SRC modifies the P1 but not the P2 variant. The net result is loss of the P1 variant in the nuclei of cells in the colon. Another factor that increased a person's susceptibility to the disease was specific single nucleotide polymorphisms or SNPs located in the *HNF4A* gene. An SNP is a DNA sequence variation, a minor change in the genomic sequence that accounts for the variations seen between individuals. SNPs are the most common type of genetic variation among people. The SRC kinase assays and the ATA-100 used are manufactured by Millipore (Billerica, MA, USA; www.millipore.com).

The authors concluded that that increased staining for active SRC is associated with a loss of nuclear P1-HNF4α in a sizeable cohort of human colorectal tumors. Their findings suggest a unique link between an oncogenic kinase, a potent differentiation factor, and human colon cancer. Frances M. Sladek, PhD, a professor of cell biology and toxicologist, who was the lead author of the study said, "Loss of nuclear P1 HNF4α protein in the colon may be an early sign of colon cancer. A healthy colon has a good but delicate balance of the two *HNF4A* variants. If you could prevent the loss of the P1 variant via drugs, you might be able to maintain a normal colon and prevent colon cancer." The study was published on Febraury 14, 2012, in the *Proceedings of the National Academy of Science of the United States* (*PNAS*).

POC D-Dimer Assays Compared with Standard Method

D-dimer assays are effective for the exclusion of deep-vein thrombosis (DVT), but point-of-care (POC) D-dimer assays have only recently been fully evaluated.

Measurement of D-dimer has been enabled after the development of monoclonal antibodies used in enzyme-linked immunosorbent assays (ELISAs) which have a sensitivity of 98% with a negative predictive value of greater than 95%.

However, ELISAs are complicated, time-consuming, and labor intensive and could generally only be performed in laboratories during daytime working hours. Scientists at the Karolinska Institutet, (Stockholm, Sweden; www.ki.se) compared five POC D-dimer assays with their routine Tinaquant fully automated quantitative immunoturbidimetric assay that utilizes microlatex particles coated with anti-human D-dimer monoclonal antibody. They tested 60 samples from patients with suspected DVT. The cut-off value was 0.25 µg/mL of D-dimer, which corresponds to 0.5 µg/mL of fibrinogen equivalent units (FEU).

The five POC assays tested were the Pathfast D-dimer chemiluminescent enzyme immunoassay (CLEIA) magnetic filtration (Mitsubishi Chemical; Tokyo, Japan; www.mitsubishichemical.com); the Cardiac D-dimer sandwich method, using monoclonal gold-labeled antibodies which like the standard Tinaquant assay is from Roche Diagnostics, (Mannheim, Germany; www.roche.com); the Vidas D-dimer, a sandwich method, using monoclonal antibodies with fluorescence detection (BioMérieux; Marcy l'Etoile, France; www.biomerieux.com); the Stratus CS D-dimer sandwich method using monoclonal antibodies radial partition (Siemens Diagnostics; Marburg, Germany; www.siemens.com); and the NycoCard D-dimer sandwich method, which uses monoclonal antibodies gold colloids (Nycomed Pharma; Oslo, Norway; www.nycomed.com).

The results of the study showed that using 0.5 µg/mL as a cut-off value, four samples tested negative with Tinaquant were positive with Pathfast. There were no Tinaquant-positive samples tested negative with Pathfast, while the overall agreement was very good. Four samples were discrepant between Tinaquant and Cardiac with the lower cut-off of 0.4 µg/mL. Eight samples of 27 were negative with NycoCard although they were positive with the standard Tinaquant assay. The agreement with Tinaquant was excellent for both Vidas and Stratus.

The authors concluded that that the four of five tested POC D-dimer assays have an analytical profile comparable to that obtained using standard laboratory assay, while three of them may be used for rapid bed-side analysis. Their evaluation indicates that Pathfast D-dimer, Cardiac D-dimer and Stratus CS D-dimer can be used for rapid bed-side analysis and offers a possibility to adequately rule out DVT in outpatients within minutes after admission. The study was published on April 5, 2012, in the *International Journal of Laboratory Hematology.*

Molecular Analysis Identifies Specific Cancers

A method has been described that identifies cancer-causing rearrangements of genetic material called chromosomal translocations quickly, accurately, and inexpensively.

The technique developed combines microarray technology, which can look for thousands of translocations in a single test, with a novel antibody that is used to detect the presence of the translocation.

Scientists at the University of Utah (Salt Lake City, UT, USA; www.utah.edu) developed a new approach, called antibody detection of translocations (ADOT), to identify Ewing's sarcoma and which avoids the shortcomings of current techniques. The technique is applied to frozen or formalin fixed paraffin embedded (FFPE) primary tumor samples. Ribonucleic acid (RNA) is extracted, followed by microarray hybridization and antibody detection. Reverse-transcriptase polymerase (RT-PCR) chain reaction was performed using iScript SYBR green RT-PCR kit (Bio-Rad; Hercules, CA, USA; www.bio-rad.com).

Total RNA from tumor cells or tissues was hybridized on the array. Bound RNA was detected with a monoclonal antibody that recognizes RNA-DNA duplexes in a sequence-independent fashion. Many cancers result from chromosomal translocations in tumor cells. Hundreds of cancer-causing translocations have been discovered, but current methods for detecting them have significant shortcomings. The investigators were able to detect specific translocation from three out of four FFPE samples. The method is much better with real-life specimens than the current standard techniques. ADOT is capable of detecting known or unknown translocations in biological samples, including those most commonly encountered during the diagnostic work-up of a patient. ADOT bears promise as a discovery tool for identifying fusion transcripts in cancers, as well as a diagnostic tool for patients with translocation-associated tumors.

Stephen L. Lessnick, MD, PhD, a lead author of the study, said, "We're moving past the age when a pathologist looking through the microscope at a tumor sample is the best way to diagnose what type of cancer it is. The molecular tests currently available are slow, inefficient, and expensive, and one of the biggest issues is that you need high-quality tumor samples, not always available in the clinical setting, to do them. With this method, there's potential to develop a single array that could test for every known cancer-causing translocation simultaneously. Currently, a clinician has to decide beforehand which specific cancer to test." The study was published online on March 15, 2012, in the journal *European Molecular Biology Organization* (*EMBO*) *Molecular Medicine.*

Inflammatory Biomarkers Predict Chronic Pulmonary Disease Outcome

Changes in inflammatory biomarkers establish clinical variables and improve the prediction of mortality in patients with chronic obstructive pulmonary disease (COPD). COPD is characterized by low-grade systemic inflammation and the addition of inflammatory biomarker blood tests would establish predictive factors that will improve accuracy of a prognostic model for mortality. An international multicenter team of scientists led by those at Brigham and Women's Hospital (Boston, MA, USA; www.brighamandwomens.org) prospectively collected data on 1,843 COPD patients from the Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints (ECLIPSE) study. Of these 1,843 patients, 168 (9.1%) died during the three-year follow-up.

The biomarkers measured from serum samples were: Chemokine (C-C motif) ligand 18 (CCL-18 or pulmonary and activation-regulated chemokine, PARC), surfactant protein D (SP-D), interleukin 8 (IL-8), Clara cell secretory protein 16 (CC-16), and tumor necrosis factor alpha (TNFα). Fibrinogen and C-reactive protein (CRP using a high sensitivity method) were measured in plasma samples. All protein biomarkers were measured by validated immunoassays. Total white blood cells (WBC) and neutrophils were counted by an automated method.

The results of the study show that a panel of selected biomarkers, WBC counts, IL-6, fibrinogen, CCL-18, CRP, IL-8, and SP-D were not only elevated in nonsurvivors compared with survivors, but were also associated with mortality over three years after adjusting for clinical variables known to predict death in COPD. Bartolome M. Celli, MD, the lead author of the study, said, "Adding white blood cell counts and measurement of changes in systemic levels of IL-6, CRP, IL-8, fibrinogen, CCL-18, and SP-D significantly improves the ability of clinical variables to predict mortality in patients with COPD." The study was published on March 23, 2012, in the *American Journal of Respiratory and Critical Care Medicine.*

Microprocessor-Controlled PCR Workstations Reduce Risk of Contamination

The AC600 series of mobile PCR workstations provides an improved level of prevention against contamination while preparing DNA/RNA samples for amplification.

The ductless, hood-like workstation combines a Class 100 clean air environment with UV light sterilization for optimal protection from sample contamination, including from cross-contamination between samples. Features include built-in 254 nm ultraviolet lights for irradiation and HEPA filtration for a clean work area. Each workstation includes an interlocking bi-fold sash with a safety switch that automatically turns off the UV light and activates the blower and fluorescent light when the sash is raised.

Developed and released by AirClean Systems (Raleigh, NC, USA; www.aircleansystems.com), these PCR workstations are available in 60.96 cm, 81.28 cm, and 121.92 cm widths. Standard on 81.28 cm and 121.92 cm wide models: a UVTect Microprocessor Controller maintains airflow to provide a clean Class 100 work area during PCR preparation. UVTect also allows the operator to digitally set the irradiation timer and lab-event timer to current application requirements. This microprocessor controller constantly monitors the effectiveness of the workstation and includes audible and visible alarms to alert the user of insufficient airflow and if the HEPA filter or UV bulb needs replacement. The user is also able to adjust the airflow manually, accommodating even the most fragile samples.

The unit offers innovative seamless UV-reflective Lexan construction with 360-degree visibility. The unibody design has overlapping parts to ensure that no harmful ultraviolet energy escapes the chamber during sterilization. The base is made of a custom extruded polypropylene blend that not only reflects ultraviolet energy but allows for easy cleaning between amplifications. AC600 Series PCR workstations are shipped fully assembled.

Image: The AC600 series PCR workstation (Photo courtesy of AirClean Systems).

Fecal DNA Test Accurately Diagnoses Colorectal Neoplasia

A fecal DNA test is significantly more accurate than a new plasma test for identifying patients with large precancerous polyps or colorectal cancer (CRC). The sensitivities of a multimarker test for stool DNA (sDNA) and a plasma test for methylated Septin 9 (SEPT9) have been compared in identifying patients with large adenomas or CRC.

Scientists at the Mayo Clinic (Rochester, MN, USA; www.mayoclinic.org) analyzed paired stool and plasma samples from 30 patients with CRC and 22 with large adenomas from the clinic's archives. Control included 46 fecal and 49 plasma samples from age- and sex-matched patients with normal colonoscopy results. The sDNA test is an assay for four methylated genes; a mutant form of the Kirsten rat sarcoma viral oncogene (KRAS); the β-actin gene, and measures hemoglobin levels by the porphyrin method.

The sDNA assay was performed at Exact Sciences Laboratories (Madison, WI, USA; www.exactsciences.com) and the plasma test, the methylated DNA detection by real-time polymerase chain reaction (PCR) for Septin 9 (SEPT9) was performed at the ARUP Laboratories (Salt Lake City, UT, USA; www.aruplab.com). Results were considered positive, based on the manufacturer's specificity cutoff values of 90% and 89%, respectively.

The sDNA test detected 82% of precancerous polyps compared to only 14% percent detected by SEPT9. The sDNA test identified 87% of cancers at any stage, compared to 60% with SEPT9. The sDNA was even more effective at detecting curable-stage cancer, that is stages I, II or III, and detecting such cases 91% of the time, compared to just 50% with SEPT9. The SEPT9's rate of false-positives was 27%, which is nearly four times that of stool DNA at 7%. The authors concluded that based on analyses of paired samples, the sDNA test detects nonmetastatic CRC and large adenomas with significantly greater levels of sensitivity than the SEPT9 test. These findings might be used to modify approaches for CRC prevention and early detection assays.

David A Ahlquist, MD, the senior author of the study, said "It was important to compare tests head-to-head. Our findings are clear and entirely consistent with the biology of the marker release. Cancerous and precancer cells are shed into the stool and detected by the stool DNA test long before tumors progress to invade the bloodstream for later detection by the plasma SEPT9 screening test." The study is slated for publication in the March 2012 issue of the journal *Clinical Gastroenterology and Hepatology.*

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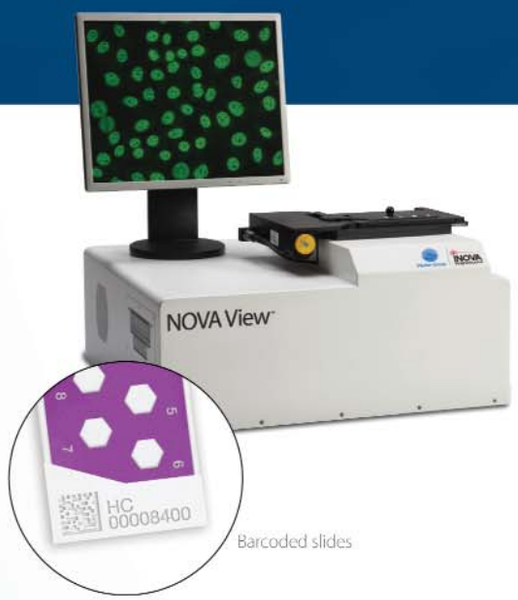

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Molecular Assays Evaluated for Influenza in Blood Donors

Sensitive molecular assays have been used to screen blood donors for the presence of influenza viremia via ribonucleic acid (RNA) testing.

Several influenza RNA amplification assays, including transcription-mediated amplification (TMA) and two reverse-transcription polymerase chain reaction (RT-PCR) assays were evaluated and used to test donor samples.

Scientists at the Blood Systems Research Institute (San Francisco, CA, USA; www.bsrisf.org) collaborating with other institutes, retrospectively tested samples from 478 subjects drawn at sites with high influenza activity. They collected prospective samples from 1,004 blood donors who called their donation center within three days of donation complaining of influenza-like illness (ILI). The plasma collected on the day of donation for these subjects was tested.

A number of different influenza RNA detection assays were evaluated prior to testing donor samples, all of which were previously shown to detect commonly circulating contemporary influenza viruses. The MGB Alert system (Epoch Biosciences; Bothell, WA, USA; www.epochbio.com) uses RNA extraction followed by RT-PCR. The Prodesse ProFlu-1 assay (Gen-Probe, San Diego, CA, USA; www.gen-probe.com) uses RNA extraction followed by a TaqMan-based, real-time RT-PCR amplification targeting the influenza A matrix gene. Transcription-mediated amplification, also from Gen-Probe, uses a target-capture probe for influenza A matrix gene during RNA extraction followed by isothermal amplification using bacteriophage T7 RNA polymerase and Moloney murine leukemia virus reverse transcriptase. The assays were validated on spiked samples and an animal model.

Of the repository samples, two of 478 plasma samples were initially reactive, but were not repeat reactive by influenza TMA. Of blood donors reporting ILI symptoms after donation, only 1 of 1,004 samples was TMA initially reactive, but was not repeat reactive, while all samples were nonreactive by RT-PCR testing. The authors 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. The study was published on March 15, 2012, in the *Journal of Infectious Diseases*

Immunoassay Assessed for Diagnosis of Norovirus Gastroenteritis

The sensitivity and specificity of a commercial *Norovirus* immunochromatographic test has been evaluated on human stool samples.

The immunochromatographic test is based on reverse 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.

Scientists at Mahidol University (Bangkok, Thailand; www.mahidol.ac.th) tested 86 stool samples for noroviruses using the commercial immunochromatographic test RIDA QUICK *Norovirus,* which uses the biotin-streptavidin-peroxidase method. In addition, 54 *Norovirus*-positive samples from a second test group were also detected, and the copy number of *Norovirus* quantified by using a commercial real-time RT-PCR. *Norovirus* GI and GII antigens in stool samples can be detected using the RIDA QUICK *Norovirus* Test.

The sensitivity was analyzed using stool samples of the two test groups, which were confirmed for *Norovirus* infection by RT-PCR and RT-nested PCR, respectively. Based on the RT-PCR, the sensitivity of the RIDAQUICK *Norovirus* assay (R-Biopharm; Darmstadt, Germany; www.r-biopharm.com) was 83.3% (15/18 samples), but compared with the RT-nested PCR, the sensitivity decreased to 48.2% (26/54 samples). The specificity of the assay was analyzed using *Norovirus*-negative stool samples from the control group and accounted for 87.5% (28/32 samples). The assay revealed false positives of 12.5%.

Among 23 stool samples showing *Norovirus* positive by both the RIDA QUICK *Norovirus* assay and the real-time RT-PCR (Shanghai ZJ Bio-Tech, Shanghai, China; www.liferiver.com.cn), the virus could be detected in samples taken on days 1–8 after onset of illness and these samples harbored *Norovirus* GII. The real-time RT-PCR for the simultaneous detection of *Norovirus* GI and GII and quantitation was completed on the LightCycler 1.5 Instrument Real Time PCR System (Roche Diagnostics, Mannheim, Germany; www.roche.com). Viral ribonucleic acid (RNA) was extracted using the QIAam Viral RNA extraction kit (QIAGEN GmbH, Hilden, Germany; www.qiagen.com).

The authors concluded that the RIDA QUICK *Norovirus* assay is rapid and simple to perform. The assay has high sensitivity and specificity. This method 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 in both developed and developing countries 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*

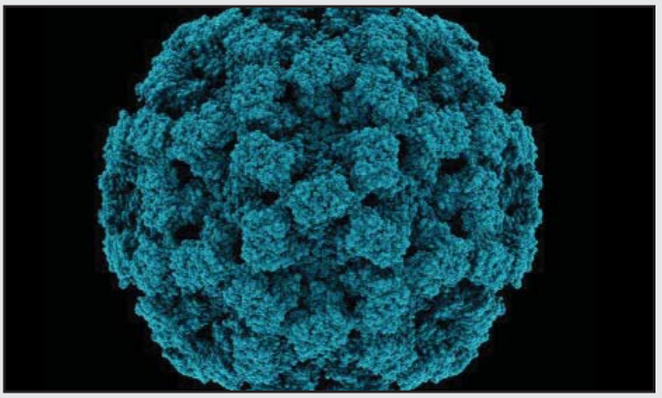

Image: Computer artwork of the capsid of the Norwalk virus (Norovirus sp.), a major cause of acute gastroenteritis worldwide (Photo courtesy of Laguna Design).

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, and the most common nonviral sexually transmitted pathogen with more than 7 million cases of trichomoniasis each year in the US.

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). This test was developed using 100 well-characterized *T. vaginalis* isolates from the US Centers of Disease Control (CDC; Atlanta, GA, USA; www.cdc.gov).

Patients are normally treated with a single oral dose of metronidazole, an antibiotic used to treat infections caused by anaerobic bacteria and parasites. Although generally effective, some *T. vaginalis* strains are resistant to metronidazole. If metronidazole treatment fails, the only other approved treatment is the related drug tinidazole. Therefore, identifying *T. vaginalis* resistance to metronidazole can help guide clinicians in prescribing an effective therapy for their *T. vaginalis* patients at the time of diagnosis.

Although metronidazole treatment is reported to be 85% to 95% effective, recent reports suggest that between 2.5% and 10% of clinical *T. vaginalis* isolates exhibit some degree of metronidazole resistance. A viable culture of *T. vaginalis* must be obtained using a specialized collection and transport device. The assay was developed by Medical Diagnostic Laboratories, (MDL; Hamilton, NJ, USA; www.mdlab.com).

Eli Mordechai, PhD, Chief Executive Officer of MDL said, "We are pleased to offer this new diagnostic test for patients infected with *Trichomonas vaginalis*, an extremely common sexually transmitted infection. This test will be especially useful in identifying select strains of *Trichomonas vaginalis* that are resistant to the most widely prescribed drug, metronidazole."

Image: Scanning electron micrograph (SEM) of Trichomonas vaginalis, the human parasitic flagellate that causes the sexually transmitted disease trichomoniasis (Photo courtesy of David Phillips / SPL).

The Future for Laboratory Technology Projected

Biomedical laboratories need to be able to deal with a high throughput of samples while reliably documenting each step in the testing process.

The fact that it takes so long for laboratories to analyze samples is in no small part due to all the cumbersome paperwork as each sample must be accompanied by meticulous records. At the Fraunhofer Institute for Biomedical Engineering (IBMT; St. Ingbert, Germany; www.ibmt.fraunhofer.de) scientists are developing a fully automated approach to testing, with a particular emphasis on automating the documenting of samples. The main aim is to enable sample data to be processed automatically. A tiny microchip is embedded in the plastic of the test tube and used to store all relevant information, such as when and where a sample is from and the patient's name. In the past, test tubes would be written on by hand; more recently, the data has been stored in a barcode for easy scanning.

When the test tube is placed into an analyzer, the equipment can record details on the embedded chip of exactly what went on in the analysis. This means the test tube itself carries the sample's entire history, with no need for technicians to write up a laborious report including the patient's details, the results of the analysis and the testing methods employed. Scientists at IBMT are working together with Soventec GmbH (Dannewerk, Germany; www.soventec.de) to develop the LabOS laboratory management system. Working with LabOS, as soon as a test tube is placed in a reader, a screen displays data on the sample's history and also what the next steps are without the need for any paperwork.

Daniel Schmitt, Dipl. Phys., a project leader for the IBMT, said, "Usually, samples are accompanied by a report slip. Alternatively, the laboratory will know to expect a sample when it receives an e-mail containing all the necessary information. With test tube chips, the sample and the information are inseparably linked, and there is no way for information to go astray." For some time now, the project partners have been able to demonstrate just how well all this technology works together thanks to a mobile laboratory. Housed in a truck that is traveling all over South Africa, it is mainly working to diagnose AIDS and tuberculosis. The scientists showed the effectiveness of their concept at the MEDTEC Europe trade fair in Stuttgart, Germany from March 13 to 15, 2012 (www.medteceurope.com).

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Human Granulocytic Anaplasmosis Confirmed by Molecular Assay

Human granulocytic anaplasmosis (HGA) is a tick-borne infection, yet few clinical cases have been diagnosed by a positive polymerase chain reaction (PCR) assay.

Subsequent seroconversion against the antigen of the causative intraerythrocytic agent, *Anaplasma phagocytophilum*, would fulfill the epidemiologic, clinical, and biological criteria for HGA, which is characterized by an acute, nonspecific febrile illness.

At the Hôpitaux Universitaires de Strasbourg (France; www.chru-strasbourg.fr), 15 patients presented with a febrile syndrome with a recent history of tick bites or exposures to ticks were tested for HGA, during the period June to September 2009. Whole blood samples with ethylenediaminetetraacetic acid (EDTA) were systematically collected for blood smear and specific PCR assay during the febrile phase of the disease. For serologic testing, two sera were also collected: the first during the acute phase and the second two to three weeks afterwards, during the convalescent phase.

DNA was extracted from whole-blood samples and real-time PCR was performed on the ABI Prism 7000 SDS (Applied Biosystems; Foster City, CA, USA; www.appliedbiosystems.com). Serologic diagnosis of infection with *A. phagocytophilum* was made by immunofluorescent antibody test (IFA) (Focus Diagnostics, Cypress, CA, USA; www.focusdx.com). Serum specimens with immunoglobulin M (IgM) titers of equal or greater than 1:40 and IgG titers equal to or greater than 1:64 were considered positive. Blood smears were obtained from whole blood samples, stained with May-Grünwald-Giemsa and examined for the presence of morulae within the cytoplasm of neutrophils.

Molecular testing using the major surface protein 2 (msp2)/p44 gene yielded positive results in the acute-phase blood of three of the 15 patients tested. For the 12 patients with negative PCR assay, microscopic examination was negative and no specific antibodies were detected in acute-phase serum. Laboratory findings were available for 6 patients among the 12 with a negative PCR assay; all these 6 presented leucopenia, thrombocytopenia, and increased levels of liver enzymes. For the three patients with positive PCR results, examination of peripheral blood smears revealed cytoplasmic inclusions suggestive of *A. phagocytophilum* morulae and elevated serum levels of liver enzymes.

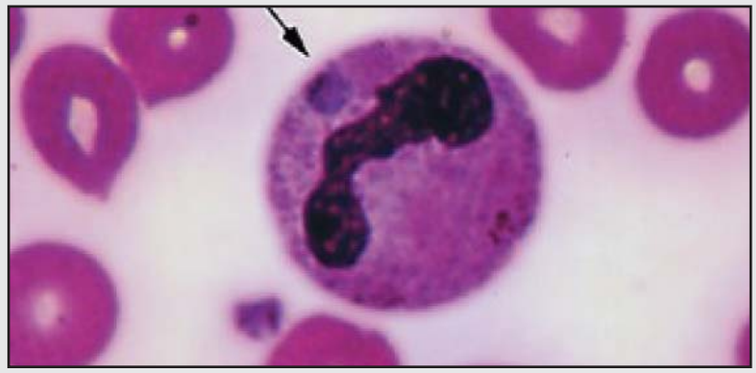

Image: Anaplasma phagocytophilum, causative agent for anaplasmosis (Photo courtesy of Medscape).

The authors concluded that a specific PCR assay on EDTA anticoagulated blood may be the diagnostic test of choice for HGA during the first two weeks following the onset of symptoms, allowing a faster diagnosis than serology. HGA should be included in the differential diagnosis of patients presenting febrile illness associated with bicytopenia, elevated rates of liver enzymes, increased C-reactive protein values, and whose medical history reveals recent exposure to ticks. The study was published in the March 2012 issue of the journal *Diagnostic Microbiology and Infectious Disease.*

Novel Biomarker Facilitates Diagnosis of Alzheimer's

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).

The method directed against the aggregated beta-amyloid, which is a protein complex believed to cause major nerve cell damage and dysfunction in AD, could also help development of drugs for the treatment of AD.

An international team of scientists, including those Lund University (Sweden; www.lunduniversity.lu.se) and also from Germany, and the USA, have used a novel method to quantify soluble variants of aggregated beta-amyloid (Aβ oligomers) in cerebrospinal fluid by flow cytometry. They analyzed the cerebrospinal fluid of 30 neurological patients, including 14 Alzheimer's patients. They found that patients had a more pronounced disease when they had greater number of Aβ oligomers in the cerebrospinal fluid.

The neuropathology of Alzheimer's disease has recently been linked to the neurotoxic Aβ oligomers. The crucial role of Aβ oligomers in the early events of AD is experimentally underlined. Several recent results suggest that those oligomers may cause the death of neurons and neurological dysfunctions relevant to memory. Furthermore Aβ oligomers levels are increased in brain and cerebrospinal fluid samples from people with Alzheimer's disease. This reflects the potential of Aβ oligomers as a marker for the early diagnosis of the disease.

The test might not only be used for the early detection of AD but can also be used when developing new and effective therapies for AD. A decline in the number of Aβ oligomers in cerebrospinal fluids could be a hint for the effectiveness of new drug therapies. Harald Hampel, MA, MD, MSc, a professor at Frankfurt University (Germany; www.uni-frankfurt.de) and lead investigator of the study said, "These samples provided from leading expert academic memory clinics in Germany and Sweden are of the best quality and are highly characterized in order to provide robust and reliable results on promising novel biomarker candidates." The study was published in the March 2012, issue of *Journal of Alzheimer's Disease.*

Cytolytic Cell Expression Predicts HIV Prognosis

A subpopulation of the immune cells targeted by the Human immunodeficiency virus (HIV) may play an important role in controlling viral loads after initial infection.

The role of HIV-specific cluster of differentiation 4 (CD4) thymocyte (T) cell responses in the control of viral replication after acute infection is unknown, but may have the capacity to directly recognize and kill virally infected cells.

To investigate whether CD4 T cell responses are important in the early control of HIV infection, a team at the Ragon Institute (Charlestown, MA, USA; www.ragoninstitute.org) conducted a longitudinal cohort study enrolling a group of 11 volunteers who were in the earliest stages of HIV infection, a time when viral levels are exceedingly high. A year into the study, participants were divided into two groups based on the level of HIV in their bodies. One group was able to keep HIV at low levels while the other group apparently had no immune control over HIV replication.

Retrospective analysis of samples taken throughout the year showed striking differences in the CD4 T cell responses in both groups. While the HIV-specific CD4 responses in the group that did not control HIV replication quickly dropped and stayed low, the same response increased significantly in participants able to effectively control the virus, suggesting a role for HIV-specific CD4 cells in viral control. The HIV-specific CD4 T cell responses showed activity associated with cell killing and could even destroy HIV-infected macrophages, which is an unusual function for CD4 T cells, which have traditionally been seen as helper cells.

In addition, the scientists determined that the presence of a specific cell-death protein called granzyme A prominently distinguished HIV-specific CD4 cells of participants maintaining a lower "viral set point" from those less able to control viral levels. A larger group of HIV-infected individuals were examined and it found that those with higher levels of granzyme A in their HIV-specific CD4 T cell response immediately after infection progressed more slowly to acquired immunodeficiency syndrome (AIDS) and did not require antiretroviral therapy as quickly as did those with lower levels of the protein.

The authors concluded that the association of granzyme A expression with a more effective HIV-specific CD4 cell response suggests that measuring levels of the protein may allow prediction of disease outcome at the earliest stages of infection, something which is not currently possible. Hendrik Streeck, MD, PhD, a senior author of the study said, "We observed the emergence of CD4 T cells able to kill HIV-infected cells in those patients who are able to control viral replication soon after acute infection. These cells appear very early in HIV infection, and we believe they may set the stage for the course of the disease." The study was published on February 29, 2012, in the journal *Science Translational Medicine*.

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Molecular Test Identifies Hormone-Responsive Breast Cancer

A molecular test may play a significant role in identifying hormone-responsive breast cancer.

Breast Cancer Index(SM) (BCI) with its novel mechanism of action, provides oncologists with insight into the risk of late recurrence for estrogen receptor positive and lymph node negative (ER+, LN-) breast cancer patients. In addition, BCI appears to demonstrate significant predictive utility in determining which patients will benefit from neoadjuvant (preoperative) chemotherapy and are candidates for breast conserving surgery (BCS).

bioTheranostics, Inc. (San Diego, CA, USA; www.bioTheranostics.com) a bioMerieux (Marcy l'Etoile, France; www.bioMerieux.com) company that develops oncology diagnostic tests to direct personalized treatment, announced results from studies that demonstrated the increased clinical utility of the Breast Cancer Index(SM) (BCI). Data from the studies, presented at the Cancer Therapy and Research Center – American Association for Cancer Research (CTRC-AACR) San Antonio Breast Cancer Symposium (SABCS) held from December 6-10, 2011, in San Antonio, (TX, USA) suggest that BCI, with its novel mechanism of action, provides oncologists with insight into the risk of late recurrence for estrogen receptor positive and lymph node negative (ER+, LN-) breast cancer patients.

In addition, BCI appears to demonstrate significant predictive utility in determining which patients will benefit from neoadjuvant (preoperative) chemotherapy, and are candidates for breast conserving surgery (BCS).

Mark Erlander, PhD, CSO of bioTheranostics said, "Although first-generation multigene signatures provide prognostic information, their utility is strongest for predicting relapse within five years of the breast cancer diagnosis. Breast Cancer Index demonstrates sustainable prognostic power and particularly addresses the unmet medical need of late recurrence."

Neoadjuvant chemotherapy is very important for physicians because oncologists want to identify which patients would have the greatest likelihood of being eligible for breast conserving surgery after neoadjuvant chemotherapy.

Iron Levels Linked to Blood Clots

In patients with an inherited blood vessel disease, treating their iron deficiency might be important to prevent potentially lethal blood clots.

People with low levels of iron in the blood have a higher risk of dangerous blood clots, which can cause pain and swelling, but can be fatal if the clot is dislodged and travels into the blood vessels of the lungs.

Scientists at Imperial College London (UK; www.imperial.ac.uk) analyzed blood from 609 patients reviewed at the hereditary hemorrhagic telangiectasia (HHT) clinic at Hammersmith Hospital (London, UK; www.imperial.nhs.uk) from 1999 to 2011, to look for differences between the patients who had blood clots and those who did not. HHT is an inherited disease of the blood vessels, the main symptoms of which are excessive bleeding from the nose and gut. Many of the patients had low iron levels because of iron lost through bleeding. The scientists found that low levels of iron in the blood were a strong risk factor for blood clots. Patients who took iron supplements did not have higher risk, suggesting that treatment for iron deficiency can prevent blood clots.

The link between iron levels and blood clots appears to be dependent on coagulation factor VIII, a blood protein that promotes normal clotting. High levels of factor VIII in the blood are also a strong risk factor for blood clots, and low iron levels were strongly associated with higher levels of factor VIII. The gene encoding factor VIII has sites where iron-binding proteins can bind, making it plausible that iron levels could regulate the factor VIII gene, and that this might be the mechanism for the link.

Claire Shovlin, PhD, lead author of the study, said, "Most of our patients who had blood clots did not have any of the known risk factors. We thought that studying people with HHT might tell us something important about the wider population. We can speculate that in evolutionary terms, it might be advantageous to promote blood clotting when your blood is low in iron, in order to prevent further blood loss." In this population, low serum iron levels attributed to inadequate replacement of hemorrhagic iron losses are associated with elevated plasma levels of coagulation factor VIII and venous thromboembolic risk. The study was published on December 14, 2011, in the journal *Thorax.*

Lactate Added to Critical Care Analyzer Menu

A lactate assay has become available for cartridge-based critical care testing at the Point of Care (POC). Lactate joins an already extensive assay menu that includes blood gas, electrolytes, metabolites, and CO-oximetry.

Siemens (Erlangen, Germany; www.siemens.com/healthcare) continues to expand the assay menu of its RAPIDPoint 500 critical care analyzer. The easy-to-use RAPIDPoint 500 system uses Siemens technology to deliver rapid and accurate test results in approximately 60 seconds.

The value of measuring lactate levels is expanding. Though generally considered a non-specific biomarker, knowing lactate levels early in a patient's presentation can provide valuable information to help guide patient assessment and treatment.

It can be particularly useful in the Intensive Care Unit (ICU) and Emergency Department (ED) settings where the presentation of symptoms may be inconclusive while diseases progress rapidly with severe pathology; lactate testing can open a critical window for early intervention when treatment is most likely to be successful. This allows clinicians to quickly gain diagnostic information for treatment planning.

Afia Boamah, blood gas and stratus CS product manager at Siemens Healthcare Diagnostics, stated, "The addition of Lactate to the already extensive assay range on the RAPIDPoint 500 follows an extremely successful Controlled Release Program. Over 21,000 samples were run with zero cartridge failures attributable to the lactate sensor. Such results underpin the confidence we have in our cartridge based technology and the functionality it adds to the RAPIDPoint 500 System."

The RAPIDPoint 500 Lactate Cartridge received the CE Marking, December 16, 2011.

RAPIDPoint 500 Analyzer received the CE Marking, September 26, 2011.

Image: The RAPIDPoint 500 POC analyzer (Photo courtesy of Siemens Healthcare Diagnostics).

Biomarkers May Predict Chemo-Resistant Breast Cancers

A family of proteins has been identified that could potentially be used as biomarkers to predict resistance to chemotherapy in breast cancer patients.

Protein biomarkers have been identified that are associated with response to neoadjuvant chemotherapy using comparative high-throughput processes based on antibodies and using mass spectrometry, and proteomic analysis of estrogen receptor-positive (ER-positive) breast tumor samples.

Scientists at the University of Hull (UK; www2.hull.ac.uk) conducted comparative proteomic studies using the two dimensional gel electrophoresis, matrix-assisted laser desorption/ionization time-of-flight mass spectrometer (2-DE MALDI TOF/TOF MS) on fresh tumor samples. They identified 132 unique proteins that were significantly differently expressed, more than two-fold, in chemotherapy resistant samples, 57 of which were identified in at least two studies.

Five of the proteins in the 57 candidates belong to the 14-3-3 protein family, namely the isoforms: theta/tau, gamma, epsilon, beta/alpha and zeta/delta, which have previously been associated with chemotherapy resistance in breast cancer. The team says their findings confirm the 14-3-3 protein family as a strong candidate for a predictive test for chemotherapy resistance. Without a means to predict whether chemotherapy will work, some patients with resistant cancers undergo much hardship while suffering the side effects of ineffective chemotherapy options without the benefits, plus they lose valuable time until an effective therapy is found.

The Ultraflex III MALDI TOF/TOF MS used in the study was manufactured by Bruker Daltonics (Billerica, MA, USA; www.bdal.com). Lynn Cawkwell, PhD, the senior author of the study, said, "If we're correct, we hope that by testing for these proteins, doctors will be able to anticipate a patient's response to different chemotherapies, and decide which course of treatment is most appropriate for them." The team is also investigating radiotherapy resistance in a number of different cancers. The study was published on April 3, 2012, in the *Journal of Proteomics.*

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Diagnostic Automation / Cortez Diagnostics

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EIA ASSAY
Fujirebio Diagnostics

The HE4 Test in ROMA algorithm combines the HE4 EIA assay with the ARCHITECT CA 125 II and menopausal status into a numerical score. ROMA is intended to help assess the malignancy of ovarian adnexal masses in pre- or post-menopausal women.

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Transport Medium Evaluated for Gut Bacterium

An alternative transport medium supplemented with a cyanobacterial extract (CE) has been evaluated for the preservation and viability of *Helicobacter pylori* strains.

The transport medium was free of animal derivatives, and was compared with other media during long-term transportation and the recovery of *H. pylori* from biopsy samples.

Microbiologists at the Universidad Nacional de San Luis (Argentina; www.unsl.edu.ar), collected four gastric antral biopsy specimens from 134 patients with gastroduodenal disease and were positive *H. pylori* infection. The transport media were based on an agar soft medium prepared with Mueller–Hinton broth 0.3% agar (MH) and 0.3% of CE (MH-CE). MH 5% fetal calf serum (FCS) was used as the reference medium (MH-FCS). Two gastric biopsy samples were placed into MH-CE or MH-FCS transport media and stored at 4 °C and at room temperature. Another biopsy sample was used for the urease test and polymerase chain reaction (PCR) identification. The remainder of the biopsy specimen was Gram stained. The diagnosis of *H. pylori* infection was established when two of three diagnostic methods, urease test, Gram or culture) were positive, followed by confirmation with PCR.

The recovery rate of *H. pylori* at 4 °C was similar among MH-CE and MH-FCS transport media between 24 to 72 hours, whereas a higher recovery was obtained with MH-CE after 96 and 120 hours. Only MH-CE allowed recovery after 120 hours. The *H. pylori* recovery at room temperature after 96 hour was higher in MH-CE than in MH-FCS. Similar survival rates were observed in biopsy samples conserved in MH-CE and MH-FCS at 4 °C. The recovery after 48 hours at room temperature in MH-CE was higher than MH-FCS and was the only medium allowing recovery after 72 hours. The viability of *H. pylori* strains stored within agar plugs in transport media and from biopsy specimens was assessed by viable count determinations (colony-forming units) on Mueller–Hinton agar supplemented with 7% horse blood (MHA-B) and direct fluorescence microscopy with the LIVE/DEAD BacLight Bacterial Viability Kit (Invitrogen Corporation, Eugene, OR, USA; www.invitrogen.com).

The authors concluded that MH-CE could be used as a transport medium to minimize the loss of bacterial viability when immediate culture or cool shipping is not possible. The transport medium proposed is simple to handle, inexpensive and complies with the present tendency of avoiding the use of animal derivatives. The study was published in the February 2012 edition of the *European Journal of Clinical Microbiology and Infectious Diseases.*

Image: Colored scanning electron micrograph (SEM) of Helicobacter pylori bacteria, a Gram-negative spiral-shaped bacterium found in the mucus lining of the stomach (Photo courtesy of Juergen Berger / SPL).

Blood Type Predisposes to Certain Viral Infections

Some strains of *Rotavirus* find their way into the cells of the gastrointestinal tract by recognizing antigens associated with the type A blood group.

Histo-blood group antigens are known to promote binding of *Norovirus* and *Helicobacter pylori* cells to intestinal cells, but this had never been demonstrated in *Rotavirus*, a major intestinal pathogen that is the leading cause of severe dehydration and diarrhea in infants around the world.

Scientists at Baylor College of Medicine (Houston, TX, USA; www.bcm.edu) examined the structure of a key part of a strain of the virus known as P[14] which provides a clue to how the virus infects human cells. The scientists used various techniques including protein expression and purification, crystallization, glycan array screening, inhibition and infectivity assays, and hemagglutination assays.

In strains of *Rotavirus* that infect animals, the top of a spike on the virus attaches to the cell via a glycan, one of many sugars linked together to form complex branched-chain structures with a terminal molecule of sialic acid. The same did not appear to be true of virus strains that infect humans, and scientists believed the human *Rotavirus* strains were bound to glycans with an internal sialic acid molecule, but they did not know how this occurs.

The investigators determined the structure of the top of the virus spike domain, known as VP8, and found that the type A glycan bound to the *Rotavirus* spike protein at the same place as the sialic acid would have in an animal *Rotavirus*. They used crystallography, to show subtle changes in the structure of the VP8* domain of the virus that allowed it to use the histo-blood group antigen A as a receptor. An antibody to the histo-blood group antigen A blocked infection by the virus into human intestinal cells in culture. The authors found humans infected with the P[14] strain had type A blood, but more studies are needed to confirm the connection.

B. V. Venkataram Prasad, PhD, the lead author and professor of biochemistry and molecular biology at Baylor College of Medicine, said, "We wondered how this genotype of *Rotavirus* recognized a cellular glycan. We did a glycan array analysis to see which glycans interacted with the top of the virus spike, called VP8. No one expected this. Is there an emerging theme here with these intestinal pathogens? Do other viruses use these blood group antigens as a door to enter the cell? The question now is do different strains use other histo-blood group antigens in this way?" Further studies identified a second *Rotavirus* strain P[9] that uses the histo-blood group antigen as a receptor. The study was published online on April 15, 2012 in the journal *Nature*.

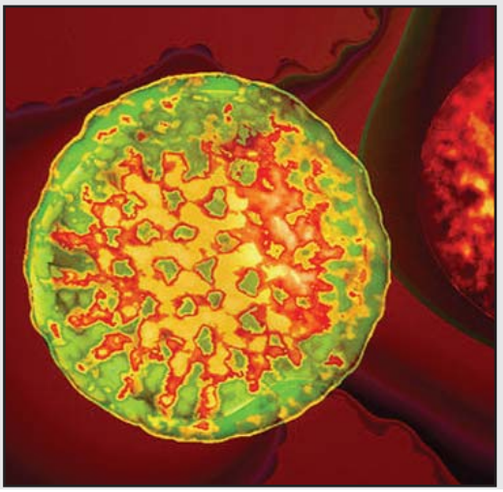

Image: Colored transmission electron micrograph (TEM) of two rotaviruses on a fractal background (Photo courtesy of Dr. Linda Stannard, UCT).

PSA Screening Significantly Reduces Death from Prostate Cancer

A study of screening for prostate cancer has found that a man who undergoes prostate specific antigen (PSA) testing will have his risk of dying from prostate cancer reduced by 29%.

Participants in the randomized study totaled 182,000, of which 162,000 men contribute to the core age group 55-69. Men randomized to the group being offered screening were tested using the prostate specific antigen (PSA) marker, every two or four years with an average follow-up of 11 years. The cut-off value for deciding if further investigation was needed was set at a PSA level of 3.0 ng/mL or more. Men with this reading were then offered a biopsy.

The long-running European Randomized Study of Screening for Prostate Cancer (ERSPC; www.erspc.org) is the world's largest prostate cancer screening study and involves eight countries–Belgium, Finland, France, Italy, Netherlands, Spain, Sweden, and Switzerland.

Prof Fritz Schroeder, the international coordinator of the ERSPC study, explained, "Extending the follow up period strengthens the argument for screening. But it does not decide it. Even so, the risk reduction trend in our study is promising and it is imperative that we continue the follow-up. So far, only about 30% of all men in the study have died. If a larger reduction of prostate cancer mortality is seen by further extending the study beyond the current median of 11 years, we can determine with greater certainty whether the benefit of screening outweighs the disadvantages."

The main negative aspect of screening is over diagnosis; the diagnosis of cancer that does not pose any threat to the patient because they are slow growing or "indolent." Separate ERSPC findings already confirm that approximately 30% of detected cancers are unlikely to progress and cause a patient's death. Even so, the patient has received a diagnosis of cancer and he could face the side effects of "unnecessary" treatment.

Currently, the only way for men with potentially insignificant cancers to avoid what could be unnecessary treatment is to direct them towards an Active Surveillance program. This offers them regular check-ups while delaying, at least temporarily, invasive treatment.

The study appeared on March 15, 2012, in the *New England Medical Journal (NEJM)*.

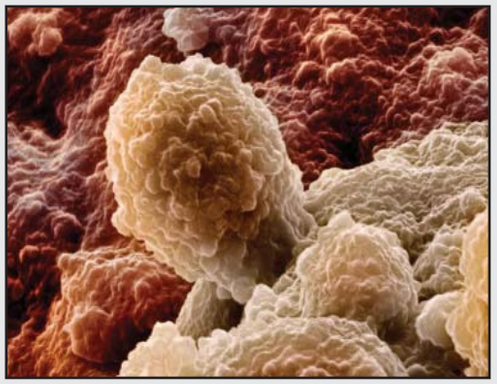

Image: Colored scanning electron micrograph (SEM) of prostate cancer cells (Photo courtesy of David McCarthy / SPL).

Cryopreserved Erythrocytes Processed for Blood Transfusion

Cryostorage of red blood cells (RBCs) represents a valid alternative to liquid storage, since units can be preserved safely for at least a decade while conserving cell viability.

Preservation of blood for transfusion purposes has represented a lifesaving advance in clinical practice over many years, but although cryostorage has attracted a great deal of attention clinically, little is known about the biochemistry and physiology of cryostored erythrocyte concentrates.

Specialists at the University of Tuscia (Viterbo, Italy; www.unitus.it) investigated cryostorage of RBCs through monitoring of cell processing steps, from fresh blood, to glycerolization, thawing, and deglycerolization, followed by washing. Whole blood was collected from 10 healthy donor volunteers into 63 mL of citrate phosphate dextrose (CPD) anticoagulant, and leukodepleted. All glycerolized RBC units were frozen and stored at 80 ± 10 °C in a mechanical freezer for at least 12 months.

The erythrocytes were monitored through repeated assays of standard parameters of mean cell volume (MCV), red cell distribution width-standard deviation (RDW-SD), the mean cell hemoglobin concentration (MCHC), and the hematocrit (Hct). These were determined with a CA 530-Oden hematology analyzer. Scanning electron microscopy was also performed. Other standard biological indicators, such as hemoglobin content, pH values both internal and in the supernatant, lactate levels, osmotic fragility and hemolysis, were also calculated.

Cell processing for cryostorage resulted in increased RBC volumes. Mean cell volume (MCV) increased significantly upon glycerolization, from 89.4 ± 4.5 fL of fresh RBCs to 126.04 ± 2.3 fL of glycerolized RBCs, while it remained constant at 129.6 ± 3.3 fL upon cryostorage even after thawing. Deglycerolization and washing restored lower MCV values 93.7 ± 5.9 fL, though they were still higher than controls. Shape alterations caused an increase in osmotic fragility and permeability to ions. A significant pH drop was observed which could not to be attributed to a higher metabolic rate, since the levels of lactate did not show substantial fluctuation during the cell processing steps tested in this study. The membrane anomalies reported are likely related to the hemolysis observed which preferentially affected the densest and oldest cell sub-populations, as confirmed by means of discontinuous density gradients. The CA 530-Oden hematology analyzer used in the study is manufactured by Medonic (Stockholm, Sweden; www.medonic.se).

The authors concluded that their results indicate that cryostorage itself in presence of glycerol does not significantly affect RBCs. Most of the alterations observed were related to cell processing and, in particular, to the increase of cytosolic glycerol as a consequence of the glycerolization step. Further studies might profitably investigate replacing glycerol with nonpenetrating cryoprotectants such as polyvinylpyrrolidone or polyethylene glycol, or the less toxic sucrose and trehalose. The study was published online on March 14, 2012, in the journal *Blood Cells, Molecules, and Diseases.*

Image: Colored scanning electron micrograph (SEM) of red blood cells (erythrocytes) and a white blood cell (lymphocyte) (Photo courtesy of Steve Gschmeissner / SPL).

Biomarker Links Clinical Outcome of Lethal Tumor Metabolism

The prognostic value of a metabolic biomarker has been directly linked to the clinical outcomes with a new model of tumor metabolism that has patients "feeding" their cancer cells.

The tumor microenvironment plays a critical role not only in early oncogenesis, but also in tumor progression as well as in the response of cancer cells to therapy, and therefore it is important to study both the malignant tissue and the surrounding stroma.

Scientists at the Kimmel Cancer Center (Philadelphia, PA, USA; www.kimmelcancercenter.org) implemented a retrospective analysis of over 180 women with triple negative breast cancer, one of the most deadly forms of breast cancers, with fast-growing tumors that often affect younger women. Tumor tissue-microarrays were constructed using a commercial tissue arrayer. Polyclonal antibodies were used for the specific immunostaining on tissue sections of the metabolic biomarker monocarboxylate transporter 4 (MCT4) and caveolin-1 (Cav-1).

Analyzing the human breast cancer samples, the team found that women with high levels of stromal MCT4 and a loss of stromal Cav-1 had poorer overall survival, consistent with a higher risk for recurrence, metastasis, and treatment failure. The findings suggest that when used in conjunction with the stromal Cav-1 biomarker, which the authors point out has been independently validated by six other groups worldwide, MCT4 can further stratify the intermediate-risk group into high and low risk.

Today, no such markers are applied in care of triple negative breast cancer, and as a result, patients are all treated the same. Identifying patients who are at high risk of failing standard chemotherapy and poorer outcomes could help direct them sooner to clinical trials exploring new treatments, which could ultimately improve survival. The tissue arrayer instrument used in the study was manufactured by Veridiam (Oceanside, CA, USA; www.veridiamtissuearrayer.com) and the anti-Cav-1 polyclonal antibodies are a product of Santa Cruz Biotech (Santa Cruz, CA, USA; www.scbt.com).

Michael P. Lisanti, MD, PhD, a lead author of the study, said, "The whole idea is that MCT4 is a metabolic marker for a new model of tumor metabolism and that patients with this type of metabolism are feeding their cancer cells. It is lethal and resistant to current therapy. This paper is the missing clinical proof for the paradigm shift from the "old cancer theory" to the "new cancer theory," known as the "Reverse Warburg Effect." The new theory being that aerobic glycolysis actually takes place in tumor-associated fibroblasts, and not in cancer cells, as the old theory posits. The study was published on March 15, 2012, in the journal *Cell Cycle*.

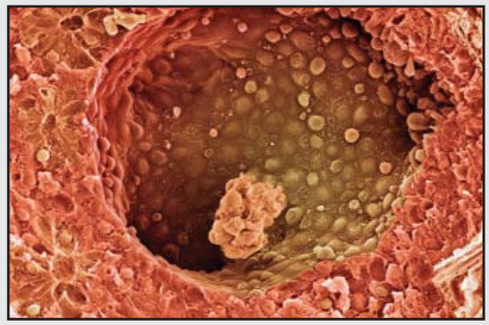

Image: Colored freeze-fracture scanning electron micrograph (SEM) of human breast cancer showing the duct (center) lined with cancerous cells (Photo courtesy of Steve Gschmeissner / SPL).

Liquid Cystatin C Assay – Good Indicator of GFR

A liquid ready-to-use cystatin C assay provides a good indicator of glomerular filtration rate (GRF). As a more sensitive maker of renal dysfunction, cystatin C offers several advantages over traditional creatinine assays.

Cystatin C is unaffected by nonrenal factors including muscle mass, weight, height, age, gender, diet and drugs. Therefore it is particularly useful in cases where creatinine measurement is not appropriate e.g., in individuals who are obese, malnourished, or who have liver disease.

The Randox (Crumlin, United Kingdom; www.randox.com) cystatin C assay is based on an immunoturbidimetric method and is suitable for use on a wide range of chemistry analyzers. All reagents are supplied liquid ready to use for added convenience; furthermore, reagents are stable for 28 days at +10 °C onboard the analyzer, minimizing the possibility of reagent waste.

The assay has a wide measuring range of 0.4 to 10 mg/L allowing both normal and abnormal values to be measured accurately and reliably without the need for additional dilutions. Further benefits include precision (CVs under 5%) and limited interference from bilirubin, hemoglobin, triglycerides, and intralipids. A full range of supporting quality controls and calibrators are also available.

Cystatin C is sensitive to changes in the "creatinine blind" range enabling detection of early reductions in GFR and subsequent early treatment of kidney disease. Cystatin C has several other advantages over creatinine; the ability of cystatin C to detect even small changes in GFR makes it the ideal marker for dosing medication eliminated by the kidneys. Cystatin C is also the preferred marker for estimating GFR in infants, the elderly, diabetics, and those with reduced muscle mass.

Traditionally creatinine was the most widely used marker of GFR and kidney function but several recent studies have documented cystatin C as a far superior and sensitive marker. Cystatin C is produced at a constant rate throughout the body and is removed and broken down by the kidneys, levels will therefore remain steady if the kidneys are working efficiently and the GFR is normal.

The prevalence of chronic kidney disease continues to increase dramatically as does the burden on healthcare resources. The early detection of kidney disease is crucial in order to lower healthcare costs, avoid disease progression, and reduce the need for dialysis or transplantation.

New Diagnostic Collection and Transport Systems Unveiled

A medical products company has launched two liquid-based multipurpose collection and transport systems for diagnostic use.

The Universal Transport Media (UTM) Transport System contains a multipurpose medium allowing for transport and maintenance of clinically relevant viruses and bacteria at room temperature. Medical grade plastic components with a leak proof, self-centering cap feature facilitate easy removal and disposal of the swabs.

The Liquid Amies Transport Systems is a self-contained, ready-to-use multipurpose collection and transport system for aerobes, anaerobes, and fastidious bacteria up to 48 hours at room temperature. It is an ideal system designed to accommodate both automation and traditional liquid specimen processing in clinical laboratories, including culturing and Gram staining.

The UIM system has recently received 510k approval in the United States, and approval for the Liquid Amies system is pending. Both systems are approved for sale in Europe.

Entirely manufactured by Puritan Medical Products (Guilford, ME, USA; www.puritanmedproducts.com) the systems are the crucial first step in the diagnosis of bacterial and viral infections and designed to facilitate safe and effective preanalytical specimen collection and transport to the laboratory. Puritan Medical Products Co. LLC Medical products launched its two liquid-based multipurpose collection and transport systems for diagnostic use through its newly created division, Puritan Diagnostics Company, LLC.

Puritan swabs are easy to use, with tips in various sizes to accommodate various sampling sites, such as nose, throat, and wounds. All handles have premolded break points for ease of use with a self-centering cap and soon will have custom handle imprinting.

Puritan's executive vice president for global sales, Timothy Templet, noted, "The new systems are available with our pure non-yellowing, patent-pending flocked swabs, which collect and elute the sample into the transport liquid better than most competing swabs." He added that a major aspect of both new collection systems is "our ability to provide contract manufacturing and work closely with our customers to create custom liquid solutions to meet essential clinical specimen collection and transport needs

Image: The Universal Transport Media (UTM) and Liquid Amies diagnostic collection and transport systems (Photo courtesy of Puritan Medical Products).

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LAB SYSTEMS
Hitachi Aloka Medical

The LabFLEX3500 Series is a variety of systems that can be configured by combining functional modules to suit the needs, size, and operational methods of facilities. The systems also allow for the configuration of a transport option for specific layout and conditions of a facility.

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LAB SOFTWARE SOLUTION
NoemaLife

The HALIA middleware is designed using a rule-based engine to deliver all-around control over lab workflow and sample processing, while improving efficiency, compliance, and QC. The software is considered ideal for clinical chemistry, microbiology, and molecular biology labs.

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HPV QUALIFICATION PANEL
SeraCare Life Sciences

The HPV Qualification Panel uses cultured human cells containing HPV DNA, and is intended to improve accuracy in diagnostic testing of HPV. The panel is part of a women's health product portfolio, and is designed for use with HPV test kits from Roche, Qiagen, and Hologic.

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URINE CHEMISTRY ANALYZER
Siemens Healthcare

The CLINITEK Novus combines dry-pad urine chemistry technology with an easy-to-use cassette format. The analyzer is designed to help laboratories deliver reliable and accurate test results, while maximizing lab productivity and efficiency.

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Biomolecular System Introduced for Proteins Quantitation

A system for rapid, simplified protein quantitation has been introduced that enables infrared-based measurement of amide bonds in protein chains.

The system does not rely on amino acid composition, dye-binding properties, or redox potential unlike conventional assays based on ultraviolet- visual (UV-Vis) spectroscopy, which do rely on absorbance by a protein's aromatic amino acids and therefore have limited utility.

The Direct Detect system employs a hydrophilic polytetrafluoroethylene (PTFE) membrane designed to be transparent in most of the infrared spectral region and enables application of biomolecular solutions directly onto the membrane. The system delivers more universally applicable and faster protein quantitation, requiring minimal sample consumption. System accuracy and precision are comparable with results obtained by amino acid analysis, an accurate standard for quantitation, yet can be time-consuming and often costly.

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; www.emd.us) 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.

John Sweeney, Head of Life Science Business Field, EMD Millipore, said, "In addition to its analytical powers, the Direct Detect system provides a groundbreaking departure from traditional sample preparation requirements typical of biomolecular quantitation. After samples are spotted on assay cards, they can be stored in ambient conditions without appreciable change in readout. Another important advantage over conventional assays is that the Direct Detect calibration standard curve requires generation once, which provides additional time savings and ease of use." EMD Millipore is a division of Merck (Darmstadt, Germany; www.merck.de.

Image: The Direct Detect Protein Quantitation system (Photo courtesy of EMD Millipore).

Immunosignaturing Provides Accurate Diagnoses

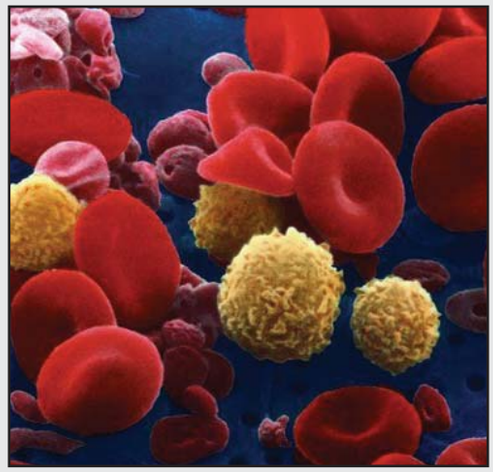

Image: Colored scanning electron micrograph (SEM) of human blood showing red and white cells, as well as platelets (Photo courtesy of the National Cancer Institute).

A technique known as immunosignaturing harnesses 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 those samples from serum, plasma, saliva and dried blood can yield reliable and highly stable diagnostic results under a variety of conditions.

A team of scientists from Arizona State University (Tempe, AZ, USA; www.asu.edu) has developed 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, each composed of 20 amino acids, can be used to screen the body's full complement of antibodies, when a single drop of blood is spread over its surface.

When the antibodies present in a sample of blood are splayed over the peptide array, they selectively bind to these peptides with varying degrees of affinity. Once the blood is washed away, a machine-readable image of immune activity is left behind, the immunosignature, potentially providing presymptomatic diagnosis for a broad range of ailments, from infectious diseases to chronic afflictions to varied forms of cancer.

The immune fingerprint thus produced will show thousands of spots fluorescing at different levels, corresponding to antibody activity. Immunosignatures may be registered repeatedly over time and will display characteristic changes following exposure to a pathogen, a vaccine, or any other factor provoking an alteration in antibody activity.

The investigators demonstrated that immunosignatures remain stable over time and largely unaffected by variance in methods of collection. Such versatility could open the door to the use of vast archival material, for example, samples from prior studies and disease epidemics. It would also allow immunosignaturing to be broadly applied as a diagnostic for routine health monitoring, particularly in developing countries.

Human saliva was assessed for its ability to provide an accurate immunosignature. Although quantities of antibodies of the immunoglobulin G (IgG) variety were low, saliva samples did contain sufficient antibodies of the IgA type to produce a useable immunosignature, making collection of saliva a plausible, noninvasive alternative for sample collection.

Stephen Albert Johnston, PhD the senior author of the study said, "The new data advance the prospects for applying immunosignaturing as a sensitive, low-cost, universal system for assessing health status. Our ultimate goal is to monitor the health of healthy people, so it is crucial we have a technique that is cheap, simple and, as we demonstrate here, robust." The study was published in the March 2012 issue of the journal *Clinical and Vaccine Immunology*.

Inflammatory Marker Levels Established in Specific Obese Adolescents

Levels of inflammatory biomarkers in the blood have been measured in obese adolescents who are glucose intolerant and possibly prediabetic.

Increased levels of systemic inflammatory markers, such as C-reactive protein (CRP), the cytokine interleukin-6 (IL-6) and elevated pteridine derivatives as well as specific enzyme levels may be influenced by glucose intolerance.

At the Ege University, (Izmir, Turkey; www.ege.edu.tr) scientists performed oral glucose tolerance tests (OGTT) on 45 pubertal obese children, 23 girls and 22 boys with a mean age of 13.52 years. Biochemical analyses were performed on the sample collection day, that included glucose, insulin, glycated hemoglobin (HbA1c), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), apolipoprotein AI (Apo A), apolipoprotein B100 (Apo B), CRP, IL-6, neopterin levels, complete blood count and chitotriosidase activities. Serum chitotriosidase activity was measured by a fluorescence method and fasting serum concentrations of IL-6 and neopterin were determined by the use of commercial enzyme-linked immunosorbent assays (ELISA).

In 21 children, normal glucose tolerance (NGT) was observed being defined as fasting glucose levels of less than 5.6 mmol/L and two hour glucose levels of less than 7.8 mmol/L. Impaired glucose tolerance (IGT) was found in 24 children where after the OGTT, the two hour glucose levels were between 7.8 and 11.1 mmol/L. The IL-6 and CRP levels were similar in the two groups. There was no significant difference in the lipid profiles or serum neopterin levels between the groups. However, the chitotriosidase activity was significantly higher in the IGT group at 124.33 ± 51.97 µmol/L/hour than the NGT group where the mean activity was 84.50 ± 53.99 µmol/L/hour. The chitotriosidase activity was measured on the F-2500 fluorometer (Hitachi Ltd., Tokyo, Japan; www.hitachi.com). The fasting serum concentrations of IL-6 was determined by the ELISA kit from DIA Source (Louvain-La-Neuve, Belgium; www.diasource-diagnostics.com) and neopterin levels with an ELISA from DRG Instruments, (Marburg, Germany; www.drg-diagnostics.de).

Activated macrophages secrete several proteins, like neopterin and chitotriosidase, which could influence the atherosclerotic process, leading to a local inflammation in the vessel wall. The authors concluded that the results of their study show that serum chitotriosidase activity is increased in obese adolescents with impaired glucose tolerance. Impaired glucose tolerant state is an important period in which atherosclerotic lesions start to emerge. The results demonstrate that the existence of glucose intolerance may aggravate the local inflammation, which mainly occurs in the vascular bed in obese children. The study was published in the March 2012 issue of the journal *Clinical Biochemistry*.

Hybridization Assay Monitors Urothelial Cell Cancer

A multicolor fluorescence in situ hybridization (FISH) assay has been used to follow patients with non-muscle-invasive urothelial cell carcinoma (NMIUCC).

The FISH assay was used with routine follow-up in the monitoring of patients with a previous history of NMIUCC, which has a high tendency to recur and affected patients must be monitored regularly using invasive cystoscopies.

Scientists at Hospital del Mar Research Institute, (Barcelona, Spain; www.imim.es) prospectively studied an unselected cohort of patients under surveillance for a previous history of NMIUCC. A total of 248 examinations in 223 patients were analyzed. Each exploration was comprised of cytological and FISH microscopic examination of voided urine samples and cystoscopy. The sensitivity, specificity, and positive (PPV) and negative (NPV) predictive values for tumor recurrence of all three techniques were determined.

Urine samples were prepared using the ThinPrep liquid-based cytology technique (Hologic Inc, Bedford, MA, USA, www.hologic.com). The UroVysion assay (Abbott Laboratories. Abbott Park, IL, USA; www.abbottmolecular.com) is a multitargeted fluorescence in situ hybridization technique designed to detect chromosomal aberrations associated with bladder cancer: aneuploidies of chromosomes 3, 7, and 17 and loss of 9p21. The sensitivities of FISH and cytoscopy were not found to be significantly different, 92.9% and 82.1%, respectively.

The authors concluded that the FISH assay is a useful initial monitoring tool in patients with a previous history of NMIUCC. A negative FISH result strongly indicates that no tumor is present without the need for an invasive cystoscopy, whereas a positive FISH result strongly indicates that a tumor is present, requiring invasive cystoscopy to detect the tumor features. Given the lack of statistically significant differences in the FISH and cystoscopy results, they proposed that FISH could be a useful initial diagnostic tool in the surveillance of patients with a previous history of NMIUCC. The study was published in the December 2011 issue of the journal *Cancer Cytopathology*.

Plastic Chip Identifies DNA Sequences in Drop of Blood

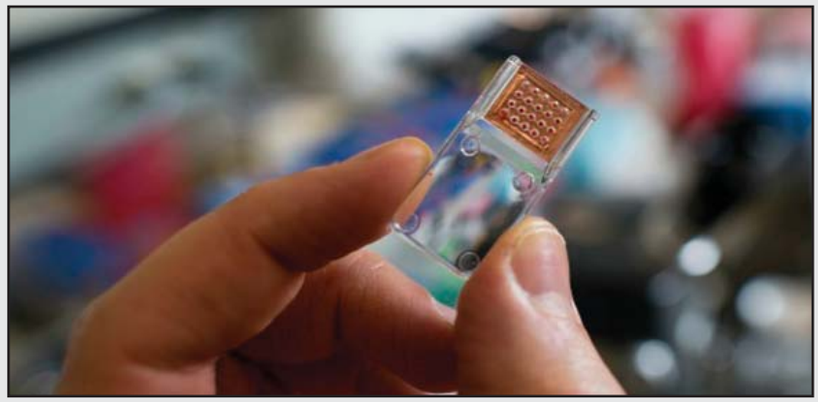

Image: The Domino technology uses a plastic chip that can perform 20 genetic tests from a single drop of blood (Photo courtesy of Aquila Diagnostic Systems).

A small plastic chip developed using nanotechnology can determine whether a patient is resistant to cancer drugs or has diseases such as malaria. The chip can also pinpoint infectious diseases in a herd of cattle.

The technology that uses the plastic chip can perform 20 genetic tests from a single drop of blood. The innovation has earned Aquila Diagnostic Systems (Edmonton, Canada; www.aquiladiagnostics.com), a finalist nod for this year's TEC (Edmonton, Canada; www.tecedmonton.com) NanoVenturePrize award. Aquila Diagnostics is a nano startup originating from the University of Alberta (U of A; Edmonton, Canada; www.ualberta.ca).

Dubbed the Domino technology, it employs miniaturized polymerase chain reaction (PCR) technology to amplify and detect targeted sequences of DNA in a form that fits on a plastic chip the size of two postage stamps. The chip contains 20 gel posts – each the size of a pinhead – capable of identifying sequences of DNA in a single drop of blood. The Domino has been used in several recently published studies, showing similar accuracy to centralized labs.

A metal cube the size of a toaster, with the small plastic chip at its core, created at the University of Alberta is capable of performing the same genetic tests as most fully equipped modern laboratories – and in a fraction of the time. Along with its versatility, two key selling points are affordability and portability, with each portable box expected to cost about USD 5,000 and each chip a few dollars, according to Aquila president David Alton. It is also designed to be easy to use and rugged for use in the field.

Each post performs its own genetic test, meaning that it is possible not only to find out whether an individual has malaria, but also to determine the type of malaria and whether the person's DNA makes him resistant to certain antimalarial drugs. It takes less than an hour to process one chip, making it possible to screen large populations in a short time.

"We [are] basically replacing millions of dollars of equipment in a conventional, consolidated lab with something that costs pennies to produce and is field portable so that it can be taken where needed. That [is] where this technology shines," said Jason Acker, an associate professor of laboratory medicine and pathology at the University of Alberta and chief technology officer with Aquila.

Aquila's relationship with the U of A and its business relationship with TEC Edmonton helped the company to license and patent Domino. TEC Edmonton is a joint venture between the U of A and Edmonton Economic Development Corp. It has resources and expertise to help startups in the early stages of operations.

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FILM ISOLATOR
Air Science

The Purair Flex features a curved film design that provides greater working volume than other glove bags available. Other key benefits include versatile tapered sleeve/glove options, easy set-up, and numerous safety options for users.

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CLINICAL CHEMISTRY ANALYZER
AMS

The Liasys automatic analyzer features primary tube sampling, liquid level sensing, and continuous loading. The benchtop system is designed for daily use in low- and medium-sized labs, and provides a flexible and cost-effective solution.

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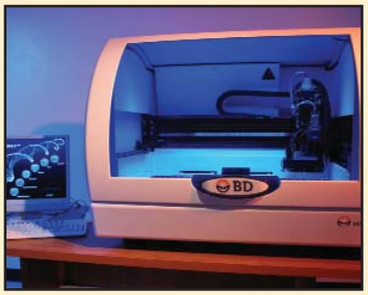

GBS ASSAY
BD

The BD MAX GBS assay is an IVD test for the detection of GBS DNA in Lim Broth cultures. The assay provides an easy-to-use, cost-effective and accurate detection method for labs, and allows labs to comply with recent CDC guidelines for GBS screening.

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REAL-TIME PCT KITS
Daan Gene

The PCR kits available offer high sensitivity with quantitative detection, well linear relation, and accuracy. The kits are fast and convenient, offer enhanced specificity, and are premixed and separated into each tube to help simplify operation.

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Leukemia Patients' Prognoses Predicted with Genetic Profiling

A set of genetic abnormalities has been identified in individuals with acute myelogenous leukemia (AML), a fast growing cancer of the blood and bone marrow.

These specific genetic abnormalities can help doctors to more accurately predict patients' prognoses as well as select therapies that are most likely beneficial for the patient.

Medical oncologists at the Memorial Sloan-Kettering Cancer Center (New York, NY, USA; www.mskcc.org) examined blood or bone marrow samples from 502 individuals with AML who took part in a clinical trial. The aim of the trial was to determine whether increasing the standard dose of chemotherapy would improve survival for individuals with AML under the age of 60. DNA was analyzed from bone marrow in the case of 277/502 (55.2%) of the samples and from peripheral blood in the case of 225/502 (44.8%). Cytogenetic, fluorescent in situ hybridization and reverse-transcriptase polymerase chain reactions (RT-PCR) assays were performed for recurrent cytogenetic lesions in conjunction with the sequencing the coding regions of specific genes.

The scientists examined the samples for mutations, or abnormalities, within 18 genes known to have variations in individuals with acute myelogenous leukemia. They examined the relationship between the mutations present in each participant and how well they coped with disease after receiving either the standard or increased chemotherapy dose. With this analysis, they were able to determine specific risk levels for a range of gene-mutation combinations. In addition, the scientists found that only some patients in the trial benefited from higher chemotherapy dose.

Ross Levine, MD, the lead author of the study, said, "We've already developed genetic tests, which can be used to test for this set of mutations in patients, and we're in the process of making sure they work well in practice. We have preliminary evidence that they perform well, and we're hoping to have a pilot study soon as a step toward getting it into the clinic." The study was published on March 14, 2012, in the *New England Journal of Medicine* (*NEJM*).

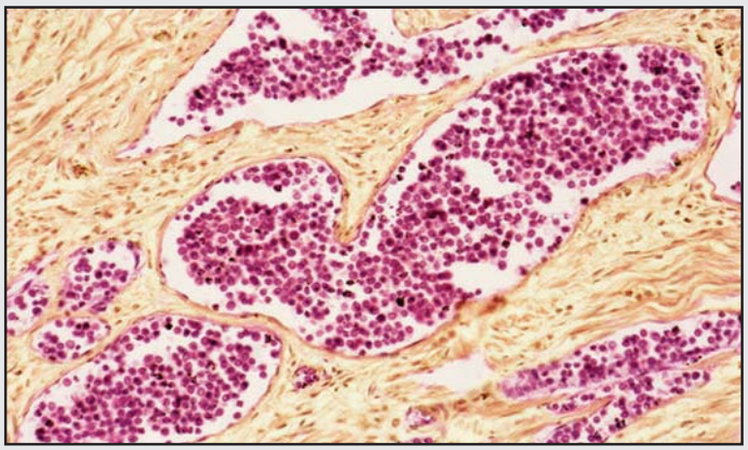

Image: Light micrograph of large numbers of white blood cells (pink) in the blood vessels (white) of a patient with myeloid leukemia (Photo courtesy of Steve Gschmeissner / SPL).

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. A simple blood test that accurately predicted mesothelioma would accelerate the diagnosis process and bypass the need for invasive procedures such as a tissue biopsy to make a diagnosis; as such uncertainty can delay treatment, allowing cancer to progress.

Scientists working on asbestos cancer at Concord Hospital (Sydney, Australia; www.adri.org.au) studied five patients with pleural mesothelioma and three healthy patients 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.

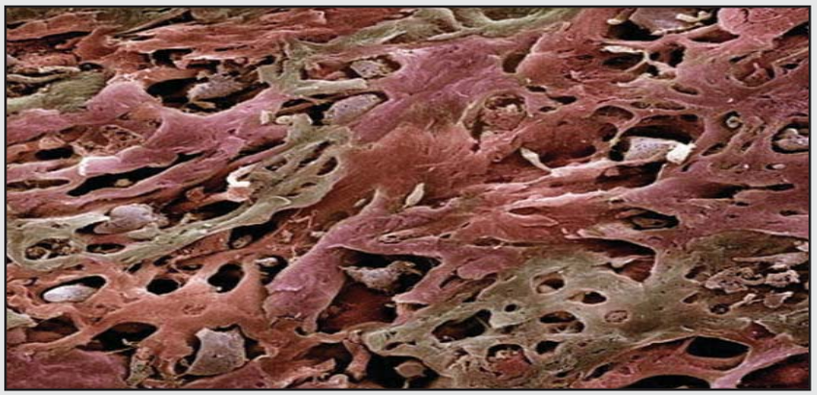

Image: Scanning electron micrograph (SEM) of a section through a mesothelioma, a malignant lung tumor usually associated with asbestos exposure (Photo courtesy of Steve Gschmeissner / SPL).

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 scientists then took blood samples from 23 patients including 15 patients with mesothelioma and measured the levels of particular microRNA. Based on the blood tests, they were able to predict with 82% accuracy which patients had mesothelioma.

MicroRNAs appear to serve an important role in reprogramming a cell to undergo uncontrolled cell division, causing growth of cancerous tumors. They offer potential as cancer markers because they exhibit properties identifiable with specific types of tumors. A number of proteins have been studied as potential red flags indicating the presence of mesothelioma. But none has demonstrated the level of reliability required for routine clinical use by doctors treating patients.

Mesothelioma is a cancer of the lining of the lung and abdomen caused by inhaling asbestos fibers. Approximately, 2,500 to 3,000 people are diagnosed with the mesothelioma each year in the United States. Many are older workers, retirees, and veterans who were exposed to asbestos in a workplace decades ago. The diagnosis of mesothelioma often comes late after the aggressive cancer is advanced and treatment options are limited.

Michaela B. Kirschner PhD, of Asbestos Diseases Research at Concord Hospital said, "Should further studies prove that microRNAs in plasma are accurate enough for the diagnosis of malignant pleural mesothelioma, this will lead to the development of a diagnostic test for routine clinical use. This test would then represent a relatively simple way to circumvent the problems associated with obtaining a tissue biopsy. For a patient this would mean that appropriate treatment could be instituted at an earlier stage." The study was presented at the 3rd European Lung Cancer Conference held April 18-21, 2012 in Geneva (Switzerland).

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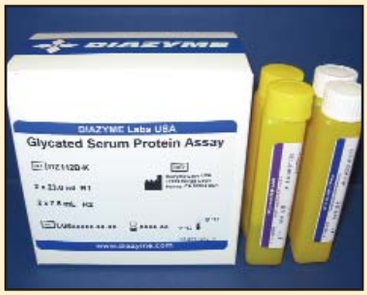

PROTEIN ASSAY
Diazyme Laboratories

The GlycoGap Glycated Albumin assay kit is a two-part liquid stable reagent that can be used with most clinical chemistry analyzers. The enzymatic assay is designed to be more specific and accurate in comparison to current non-enzymatic NBT-based fructosamine tests.

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ONE-STEP MALARIA TEST
HBI

The HiSens one-step P.f/P.v Ag Card is a rapid test for the detection of malaria P.f/P.v antigen in human blood. The test is a direct assay, requires no external pretreatment, and offers differential diagnosis of *P. falciparum* and other species.

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CHEMISTRY ANALYZER
iCubio Biomedical Technology

The iMagic-M7 is a compact, fully automatic analyzer that offers a drawer-style reagent and sample tray. Other features include sample probe with stirring function, low water consumption, up to 50 reagent positions and 70 sample positions, and X+Y+Z dispensing system.

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LIQUID HANDLING DISPENSERS
Karl Hecht

The Assistent dispensers are designed to allow users to avoid direct contact with liquids being dispensed. The dispensers are available in digital and variable models, and offer enhanced reliability, ease of use, and streamline workflow.

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Three Dimensional Paper Sensor Could Test for Disease

Origami-inspired paper sensor could test for malaria and Human Immunodeficiency Virus (HIV) for less than USD 0.10. Sensors can be printed out on an office printer, and take less than a minute to assemble. These low-cost, "point-of-care" sensors could be useful in the developing world, where resources are often lacking to pay for lab-based tests, and where, even if the money is available, there infrastructure does not exist to transport biological samples to the lab.

Inspired by the paper-folding art of origami, chemists at The University of Texas at Austin (Texas; USA; www.utexas.edu) have developed a 3-D paper sensor that may be able to test for diseases such as malaria and HIV.

One-dimensional paper sensors, such as those used in pregnancy tests, are already common but have limitations. The folded, 3-D sensors, developed by Richard Crooks, the Robert A. Welch professor of chemistry and doctoral student Hong Liu, can test for more substances in a smaller surface area and provide results for more complex tests.

"Anybody can fold them up," said Prof. Crooks. "You don't need a specialist, so you could easily imagine an [non-governmental organization] NGO with some volunteers folding these things up and passing them out. They're easy to produce as well, so the production could be shifted to the clientele as well. They don't need to be made in the developed world."

Prof. Crooks said that the principles underlying the sensor, which have been successfully tested on glucose and a common protein, are related to the home pregnancy test. A hydrophobic material, such as wax or photo resist, is laid down into tiny canyons on chromatography paper. It channels the sample to be tested – urine, blood, or saliva, for instance – to spots on the paper where test reagents have been embedded.

If the sample has whatever targets the sensor is designed to detect, it will react in an easily detectable manner. It might turn a specific color for example or fluoresce under a UV light. Then it can be read by eye.

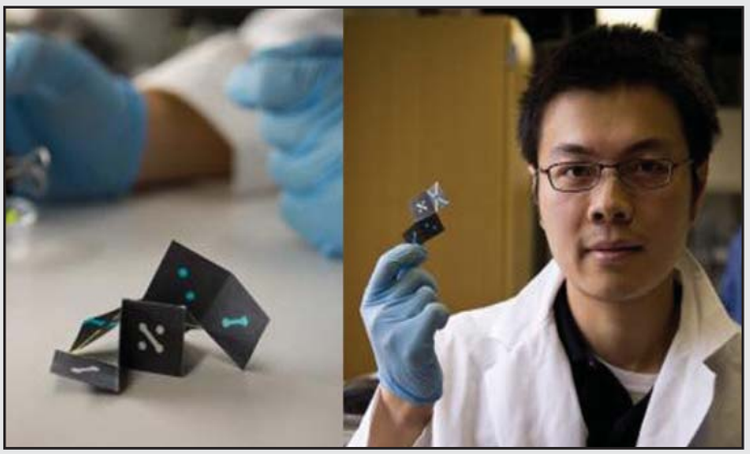

Image: An origami-inspired paper sensor, designed as an inexpensive way to test for diseases such as malaria and HIV (Photo courtesy of Alex Wang).

Leak-Proof Polypropylene Containers Resistant to Chemicals and Temperature

Durable universal polypropylene containers provide leak-proof performance and greater temperature and chemical resistance in all types of laboratories. The new containers are available in several varieties, including labeled, unlabeled, irradiated, and nonpyrogenic.

The Sterilin (Newport, UK; www.thermoscientific.com/sterilin) Quick Start containers are manufactured from clear polypropylene, which has greater temperature and chemical resistance than other materials such as polystyrene. This meets the needs of a wider range of laboratory applications, from healthcare to life science research.

Introduced by Thermo Fisher Scientific, Inc., the new containers have a Quick Start cap with a three-start thread, reducing the number of turns to open and close it. In an independent evaluation against similar products, the containers' new multi-seal design provided good leak-free performance. Additionally, a lot number is printed on each container to aid traceability, and the containers are supplied in eight handy bags of 50.

"The Thermo Scientific Sterilin Quick Start 30-mL universal containers in clear polypropylene offer significant benefits to laboratories across all industries," said Rachel Adams, marketing manager, Thermo Scientific Sterilin products. "These versatile products complement our standard polystyrene 30-mL universal containers, providing our customers with greater choice to suit both their everyday and more challenging needs."

Image: The Sterilin Quick Start 30-mL polypropylene universal containers (Photo courtesy of Thermo Fisher Scientific).

Noninvasive Stool Test Biased by Patient's Age

A DNA methylation test for colorectal cancer (CRC) 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 high detection rates of both CRC and large adenomas as aberrantly methylated genes represent attractive and broadly informative markers for these forms of malignancy.

Scientists at the Mayo Clinic (Rochester, MN, USA; www.mayoclinic.org) collected buffered stools within three years of a normal colonoscopy from 500 patients undergoing average-risk screening or polyp surveillance. The median age was 64 years old, with a range of 44-85 and 53% were women. The stool samples were promptly homogenized, aliquoted, and frozen at -80 °C.

Target genes were purified by hybrid capture from thawed and centrifuged aliquot supernatants, bisulfite treated, and assayed using the quantitative allele-specific real-time target and signal amplification the analytically-sensitive (QuARTS) method. The reference gene β-actin was assayed along with methylation of the N-Myc Downstream-Regulated gene 4 (NDRG4), Bone Morphogenetic Protein 3 gene (BMP3), the Vimentin gene, and the Tissue Factor Pathway Inhibitor 2 gene (TFPI2).

The only patient characteristic that significantly influenced all methylated marker levels in stool was age. Standardized relative change was greatest with TFPI2 at +91.3, least with BMP3 at +29.7, and intermediate with vimentin at +46.0 and NDRG4 at +45.1. David Ahlquist, MD, professor of medicine at the Mayo Clinic, said, "There was a progressive increase in background methylation levels that varied widely between methylation markers tested as a patient aged. For example, median background methylation levels of the TFPI2 gene increased 49% in patients from age 50 to age 80, whereas levels for the BMP3 gene increased by only 0.2% across this age range." 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).

Commercial Assays Detect Fungal DNA in Bronchoalveolar Lavage

The performance of two commercially available molecular assays for the detection of *Aspergillus* and *Pneumocystis* DNA has been investigated.

The assays are based on real-time polymerase chain reactions (PCR), were tested on bronchoalveolar lavage fluid, and were compared to reference diagnostic tests, including culture, and additional molecular analysis by real-time PCR, nested PCR, and sequencing was also performed.

At the University of Modena and Reggio Emilia (Italy; www.unimore.it) 20 patients were retrospectively enrolled in a study and clustered into three groups: seven patients with invasive aspergillosis group (IA), eight patients *Pneumocystis jirovecii* pneumonia (PCP), and five patients acted as a negative control group. Twenty-one samples were obtained from direct bronchoalveolar lavage (BAL) procedures required for clinical assessment, while one sample was obtained by lung biopsy.

Fungal DNA was extracted from the samples using the MycXtra Fungal DNA Extraction Kit and assessed by the MycAsp Assay and by MycPCP Assay, all of which are products of Myconostica (Cambridge, UK; www.myconostica.co.uk). The real-time PCR (RT-PCR) was carried out on the ABI 7300 platform. The Platelia *Aspergillus* commercial galactomannan enzyme-linked immunosorbent assay (GM-ELISA, Bio-Rad Laboratories; Hercules, CA, USA; www.bio-rad.com) and the MeriFluor *Pneumocystis*, immunofluorescence assay (Meridian Bioscience; Cincinnati, OH, USA; www.meridianbioscience.com) were also performed.

All the IA patients were MycAsp Assay positive, whereas 12 non-IA patients returned negative PCR results and, 7 of 8 PCP patients were MycPCP Assay positive, while 9 non-PCP patients were PCR negative. The results of the study provide the first evidence on the efficacy of the MycAsp Assay and MycPCP Assay in discriminating between BAL positive and BAL negative for *Aspergillus* or Pneumocystis DNA, when using the ABI 7300 platform (Applied Biosystems; Foster City, CA, USA; www.appliedbiosystems.com).

The authors concluded that the study provides a step forward towards the inclusion of molecular methods in the routine assessment of biological samples, especially from critical patients in whom rapid and sensitive approaches are needed to fulfill a prompt and precise diagnosis. The study was published online on April 16 2012 in the journal *Diagnostic Microbiology and Infectious Disease*.

Biomarkers Predict Kidney Problems After Cardiac Surgery

Blood and urine markers can indicate which patients with an abrupt kidney injury following heart surgery will experience progressive kidney problems.

Until now, doctors have not been able to determine which cases of acute kidney injury (AKI) that develop after heart surgery will worsen so testing for these markers soon after surgery could help doctors protect the health of patients' kidneys.

At Yale University School of Medicine (New Haven, CT, USA; www.yale.edu) investigators found that the presence of certain markers on the day that AKI is diagnosed can indicate structural injury to the kidneys that will likely cause patients to experience progressive problems. They prospectively enrolled 1,219 adults undergoing cardiac surgery (coronary artery bypass grafting or valve surgery) who were at high risk for AKI at six academic medical centers in North America between July of 2007 and December of 2009. Urine and plasma specimens collected preoperatively and daily for up to five postoperative days.

High urinary interleukin-18 (IL-18) and the albumin-to-creatinine ratio (ACR) increased patients' risk of experiencing persistent AKI by approximately three-fold, while high blood levels of a protein called neutrophil gelatinase-associated lipocalin (NGAL) increased their risk by more than seven-fold. Urine IL-18 and NGAL were measured with the ARCHITECT assay (Abbott Diagnostics, Abbott Park, IL, USA; www.abbott.com). Plasma NGAL was measured through the Triage NGAL immunoassay in conjunction with the TriageMeter (Biosite Inc., San Diego, CA, USA; www.biosite.com).

The authors concluded that urinary IL-18, ACR, and plasma NGAL measurement at the time of clinical creatinine increase forecasted the progression of AKI in adults after cardiac surgery. Chirag Parikh, MD, PhD, a lead author of the study said, "Our multicenter study is the largest acute kidney injury biomarker study performed to date in adults, and it strengthens the new paradigm that assessing structural injury at the time of clinical diagnosis with urine or blood markers of kidney injury can yield important prognostic information." The study was published online on March 1, 2012, in the *Journal of the American Society Nephrology*.

Liquid-Based Cytology Detects Urinary Pathogens

Liquid-based urine cytology (LB-URC) has been evaluated for cytological diagnosis and detection of *Human papillomavirus* (HPV), *Mycoplasma*, and *Ureaplasma*.

Liquid-based cytology (LBC) samples of urine sediment can be used to detect HPV and other microorganisms' DNA, while evaluating the cytological findings of urine sediment tests based on Papanicolaou staining and performing in situ hybridization (ISH).

At the Kanazawa University Hospital (Japan; www.m.kanazawa-u.ac.jp) 141 male patients with urethritis (urethritis group) and 154 male patients without urethritis (controls) were enrolled in a study between April 2009 and April 2010. Each patient provided a midstream urine specimen. All patients with urethritis were tested for the presence of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in urethral swabs. The HPV status for each patient was determined. *Mycoplasma*, *Ureaplasma,* and HPV genomes were determined by polymerase chain reaction (PCR)-based methods. Papanicolaou tests were performed for cytological evaluation and localization of HPV DNA in urothelial cells was examined by ISH.

HPV DNA was detected in 29 (21.0%) urethritis cases and in 5 (3.3%) controls. HPV genotyping was performed using HPV GenoArray test kits (HybriBio Limited; Hong Kong SAR, China; www.hybribio.cn) and HPV type 16 (HPV 16) was most commonly found in urethritis patients. Morphological changes suggestive of HPV infection were seen in 20.7% of the HPV-positive samples, and ISH using the Dako GenoPoint System (Dako; Carpinteria, CA, USA; www.dako.com) demonstrated the presence of HPV DNA in both squamous and urothelial cells in HPV-positive samples.

Mycoplasma genitalium, *M. hominis*, *Ureaplasma parvum*, and *U. urealyticum* were detected using a multiplex PCR assay in 14.5%, 10.9%, 6.5%, and 12.3% of urethritis patients, respectively. The authors concluded that that LB-URC is a promising method for molecular analysis of microorganisms in the urinary tract and that HPV infection occurs in urothelial cells, especially in gonococcal urethritis. The study was published in the February 2012 issue of the *Journal of Clinical Microbiology*

Some Transfusions May Do More Harm Than Good

Image: A donation bag of blood for use in transfusions, containing about half a liter of blood (Photo courtesy of Tek Image).

The lack of clear guidelines for ordering blood transfusions means there is still wide variation in the use of transfusions and frequent use of transfused blood in patients who do not need it.

The resulting overuse of blood is problematic because blood is a scarce and expensive resource and because recent studies have shown that surgical patients do no better, and may do worse, if given transfusions prematurely or unnecessarily.

Scientists at Johns Hopkins University School of Medicine (Baltimore, MD, USA; www.hopkinsmedicine.org) examined the electronic anesthesia records of more than 48,000 surgical patients at the adjacent Johns Hopkins Hospital over the 18 months from February 2010 to August 2011. Overall, 2,981 patients (6.2%) were given blood transfusions during surgery. The study found wide variation among surgeons and among anesthesiologists, compared to their peers, and how quickly they order blood.

In a healthy adult, a normal hemoglobin level, the quantity of red blood cells carrying oxygen through the body, is approximately 14 g/dL. The guidelines state that when a patient's hemoglobin level falls below 6 or 7 g/dL, a patient will benefit from a transfusion and that if the levels are above 10, a patient does not need a transfusion. But when blood levels are in-between, there has been little consensus about what to do. The study found that the use of erythrocyte salvage, fresh frozen plasma, and platelets varied threefold to fourfold among individual surgeons compared with their peers performing the same surgical procedure.

Blood transfusion, which introduces foreign substances into the body, initiates a series of complex immune reactions. Patients often develop antibodies to transfused red blood cells making it more difficult to find a match if future transfusions are needed. Transfused blood also has a suppressive effect on the immune system, which increases the risk of infections, including pneumonia and sepsis.

Blood is in short supply and expensive. In the USA it costs USD 278 to buy a unit of blood from the American Red Cross (Washington DC, USA; www.redcross.org) for example, and as much as USD 1,100 for the nonprofit to acquire, test, store and transport. The US national social insurance program, Medicare pays just USD 180 for that unit of blood. Steven M. Frank, MD, leader of the study, said, "Transfusion is not as safe as people think. Over the past five years, studies have supported giving less blood than we used to, and our study shows that practitioners have not caught up. Blood conservation is one of the few areas in medicine where outcomes can be improved, risk reduced, and costs saved all at the same time. Nothing says it's better to give a patient more blood than is needed." The study was published on April 23, 2012, in the journal *Anesthesiology*.

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LAB TEST SYSTEMS
Orgentec Diagnostika

Four test systems have been developed for the diagnosis of autoimmune liver diseases. The tests, Anti-Sp100, Anti-gp210, Anti-LKM-1, and Anti-SLA, allow for differentiation between autoimmune diseases and other diseases of the liver based on blood samples.

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COLLECTION / TRANSPORT SYSTEMS
Puritan Medical Products

The UTM Transport System and the Liquid Amies Transport System are designed to facilitate safe and effective preanalytical specimen collection and transport. The systems are intended to meet essential specimen collection and transportation needs.

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GENE EXPRESSION TEST
Pathwork Diagnostics

The Tissue of Origin test uses a tumor's own genomic information to help in the diagnosis of cancer cases. The test measures expression levels of 2,000 genes and compares the gene expression pattern to 15 different tumor types that account for 90% of all solid tumors.

LINKXPRESS.COM LMI-07-12 231

SLIDE TESTS
Spinreact

Tests available are easy to use, offer ready-to-use reagents, as well as high sensitivity and specificity. The wide tests provide results in two minutes and are intended for the diagnosis of rheumatic diseases, hCG, mononucleosis, HBsAG, toxoplasma, and syphilis.

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Regular Smear Tests Raises Chances of Cervical Cancer Cure

The detection of cervical cancer by screening can considerably increase a women's chance of surviving this malignant neoplasm, which in the early stages may be completely asymptomatic.

The rationale of cervical screening by the Papanicolaou test (Pap smear) is to reduce the incidence of cancer by the detection and treatment of precursors and a secondary aim is the early detection of invasive disease, which might improve the prognosis thereby also reducing mortality from the disease.

Scientists at the Uppsala University (Gävle, Sweden; www.uu.se) and the Karolinska Institutet, (Stockholm, Sweden; www.ki.se) examined all 1,230 women diagnosed with cervical cancer in Sweden between 1999 and 2001 in a prospective cohort study. The team examined screen-detected cancers, those with an abnormal smear result one to six months prior to cancer diagnosis, as well as symptomatic cancers, which were all the remaining cases.

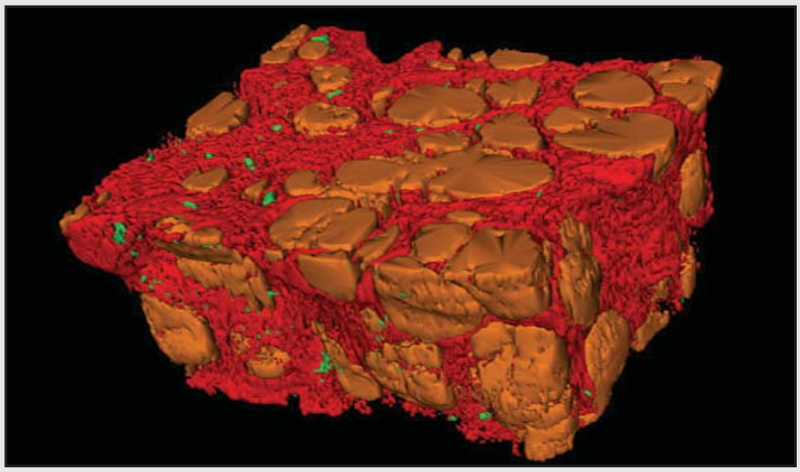
At least seven years of potential follow-up were available from diagnosis of cervical cancer for all the women. Five years after diagnosis, 440 out of the 1,230 women had died. Among them, 373 had a recorded death due to cervical cancer. Thirty-one women died from other cancers, and 36 died of diagnoses not related to cancer. Results from the study revealed that there was a 92% cure rate for women who attended cervical screening, compared to 66% of women who were diagnosed by symptoms. This finding demonstrates a considerable increase in survival chances for those who attended cervical screening than women who did not. Furthermore, the researchers found that women who were overdue for an examination had lower chances of survival than women who attended screening following an invitation.

In addition, the team found that 75% of the 373 women who died from the disease did not undergo a cervical smear in the advised time frame. Half of the women who died from cervical cancer within five years of diagnosis were over the recommended age for screening. Women with interval cancers and an abnormal smear test result during the past six years had a non-significantly higher cure proportion than women with only a normal smear test result. If this difference is real, the reason might be that women with abnormal smear test results are followed up to a greater extent than women with normal smear test results.

The authors concluded that detection of invasive cancer by cervical screening implies a favorable prognosis compared with cancer being detected based on symptoms. The effect was stronger than what is reflected in downstaging and was not attributable to lead time bias. In addition, women with symptomatic interval cancers had a better prognosis than women with symptomatic cancers who did not have a smear test within the recommended screening interval. The effect on cervical cancer cure should be included when evaluating cervical screening programs. The study was published on March 1, 2012, in the *British Medical Journal* (*BMJ*).

Image: Clinician transferring cells from a scraper to a vial of preservative solution. This equipment is used for the ThinPrep Pap (Papanicolaou) test for detecting abnormalities in cells of the uterine cervix (Photo courtesy of Tek Image).

"Virtual Slides" Reveal Disease Tissue in 3D



A fast, user-friendly system has been developed for examining tissue samples in "virtual" 3D images. The novel digital scanning 3D reconstruction system produces high-resolution, multicolored images that can be rotated and examined from any angle. Computing experts and medical researchers at the University of Leeds (Leeds, UK; www.leeds.ac.uk) have combined efforts to developed this technology as a particularly useful tool for histopathology researchers and potentially also for clinical practice, as medical imaging technology provides even higher resolution images of tissue.

Viewing tissue in 3D enables more in-depth understanding of tissue shape characteristics in ways not possible with conventional methods. Currently, hospital pathologists and medical researchers cut tissue samples into ultra-thin slices and routinely examine these by hand, one-by-one, on a microscope. This is a labor-intensive process - a single slide can contain several hundred thousand cells. To perform a 3D-like analysis, users would need to look at hundreds of different 2D sections - something that would be prohibitively expensive and time-consuming.

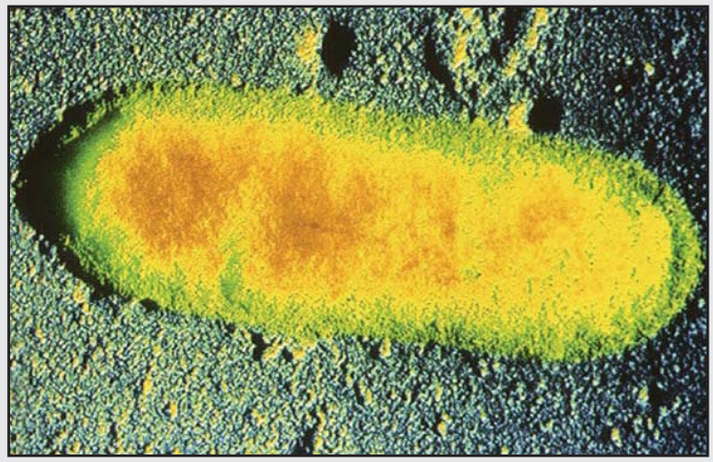
In contrast, the system developed at the University of Leeds requires almost no extra manual input once the tissue has been cut and mounted onto glass slides. An automated system turns batches of the slides into high-resolution digital images, which are then aligned using image registration software. Users, without input from computing specialists, can then study these virtual blocks of tissue in 3D and zoom in on particular areas of interest.

The researchers have now tested the system on eight different types of tissue, using more than 13,000 virtual slides to create around 400 separate 3D volumes. The system and selected case studies, including examples of liver disease, cancer, and embryology, are described in the May 2012 issue of the *American Journal of Pathology*.

This new approach to digital 3D reconstruction reveals more detailed information about disease processes – information that could be used to develop new therapies or explain why conventional treatments are not working. "Having a 3D view can often make a real difference," said Dr. Derek Magee, from the University of Leeds School of Computing, where the system's software was developed. "For instance, if you want to understand how a system of blood vessels supplying a tumor connects up, you really need to see that in 3D, not as a series of separate 2D sections."

Image: Tissue in 3D, viewed by way of "virtual" microscope slides that allow for more intricate study of diseased tissue (Photo courtesy of the University of Leeds).

Molecular Techniques Compared for Diagnosis of Rickettsioses



The diagnosis and isolation of *Rickettsia* species from skin biopsies may be replaced by a real time polymerase chain reaction (rt-PCR).

Diagnosis of *Rickettsia* infection would benefit by use of the more rapid and sensitive method of quantitative rt-PCR than the time-intensive and less sensitive method of culturing *Rickettsia* species from skin biopsies.

Scientists at the University of the Mediterranean (Marseille, France; www.ifr48.com) analyzed punch biopsies or scalpel incisions of eschars collected from patients with suspected rickettsial infections between January 2007 and January 2010. Patients were classified as definitely having rickettsiosis if there was direct evidence of infection with a *Rickettsia* species using culture or molecular assays or if serology was positive. Rickettsial diseases are zoonoses caused by obligate intracellular bacteria.

Total genomic DNA was extracted from samples using a QIAamp tissue kit (Qiagen, Hilden, Germany; www.qiagen.com). Samples were screened for the presence of *Rickettsia* species using a previously developed rt-PCR assay targeting a 109 base pairs (bp) fragment of a hypothetical protein. Quantification of *Rickettsia* species were performed using serial ten-fold dilutions of *R. africae*, *R. slovaca*, *R. raoultii*, and *R. helvetica*. Bacteria were detected by indirect immunofluorescence using human serum and antiserum. All sera were tested by immunofluorescence (IF) for spotted fever group (SFG) rickettsial antigens. Samples were cultured in human embryonic lung (HEL) fibroblasts using the centrifugation-shell vial technique.

Rickettsia species infection was diagnosed in 47/145 (32%) skin biopsies from patients with suspected rickettsiosis. By rt-PCR a positive result was obtained for 41 skin biopsies (28.2%). *Rickettsia africae* was the most common detected species, followed by *R. conorii conorii, R. slovaca, R. sibirica mongolitimonae,* and *R. raoultii*. Comparison of culture and rt-PCR to serology was done for the 26 patients with suspected rickettsiosis with a skin biopsy that also had an acute serum and a convalescent-phase serum sample. The rt-PCR sensitivity was 82% as compared to serology whereas culture sensitivity was 29.4% as compared to serology.

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. To increase the sensitivity of culture, skin biopsies should be sampled before treatment early in the course of the disease and should be inoculated as soon as possible. The study was published on March 6, 2012, in the journal *Public Library of Science Neglected Tropical Diseases*.

Image: False-color shadow transmission electron micrograph (TEM) of an individual bacterium of the genus Rickettsiae (Photo courtesy of CNRI).

Enzyme Immunoassays Employed to Diagnose Neurocysticercosis

Enzyme immunoassays have been tested for detecting antibodies against the pork tapeworm in human serum and for the diagnosis of neurocysticercosis.

All of the five commercial tests compared were enzyme immunoassays for the qualitative determination of the immunoglobulin G (IgG) class of antibodies against *Taenia solium*, the causative agent of neurocysticercosis, in human serum or plasma.

A team of investigators working at the Institut Pasteur de Madagascar (Antananarivo, Republic of Madagascar; www.pasteur.mg) tested a collection of reference serum samples which included 14 defined cysticercosis serum samples, 100 serum samples positive for *T. solium* antibodies, 99 negative samples, and 60 sera from patients with other parasitic infections. All sera were tested both by enzyme-linked immunosorbent assays (ELISA) and by an immunoblot method, the enzyme-linked immunoelectrotransfer blot (EITB). The ELISA tests compared in the study were the DRG *T. solium* IgG (Cysticercosis); RIDASCREEN *T. solium* IgG; NOVATECH NovaLisa *T. solium* IgG; CYPRESS Cysticercosis Ab (*T. solium*); and the IVD Cysticercosis (*T. solium*) Microwell Serum ELISA.

The Ridascreen test (R-Biopharm; Darmstadt, Germany; www.r-biopharm.com) had the best positive EITB concordance rate of between 85.1%-91.2%, followed by the Cypress test (Cypress; Langdorp, Belgium; www.diagnostics.be) with results between 71.0%-77.2%. The NovaLisa test (NovaTec Immunodiagnostica; Dietzenback, Germany; www.novatec-id.com) showed the optimal negative concordance rate of between 93.7%-95.6% when compared with the EITB, as did the DRG Diagnostics test (DRG International; Mountainside, NJ, USA; www.drg-international.com) at 93.7%. All tests had a sensitivity under 72% and if equivocal specimens are considered negative, four of the tests, DRG, NOVALISA, CYPRESS, and IVD (IVD Research; Carlsbad, CA, USA; www.ivdresearch.com) display a sensitivity under 50%.

Cross-reactivity with non-neurocysticercosis sera was observed for all tests for all the sera positive for *Echinococcus granulosis* antibodies. *E. multilocularis*–positive sera gave false-positive reactions for most of the tests. Except for these common cross-reactions, very few other cross-reactions were encountered with the DRG Diagnostics test and the NovaLisa test. The authors concluded that for the commercial assays they evaluated, the most appropriate ELISA test for screening might be the Ridascreen assay. However, antibody detection seems to be not appropriate for the diagnosis of neurocysticercosis because of its overall lack of sensitivity. The study was published in the January 2012 issue of the journal *Diagnostic Microbiology and Infectious Disease*.

High-Risk Prostate Cancer Predicted by Urine Test

Two biomarkers found in urine were correlated with indicators of aggressive prostate cancer disease such as tumor volume and the Gleason score.

The two investigational urine-based biomarkers are associated with prostate cancers that are likely to be aggressive and potentially life threatening among men who take a "watchful waiting," or active-surveillance approach to manage their disease.

Investigators at the Fred Hutchinson Cancer Research Center (Seattle, WA, USA; www.fhcrc.org) coordinated a multicenter study of eight institutions called the Canary Prostate Active Surveillance Study (Palo Alto, CA, USA; www.canaryfoundation.org), an endeavor dedicated to identifying and validating biomarkers of high-risk prostate cancer. Two urine-based biomarkers were found to correlate with indicators of aggressive prostate cancer, the number of biopsy samples that contain cancer (tumor volume) and predicting the aggressiveness of cancer by how it looks under a microscope (the Gleason Score).

The findings were based on an interim analysis of data collected from 401 men who opted for active surveillance of their cancer. The study compared biomarker performance to clinical data collected at the time of study entry. Ultimately, the study aims to enroll 1,000 men and follow them for at least five years. The first marker that mirrored the correlates of disease aggressiveness was the prostate cancer antigen 3 (PCA3) that is a noncoding ribonucleic acid (RNA) that is found at high levels in prostate cancer relative to benign prostate cells. The second marker was the transmembrane protease, serine 2 – Ets Related Gene (TMPRSS2-ERG), which is the fusion of TMPRSS2, a gene that is regulated by androgens, with ERG, an oncogene. These genetic rearrangements are found in about half of all prostate cancers and are thought to play a role in prostate cancer development.

Daniel Lin, MD, the principal investigator said, "The ultimate goal is that men on active surveillance could use a test based on these biomarkers or others to complement biopsy and prostate specific antigen (PSA) data to indicate or rule out the presence of an undetected aggressive cancer or future development of aggressive cancer. Prostate biopsies are invasive and don't always pick up all of the cancer. Postdigital-rectal examination urine collection is much less invasive. If a urine-based diagnostic test could be developed that could help predict aggressive disease or disease progression that would be ideal." The study was presented at the 2012 Genitourinary Cancers Symposium of the American Society of Clinical Oncology held February 2-4, in San Francisco (CA, USA; www.gucasymposium.org

Molecular Method Directly Identifies Antigens

A novel method for identifying antigens is based on the isolation of T cells present in samples of affected tissues obtained from patients with autoimmune diseases. The genetic blueprints for the specific antigen-binding T-cell receptors (TCRs) produced by these cells, have been transferred into a cultured cell line that grows well in the laboratory and contains a version of the gene for the Green Fluorescent Protein (GFP) that is specifically expressed if a TCR is activated.

Scientists at the Ludwig Maximilians University (Munich, Germany; www.uni-muenchen.de) collaborated with a team from the Max Planck Institute for Neurobiology (Munich, Germany; www.neuro.mpg.de) to develop the new method that can identify the antigens that initiate immune reactions and may help to prevent misdirected attacks in the future. They used genetic engineering techniques, to generate cells that emit green fluorescent light when stimulated by the binding of a cognate antigen.

The T-cells are incubated with a collection of some 100 million peptides, which are short amino acid sequences like those normally recognized by TCRs. If even a single peptide represented in the library is recognized by a specific TCR, the corresponding cell synthesizes GFP and it can be detected by its green fluorescence, allowing the bound antigen to be identified. The method thus provides a relatively simple way of identifying single autoimmune antigens from huge numbers of possible suspects.

An initial test carried out using cells specific for a known influenza antigen confirmed the efficacy of the method. The investigators were able unequivocally to select out and identify the correct antigen from all the other peptides used in the test. The technique is so rapid and so sensitive that several million antigens can be analyzed in a matter of hours. This opens up a wide range of possible applications, ranging from the analysis of the reactive antigens responsible for autoimmune diseases like multiple sclerosis or psoriasis to the identification of new tumor or viral antigens. The practical potential is so significant that the method is the subject of a patent application. The study was published online on April 8, 2012, in the journal *Nature Medicine*.

TECHNICAL LITERATURE

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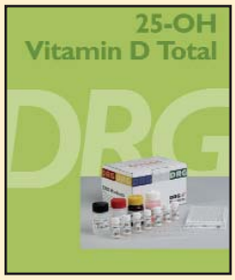

VITAMIN D ASSAY
DRG

The 25-OH Vitamin D Total assay is designed for IVD use in the quantitative determination of total 25-OH Vitamin D (D2 and D3) in human serum and Heparin plasma.

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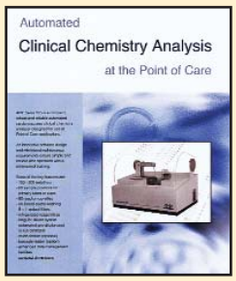

CHEMISTRY ANALYZER
AMP Diagnostics

The Seros 125 compact analyzer for POC applications offers 60 sample positions for tubes or cups, 80 reaction cuvettes, and a throughput of 125-200 tests/hour.

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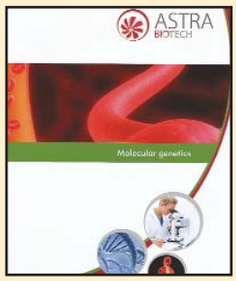

DIAGNOSTIC KITS
Astra Biotech

The range of PCR-based test kits is designed for identification of genetically influenced conditions including cardiovascular disease, osteoporosis, and sensitivity to drugs.

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CLINICAL ASSAYS
Sekisui Diagnostics

The TPLA and RPR fully automated assays are simple to use, and designed to reduce the risk of infection and human error, give accurate results, and enable high-throughput.

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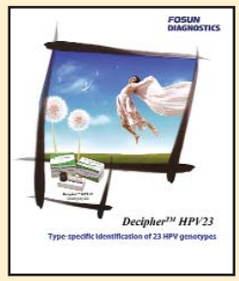

HPV GENOTYPE KIT
Fosun Diagnostics

The Decipher HPV23 kit is designed for type-specific identification of 23 HPV genotypes, and is intended as an aid in cervical cancer prevention.

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ANTIBODY RAPID TEST
Humasis

The Rapid Flu influenza A test features ready-to-use reagents, and is intended to minimize influenza-related mobidity and mortality with results available in 15 minutes.

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Endogenous Interference Impairs Arterial Blood Gas Analysis

Blood samples that show hemolysis, lipemia, or icterus may be unsuitable for arterial blood gas analysis (ABG) as these indices affect the results.

The modern ABG analyzers enables rapid analysis of traditional blood gas elements such as pH, partial pressure of carbon dioxide (pCO2) and oxygen partial pressure (pO2), and oxygen saturation as well as clinical chemistry parameters, all of which rely on the quality of the specimens.

Scientists at the University of Verona (Italy; www.univr.it) analyzed 478 ABG specimens received in their laboratory throughout a two-month study period. The serum indices (SI) were assessed after all routine and stat samples referred for ABG analysis to the clinical laboratory using RAPIDPoint 400/405 Systems, Arterial Blood Gas Analyzer were completed. The SI of plasma was then assessed on the Cobas C501 after centrifugation. Interference cut-off values were 60 for Hemolysis Index (HI, i.e., cut-off of visible hemolysis), 30 for Lipemia Index (LI, i.e. Lipemic index is determined by the turbidity qualitatively with no units) and two for Icteric Index (II).

Out of a total of 478 ABG specimens received in the laboratory throughout the two month study period, 132 (27.6%) displayed at least one SI exceeding the cut-off. This could be further categorized as 44/162 (27.2%) from the emergency department, and 88/316, (28.6%) from the clinical wards. In particular 17 samples (4%) were characterized by HI exceeding 60, 52 samples (11%) by a LI exceeding 30, and 63 (13%) by II exceeding two. The frequency of hemolyzed specimens referred from the emergency department was double that of samples referred from the clinical wards.

The RAPIDPoint 400/405 Systems, Arterial Blood Gas Analyzer is a product of Siemens Medical Solutions (Munich, Germany; www.medical.siemens.com) and the Cobas C501 is manufactured by Roche (Basle, Switzerland; www.roche.com). The authors concluded that that a significant number of AGB specimens sent to their laboratory were characterized by elevated values of the SI, which could make them unreliable for testing. In particular, the frequency of HI greater than 60 was remarkably higher for samples referred from the emergency department than in those from the clinical wards, thereby confirming the trend already observed for clinical chemistry, immunochemistry, and coagulation testing. The study was published in the March 2012 issue of the journal *Clinical Biochemistry*.

Image: The RAPIDPoint 400/405 arterial blood gas analyzer (Photo courtesy of Siemens Healthcare).

Optimal Threshold Identified for Glycated Hemoglobin Test

The measurement of glycated hemoglobin or a hemoglobin A1c (HbA1c) in blood specimens is a stable test for identifying diabetes and prediabetes over several months.

A specific HbA1c cutoff threshold for prediabetes can be used to determine eligibility for interventions to prevent progression to more serious type 2 diabetes and lowering the cutoff increases the health benefits of preventive interventions, although at higher cost.

A study led by the US Centers for Disease Control and Prevention (CDC; Atlanta, GA, USA; www.cdc.gov) used a Markov simulation model to examine the cost effectiveness associated with each progressive 0.1% decrease in the HbA1c cutoff from 6.4% to 5.5% as 6.5% is currently the diagnostic cutoff for diabetes. The simulation used the data of nondiabetic American adults from the National Health and Nutritional Examination Survey (NHANES 1999-2006). The study looked at two different interventions: a high cost resource-intensive approach that would cost on average almost USD 1,000 per year, and a low cost intervention with an annual cost of USD 300 per year.

The scientists measured the cost per each quality-adjusted life year (QALY), a measure of the quality and quantity of life generated by a medical intervention, at each HbA1c cutoff for both interventions. They found that cutoffs of 5.7% and above were cost effective, based on the conventional USD 50,000/QALY cost-effectiveness benchmark. Further, the results suggested that the optimal cut-off may be lower if the cost of preventive interventions could be lowered without compromising effectiveness.

Leading clinical and policy-guiding organizations have recommended the HbA1c as an additional diagnostic tool. The use of this test will probably increase as a screening tool to identify those at high risk for type 2 diabetes. Xiaohui Zhuo, PhD, the lead investigator said, "Therefore, the economic implications of its use need to be well understood. This study will hopefully stimulate more research on the best strategy for optimizing benefits from type 2 diabetes prevention programs at minimum cost." The study is available online in the April 2012 issue of *American Journal of Preventive Medicine*.

Spinal Fluid Marker Strongly Predicts Mental Decline

A novel marker of Alzheimer's disease (AD) can predict how rapidly a patient's memory and other mental abilities will decline after the disorder is diagnosed.

Higher levels of the marker, visinin-like protein 1 (VILIP-1), in the cerebrospinal fluid (CSF) of Alzheimer's patients have been linked to a more rapid mental decline in the years that followed.

Scientists at Washington University School of Medicine (St. Louis, MO, USA; www.wustl.edu) studied 60 individuals with a clinical diagnosis of very mild or mild AD and measuring baseline CSF protein levels of VILIP-1, Tau, phosphorylated

Tau-181 (p-tau181), and amyloid-beta 1–42 (Aβ42), and these were followed longitudinally for an average of 2.6 years.

Baseline CSF VILIP-1 and VILIP-1/Aβ42 levels predicted rates of future decline in the clinical dementia rating and global composite scores over the follow-up period. Individuals with CSF VILIP-1 equal to or greater than 560 pg/mL progressed much more rapidly than individuals with lower values. CSF tau, p-tau181, tau/ Aβ42, and p-tau181/ Aβ42 also predicted more rapid cognitive decline overtime. Scientists think VILIP-1 serves as a calcium sensor in brain cells. It is released into the cerebrospinal fluid when the cells are injured. CSF samples were analyzed for total tau, p-tau181, Aβ42 using Innotest, (Innogenetics, Ghent, Belgium; www.innogenetics.com), and CSF Aβ40 by an enzyme-linked immunosorbent assay. CSF samples were analyzed for VILIP-1 by Erenna, a microparticle-base immunoassay (Singulex, CA, USA; www.singulex.com).

Rawan Tarawneh, MD, the lead author of the study, said "VILIP-1 appears to be a strong indicator of ongoing injury to brain cells as a result of Alzheimer's disease. That could be very useful in predicting the course of the disease and in evaluating new treatments in clinical trials. These results are intriguing, but we need a larger study to fully understand how the insights provided by VILIP-1 compare to those we can gain from other markers." The study was published online on February 22, 2012, in the journal *Neurology*.

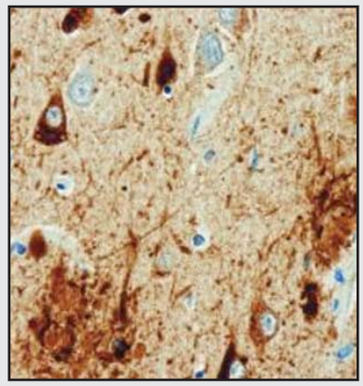

Image: Tissue from the hippocampal region of the brain is stained brown to display the tau protein. The triangular shapes are neurofibrillary tangles. Amyloid plaques are the round, less dense structures, which contain amyloid-beta, but are stained only for tau in this image (Photo courtesy of the Washington University School of Medicine).

Liquid Media Found Practical for Diarrheagenic Parasite

A common protozoan in the human intestinal tract that can cause the so-called blastocystosis characterized by diarrhea, can be grown in liquid culture media. In vitro culture methods could be safe alternatives to identify *Blastocystis hominis* for both clinical diagnosis and field study purposes, as present methods are potentially toxic to laboratory personnel.

Scientists at Xi'an Jiaotong University (Peoples Republic of China; www.xjtu.edu.cn) isolated eight samples of *B. hominis* from symptomatic patient fresh stool samples. More than five *B. hominis* cells were seen per high-power magnification field. To determine whether in vitro culture could be an environmentally safe alternative, the culture growth of *B. hominis* observed and compared in three commercially available liquid media: Roswell Park Memorial Institute (RPMI) 1640, 199 Medium, and Dulbecco's modified Eagle's medium (DMEM). The sensitivity and specificity of these culture methods to identify *B. hominis* were compared with those of existing methods used clinically.

The anaerobic culture of *B. hominis* in these media required a total inoculum sizes of no less than 105 cells; pH values ranging from 7.0 to 7.5; concentrations of calf or horse serum ranging from 10% to 30%; and basic antibiotics have to be added. Growth peaking times were at days 3, 6, and 9 at pH 7.5 or days 4 and 8 or 9 at pH 7.0 at 37 °C. No significant differences were noted in multiplication or generation times for the cultivation of *B. hominis*. In 56 of 398 positive cases, the short-term in vitro culture method achieved the best performance with regard to sensitivity and specificity of the five methods studied. All three culture media were from the Gibco (Carlsbad, CA, USA; www.invitrogen.com) range of culture media. *B. hominis* identification has depended on the discovery of vacuolar, granular, amoebic, or cystic forms in stool samples using wet mount smears, iodine staining, trichrome staining, or iron hematoxylin staining.

The authors concluded that the in vitro culture method had the advantage of environmental safety, convenience in preparation and storage, facility in morphologic discrimination, and outstanding performance in terms of sensitivity and specificity, and could be applied to identify *B. hominis* for clinical diagnosis except in emergency situations. Prevalence surveys in China suggest that about 6% of patients with diarrhea have *blastocystosis*. The study was published on November 11, 2011, in the *International Journal of Infectious Diseases*.

TECHNICAL LITERATURE

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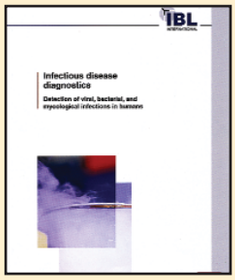

DIAGNOSTIC PRODUCTS
IBL International

Products available include a comprehensive ELISA portfolio for the detection of viral, bacterial, and mycological infections in humans using various body fluids.

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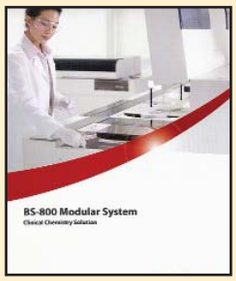

MODULAR LAB SYSTEM
Mindray

The BS-800 offers an expandable platform and a complete line of reagents, along with calibrators and controls for convenience and cost-effectiveness.

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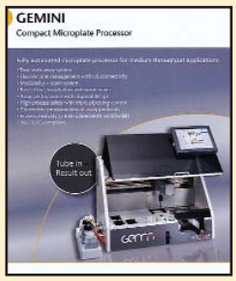

MICROPLATE PROCESSOR
R-Biopharm

The Gemini is a compact, fully automated walk-away system that offers ease of use, installation, and maintenance in medium throughput applications.

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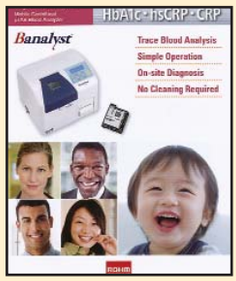

MOBILE BLOOD ANALYZER
ROHM

The Banalyst single-drop analyzer is designed for infection prevention and features simple operation, trace blood analysis, on-site diagnosis, with no cleaning required.

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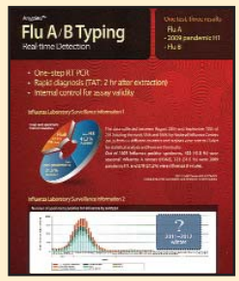

ONE-STEP PCR TEST
Seegene

The Anyplex Flu A/B Typing one-step, real-time PCR test offers internal control for assay validity, and rapid diagnosis with a two-hour turnaround time.

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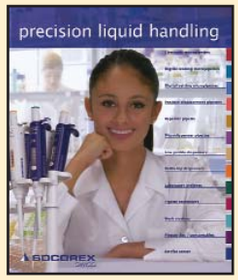

LIQUID HANDLING PRODUCTS
Socorex

Products available include a range of micropipettes and pipettes, low-profile and bottle-top dispensers, lab syringes, workstations, and consumables.

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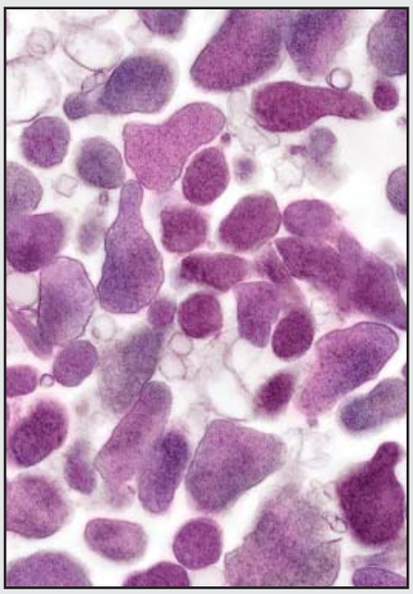
STD Bacteria Leads to Potential HIV Infection

African women who are infected with a common sexually transmitted bacterial infection are two times more likely to acquire Human immunodeficiency virus (HIV) infection.

Mycoplasma genitalium is an emerging sexually transmitted infection (STI) associated with reproductive tract syndromes in men causing urethritis, and in women, it is associated with cervicitis and pelvic inflammatory disease.

In a multiinstitute study, conducted by the Research Triangle Institute (RTI International; San Francisco, CA, USA; www.rti.org) HIV-negative women from Zimbabwe and Uganda were tested once every 12 weeks for a median of 22 months. Blood was collected for HIV diagnosis using several different enzyme-linked immunosorbent assays (ELISA). *M. genitalium* testing was performed on samples at the HIV detection visit and the last HIV-negative visit for cases, and equivalent visits in follow-up time for controls. Presence of *M. genitalium* DNA was assessed by in-house polymerase chain reaction (PCR)-ELISA, using the archived cervical swab samples, which had been stored at -20 °C.



The scientists compared 190 women who became infected with HIV during follow-up to women of a comparable age and risk who were not infected with HIV. The team examined women in both groups for the presence of *M. genitalium*, which was assessed as a risk factor for HIV infection. They found that in initial samples when all participants were HIV free, approximately 15% of women who later developed HIV were infected with *M. genitalium* compared with 6.5% in women who did not develop the disease. Furthermore, the team found that *M. genitalium* was more prevalent that other bacterial sexually transmitted diseases caused by *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

According to the team, *M. genitalium* was responsible for approximately 9% of all HIV infections occurring in the study. Other factors, such as having a partner with HIV risk factors, or the presence of herpes simplex virus 2, which causes genital herpes, were more strongly linked to HIV risk. Sue Napierala Mavedzenge, PhD, a lead researcher of the study, said, "Further research will be required to confirm a causal relationship and to identify risk factors for *M. genitalium* infection in African populations. If findings from this research are confirmed, *M. genitalium* screening and treatment among women at high risk for HIV-1 infection may be warranted as part of an HIV-1 prevention strategy." The study was published March 13, 2012 in the journal *AIDS*.

Image: Colored transmission electron micrograph (TEM) of Mycoplasma genitalium bacteria (Photo courtesy of SPL).

Marrakech Hosts ArabMedLab 2012

Edited by Edgard Delvin,
IFCC eNews Editor

During May 2-5, 2012, Marrakech hosted the joint meeting of the 13th Arab Congress of Clinical Biology and of the 12th Moroccan Congress of Clinical Chemistry and Laboratory Medicine, held under the auspices of the IFCC. Novel biomarkers, proficiency testing, quality management, and accreditation were central subjects to the meeting having diseases and conditions of high priority in terms of public health in the Arab world, such as hemophilia; tropical diseases; hemoglobinopathies; celiac disease, and the emerging bacterial resistance to antibiotics, as background. World-known scientists led the symposia.

Among the highlights of the meeting was the inaugural lecture delivered by Prof. Gérard Siest who gave an enlightened account of the development of pharmacogenetics in the course of the past 20 years. He also gave a glimpse of the future input of theranostics in the follow-up of pharmacologically treated patients. Prof. Nouzha Guessous also gave a lucid and vivid account of the status of bioethics in laboratory medicine in the world, referring to the seminal document published by the UNESCO under her leadership as Chair of the Committee. The poster session allowed young scientists to present and discuss their results with authorities in their respective fields. Exhibitors had ample opportunity to meet conference attendees in a very friendly atmosphere within the Marrakech Convention Center.

Several committees (IFCC-EB, IFCC-CPD, IFCC-SD, AFCB, and FIFBCML) held their business meetings before and during the meeting. Members of the Executive of the IFCC Communication and Publication Division, in the scope of a symposium, addressed the theme of Public relations and the value of laboratory medicine.

Awards and Nominations at ArabMedLab 2012

Prof. Mohammed Lahrichi and Dr. Halima Elalamy received a well-deserved recognition for their lifelong services to the Société Marocaine de Chimie Clinique, and Prof. Layachi Chabraoui, president of the Moroccan Society of Clinical Chemistry and chair of the International Scientific Committee of the ArabMedLab 2012, was nominated President of the Arab Federation of Clinical Biology.

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IFCC-IUPAC News

by Graham Beastall, IFCC President and
René Deplanque, IUPAC, Secretary-General

Graham Beastall

René Deplanque

The NPU Terminology: Contributing to Patient Safety

Globalization of healthcare is now a reality. At the touch of a button, it is possible to learn of practices and procedures that are carried out in a wide range of countries. Few can deny that instant information is an aid to understanding and to the drive for harmonization of practice. However, there are considerable risks in assuming that terminology, data and practices are universally understood and commutable across national boundaries.

In laboratory medicine one of the most basic, but important challenges to the profession is to ensure that we have a common understanding of what is being measured in what biological system and of how the results will be expressed and in what units. This area is referred to as nomenclature, properties, and units (NPU).

IFCC and IUPAC have a longstanding partnership to establish and maintain high standards in the field of NPU as an aid to harmonized practice and better patient safety.

At the centre of the IFCC-IUPAC project is the NPU terminology - a coding system for communication of examination results in clinical laboratory sciences.

It covers the fields of: Allergy; Clinical chemistry; Clinical immunology and blood banking; Clinical microbiology; Clinical pharmacology; Molecular biology and genetics; Reproduction and fertility; Thrombosis and hemostasis; Toxicology

The NPU terminology is based on structured definitions with prescribed syntax, semantic rules and format, defining coded kinds-of-property across clinical laboratory sciences. It has been used in electronic health care communication for ten years, supporting large-scale information exchange between many different laboratory information systems and electronic health care record systems.

A user guide to the NPU terminology and the NPU database has been published in both chemistry and clinical chemistry literature. This guide provides a clear explanation of the system and of its operation. Access to the NPU terminology in English is available from the Danish Release Center (www.labterm.dk) and also from the IFCC website (www.ifcc.org).

IFCC and IUPAC encourage the widespread adoption and application of the NPU terminology.

Persons wishing to know more about the NPU terminology and its database should contact:

Ulla Magdal Petersen, scientific lead for the NPU database at UMP@sst.dk, or Robert Flatman, chair of the IFCC-IUPAC Committee on NPU robert_flatman@snp.com.au

References:

Petersen UM, Dybkaer, R, Olesen H. Properties and units in the clinical laboratory sciences. Part XXII. The NPU terminology, principles, and implementation: A user's guide. Pure Appl Chem 2012; 84: 137-165; Clin Chem Lab Med 2012; 50: 35-50

New EMD Committee on Distance Learning (C-DL)

A new Committee inside the IFCC Education and Management Division has been established to develop an IFCC strategy for distance learning: It is the EMD Committee on Distance Learning (C-DL).

The Committee will work in partnership with the Communications and Publications Division Committee on Internet and eLearning (CPD C-leL) identifying and developing educational material that can be used for online learning modules on specific topic areas of value to IFCC.

The C-DL membership is as follows (April 2012 - December 2014): J. Smith (UK), Chair; R. Greaves (AU), Member; D. Gruson (BE), Member; E. Hoyaranda (ID) Member; C. Webster (UK) Member

New CPD Committee on Internet and e-Learning (C-leL)

The Committee, chaired by Peter Vervaart (AU), has as its primary goal developing and maintaining the IFCC website by working with the IFCC office, committees, working groups, task forces, National Societies and Corporate Members as well as the website host, software developers and other interested parties.

The Committee will work in partnership with the Education and Management Division Committee on Distance Learning (EMD C-DL) in identifying and developing educational material, which can be used for online learning modules on specific topic areas of value to IFCC members.

For further information on the aims and the projects of the new C-leL, please visit the C-leL page of the IFCC Website (www.ifcc.org).

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News from the WG Ibero-American Nomenclature and Translations

by M Felix Hernan Fares Taie, Director, Laboratory FT Institute of Analysis

"The Microscope" is an online radio program transmitted every Wednesday from 1:00 to 2:00 pm, Argentina (UTC -3). The programs will be stored online after their live transmissions on the website www.infobioquimica.com and anyone with only an Internet connection will be able to play them anytime or download the files in mp3 format. The idea has been developed from the need to improve communication between clinical laboratories of Ibero-America and the IFCC, and from the need to spread scientific, strategic, and updated topics.

The programs will be covering the use and interpretation of laboratory tests, the performance and methods of the technologies, laboratory management, and social, legal, political, and union issues. Moreover, the programs will encourage social and environmental commitment between laboratories and the community to improve communication between health teams and patients.

"The Microscope" will be a tool to promote strategies and activities to increase the value of the clinical laboratory in healthcare processes, to spread courses and congresses and to encourage social and cultural activities in the context of clinical laboratories, such as tourism and art. We invite you to participate in the discussion forums to increase communication among scientist, residents, and students from Ibero-America.

Report on the 12th Iranian Congress of Biochemistry & 4th International Congress of Biochemistry and Molecular Biology

by M.J. Rasaee, National representative for Biochemical Society of Iran

The 12th Iranian Congress of Biochemistry (ICB) and the 4th International Congress of Biochemistry and Molecular Biology (ICBMB) were held during September 6-9, 2011, in Mashhad, Iran. The Department of Medical Biochemistry, Mashhad University of Medical Sciences (MUMS) and the Biochemical Society of I.R. Iran organized the congress that was supported by the International Union of Biochemistry and Molecular Biology (IUBMB), the Federation of Asian and Oceania Biochemists and Molecular Biologists (FAOBMB) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

The conference covered the recent advances in biochemistry and molecular biology, and included as examples themes that ranged from bioinformatics, herbal medicine, and nanotechnologies to inborn metabolic diseases and nutritional biochemistry. Importantly, 12th ICB & 4th ICBMB also served the purpose of training young scientists and integrating them into the broader scientific community along with providing a forum for them to interact with peers in the field. In cooperation with the congress executive committee, 18 different workshops were offered to participants and researchers to enhance their scientific and technical skills.

Of the 1,200 abstracts received from 30 different countries covering all continents, 1,113 were accepted for presentation after peer reviewing, 154 for oral presentations, 284 as electronic posters, and 675 as hard copy posters. The abstract book was published as a supplementary issue of *Clinical Biochemistry* that is available at www.sciencedirect.com

Prof. Angelo Azzi (the President of the IUBMB), Prof. Susan Hamilton (chair of Education Committee of IUBMB) and Prof. Khosrow Adeli (vice-chair of Publications and Communications Division of IFCC) were among the high-profile invited guests to this congress.

In the opening ceremony, held in the Great Hall of the Faculty of Science, Ferdowsi University of Mashhad, Dr. Mahmoud Shabestary, the Mashhad University of Medical Sciences Chancellor, and the Congress Presidents all underlined the efforts of the Scientific and Local Organizing Committees to provide a forum favoring the transmission of new knowledge through interdisciplinary educational courses and research projects. The Medical Science Chancellor also highlighted the steep progression of the Mashhad University in the international ranking of world top universities.

The Biochemical Society also held its second meeting on September 9, 2011, during which Yazd University of Medical University was officially named as the host for the upcoming National Biochemistry Congress on 2012. Isfahan University of Medical Sciences, Isfahan, Iran, and Shahid Beheshti University of Medical Sciences, Tehran, Iran, were nominated for hosting the 5th International Congress on Biochemistry and Molecular Biology to be held in 2013.

During the closing ceremony, the Congress President gave three research excellence awards to Dr. Majid Ghayour-Mobarhan, Dr. Saman Hoseinkhani, Dr. Aadeleh Divsalar based on their publications. In addition, five overseas participants received travel grants awards from the University Chancellor. Three best speakers, as well as electronic and hard copy poster presenters also received awards for the quality of their work. Finally Prof. Angelo Azzi , IUBMB president, granted IUBMB medals to Dr. M. Shabestari, Dr. M. Taghikhani and Dr. M. Ghayour-Mobarhan in appreciation of their success in organizing the Congress.

Pakistan's 4th Biennial Course in Chemical Pathology Held in Rawalpindi

by Dr. Aysha Habib Khan, member of the Executive council of PSCP

Photo: Members of the Executive Council of the Pakistan Society of Chemical Pathologist

The Pakistan Society of Chemical Pathologist (PSCP) organized the fourth Biennial Course in Chemical Pathology and Endocrinology at Armed Forces Institute of Pathology, Rawalpindi on March 16-17, 2012.

Pathologists and their trainees from all over Pakistan attended the inaugural session. In his inaugural welcome address, Commandant AFIP, Major General Farooq Ahmed Khan, patron PSCP, updated the audience with the recent advances and trends in the field of Chemical Pathology. Chief guest Lt. General Azhar Rasheed (Director General Medical Services, Pakistan Army) underlined the efforts of the Society in educating and training the specialists as well as other medical practitioners.

The course comprised of four teaching sessions followed by a workshop on ethical practices in profession. The speakers from abroad included Dr. Shahzad Ahmed, Clinical Endocrinologist (USA), Dr. Jawaid Malick, Rheumatologist Fauji Foundation Hospital, Brigadier Tahir Aziz, Immunologist from AFIP, Lt. Col. Shakil Mirza, Hepatologist, Army Medical Services.

The presentations in the course covered broad clinical areas like diabetes, thyroid, osteoporosis, vitamin D deficiency, role of autoantibodies, insulin resistance in liver disease, placenta, and fetal well-being, cystatin C as a marker of renal function, biochemical investigations in liver diseases, a view of novel cardiac biomarkers in heart failure. A wide range of topics related to laboratory science were also covered including metabolomic vs. clinical chemistry, improving efficiency in clinical lab, the impact of STAT laboratory services in the management of patients, selection of a clinical chemistry instrument and a contrast approach and now lines of investigation including genomics and metabolomics.

The post-course workshop was well attended by postgraduate trainees. It covered instrument handling, scenarios related to lab management and data interpretations.

Dr. Imran Siddiqui; Secretary of PSCP chaired the Executive Council and general assembly meeting held on March 16. The committee discussed the IFCC scholarship award for enhancing the skills of trainees below 40 years of age, and the increasing the membership. The committee decided to hold the fifth Annual conference of the society in February 2013 in Karachi.

The Executive Council thanked Brigadier Dilshad, the organizing secretary of the Biennial course for his dedication in organizing the course.

How Do Residents in Spain See their Scientific and Professional Future?

by Felip Antoja Ribó,
Liaison to the IFCC eNewsletter

On March 23, 2012, the Second Conference for Laboratory Residents, organized by the Group of Residents of the Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC), was held in Barcelona, under the name "Future lab specialist: Are we heading the right way?"

Following a similar format to the first meeting held in Madrid in 2011, we tried to solve the main concerns of Spanish residents at all stages of their training. Am I receiving good training? How can I go beyond my basic training to be better prepared? What are the specialties in the rest of Europe? All these questions and many more were addressed during the seminar and during the final discussion. Regarding the last question, the interest of our future specialists about their chances to work and learn outside of Spain became clear. Specialists and residents presented the various topics, helping participants obtain a clear picture of the minimal requirements to become a professional laboratory specialist and discover what can be done to enhance their training over the four-year residency program.

POCT at Crossroads of Innovation and Successful Strategies

by Dr. Bernard Gouget

SFBC-EFLM Representative; IFCC Treasure;
Secretary General, International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML)

Diagnostic tests performed outside the central laboratory or decentralized testing is generally known as point-of-care testing (POC). Biosensors and new technologies for patient-proximal diagnostic products and the new attitudes of patients and healthcare providers and systems will transform the organization and the practice of laboratory medicine for more efficient medical service and economic perspective. Over the years, its use has increased over the past decades in response to pressures for cost-containment, faster results and smaller sample volumes. The drive toward centralized laboratory operations has catalyzed the value of POCT in hospitals. Now, with testing centralized in a core laboratory, point-of-care testing becomes a more viable option for many time-sensitive tests.

POCT has the potential to enhance clinical outcome. POCT encompasses a large variety of IVD products ranging from moderate sized instrumented diagnostic systems serving larger institutional uses to single-use, disposable tests for individual home use. Near patient tests, including those for blood glucose, pregnancy, fertility, coagulation, cholesterol, drugs, cardiovascular and infectious diseases, drugs of abuse, and various urine components, are in high demand as physicians and patients realize their potential for promoting improved healthcare in different segments: hospital sector, private practice, primary care settings, and home monitoring. Existing new technology areas such as protein sequencing, DNA sequencing, and the human project have to be placed into the context of their impact on rapid diagnosis new developments and forecasts in POCT. In addition, the drive for wellness and the attention surrounding healthcare reforms will focus on rapid diagnosis and prevention. However, there are many challenges, which must be overcome for POCT to be fully utilized.

The value of immediate results is also evident in testing for chronic diseases where rapid diagnosis can limit the spread of disease and lead to prompt initiation of therapy in the increasing numbers of diagnosed diabetic patients, people with cardiovascular disease and other chronic conditions, or in people with infectious diseases. For serious diseases such as the human immunodeficiency virus (HIV), the ability to rapidly detect the virus in a single doctor visit is crucial in initiating therapy as quickly as possible and ensuring that patients are aware of their test results. In many countries studies demonstrated that 25%-35% of those tested for HIV, using nonrapid methods did not return for test results!

Factors driving growth are the increasing patient and physician demands for more efficient testing approaches, availability of new biosensors technologies for more effective diagnosis and triage, and reduction of healthcare costs. Although the benefits of POCT are clear, this industry is not without challenges. Tests performed on clinical laboratory analyzers continue to be perceived as superior to POCT. Companies entering the POCT market must demonstrate that their tests have more clinical utility than those performed in laboratories.

POC testing appears to be headed for an even bigger role in diagnosis and monitoring patient care and the world market for POC tests has shown consistent growth, a trend that is expected to continue. The worldwide Point of Care Diagnostic testing sector (POCT) is the fastest growing sector of the worldwide diagnostic industry. The global testing POC market is around USD 14 billion. It will further grow to USD 16.5 billion in 2016 for a compound annual growth rate (CAGR) of 3.7% between 2011 and 2016. The glucose-monitoring segment of the POC market reached USD 7.5 billion in 2011. The blood chemistry and electrolyte segments of the POC market reached USD 2.2 billion in 2010 and will further grow to USD 2.8 billion in 2016 for a CAGR of 4.8% between 2011 and 2016. The fastest-growing segment, cardiac markers, is projected to increase at a CAGR of 14.4 percent, rising from USD 1 billion in 2011 to USD 2 billion in 2016. The infectious disease and tumor marker segments have the next highest projected growth rates, with both expected to increase at CAGR of more than 10%.

Globally, the diagnostic business is typified by intense competition and areas with high growth. The constant pressure to reduce healthcare spending is shifting healthcare utilization in favor of the medical laboratory, making it an ever more valuable part of the treatment plan. As hospital stays are shortened, contact between the physician and patient is reduced, which places a larger role on labs to gather, interpret, and deliver accurate information in a timely manner. POCT is a challenge for our professional maturity. Implementing POCT is complex and requires a cooperative effort at many levels. The specialist in lab med has the expertise; we should embrace and manage the POCT concept. Of course, Universal connectivity of POCT devices is the key to managing quality and accreditation, according to ISO 22870, which is a part for a successful POCT implementation. But the challenge to succeed in the task of establishing POCT must be met, so that in this 21st century medical laboratory science can exists for professionals who practice it.

12th EFLM Continuous Postgraduate Course in Clinical Chemistry

by Prof. Dr. Sc. Elizabeta Topic, chair EFLM Committee of Education and Training

Within the frame of EFLM, the Croatian Society of Medical Biochemistry, and Slovenian Association of Clinical Chemistry the 12th EFLM Continuous Postgraduate Course in Clinical Chemistry New Trends in Classification, Diagnosis and Management of Gastrointestinal Diseases, will be held at the Inter University Centre in Dubrovnik (Croatia), from November 10-11, 2012.

These courses have been launched in 2001 as postgraduate scientific courses of continuing education in clinical chemistry and laboratory medicine, organized within the frame of EFLM (former EFCC) at Inter University Center Dubrovnik for members of the EFLM societies. The common title of the courses is EFLM Continuous Postgraduate Courses in Clinical Chemistry: New Trends in Classification, Diagnosis and Management, each of them dedicated to a particular medical entity such as Diabetes Mellitus (2001), Cardiovascular Diseases (2002), Neurological Diseases (2003), Tumour Diseases (2004), Autoimmune Diseases (2005), Metabolic Syndrome (2006), Molecular Diagnosis (2007), Kidney Diseases (2008), Thyroid diseases (2009), Thrombophilia (2010), and Inflammation (2011).

This year the Course is devoted to gastrointestinal diseases (http://www.dubrovnik-course.org).

Many renowned speakers from all over Europe will present their state of the art lectures in the field. The new classification, epidemiology and screening tests in gastrointestinal diseases will be presented. From oncological point of view, attention is focused particularly on colorectal cancer and in gastrointestinal nutrition-related diseases, to the malabsorption, anorexia, refeeding syndrome and obesity. Related to gastrointestinal diseases in children the cystic fibroses, celiac disease and pancreas malfunction will be presented and the program will be concluded with lectures in chronic gastrointestinal diseases.

Travel grants are available for young course participants (under 35 years), from European countries. (www.dubrovnik-course.org/travel_grants). Grant application deadline is 30 June, 2012.

Beside the course, on offer will be an attractive scientific program designed to deliver a highly interactive and stimulating atmosphere, the participants will be able to take part in lively discussions and exchange ideas with well known experts in the field. We hope that participants will enjoy this opportunity to acquire new knowledge and experience, while also make new friends and enjoy the beauties of Dubrovnik - a city whose beauty extends beyond mere words.

It is our pleasure to invite you to participate in this weekend course and look forward to offer a truly pleasant and unforgettable stay in Dubrovnik!

5th SFBC International Symposium on Critical Care and Blood Gases

by Michel Vaubourdolle, SFBC-Chair Committee on Accreditation, and Bernard Gouget, SFBC-EFLM representative

The triennial international symposium founded by Dr. Alain Feuillu (Rennes (France), was organized this year in Deauville (France) on May 31 to June 1, 2012. Deauville is very famous for many reasons, not only with the American film festival but also for the horse races all year round, and its international horse auctions, as well as the annual polo competition, which gathers the world's best players. Deauville is the ideal setting for a cultural and scientific pause. This is one of the reasons why Dr. Michel Vaubourdolle, president of the International symposium, choose this wonderful place to discuss an important topic on critical care testing and blood gases. The symposium gathered 400 participants from more than 10 countries in presence of Ian Watson, EFLM president, Greg Miller, AACC president, Nader Rifai, editor-in-chief Clinical Chemistry, Philippe Gillery, Joelle Goudable, and Roselyne Garnotel, representing the SFBC and Bernard Gouget, who was representing Graham Beastall IFCC president.

POCT concept is at a crossroads: the technologies to make rapid testing a reality have arrived, but are we ready? This was the debate in Deauville. During the two-day symposium, organized in four sessions, it was possible to better understand the latest trends in innovation and projections for future applications. Paul Holloway presented the benefits and expectations of POCT devices. The benefits of bringing diagnostic testing closer to the patient and reducing TAT are self-evident but include the potential for more rapid clinical decision making, triaging, monitoring, identifying dangerous pathogens and reducing the financial and clinical costs of patient care. The extension of POCT to pathogen recognition and treatment sensitivity is gaining momentum, enhanced by drives to improve medical care at scenes of disaster and terror, and along with that is a strong impetus for improved sepsis biomarkers. Prof. B Carbonne and Agnès Mailloux presented the benefit of POC in neonatology using POCT device for bilirubin, Dr. J.L. Daban the new approaches in intensive care units, and Dr. Petra Wilk the impact of POCT on ward organization. During his talk, Prof. P Toulon focused on the significant increase of POCT in hemostasis in both the spectrum of tests available and the advantages of the physician. Profs. Ph Gillery and C Dukas demonstrated the value in blood Glucose and HbA1C monitoring in order to establish more tight blood glucose control in diabetes patients.

The afternoon session focused on the new biosensors beyond the traditional applications of electrochemical biosensors. Prof. M.E. Meyerhoff described the recent efforts to use simple electrochemical biosensors for the measurements of polyionic drugs and associated contaminants, including the anticoagulant heparin, low molecular weight heparins, and OSCS contaminants in biomedical grade heparin preparations. Several presentations discussed how new technologies would change diagnosis screening, testing paradigms, and provided an analysis of potential new POC applications in the clinical sector and emphasized the potential benefit of POC for various sectors of the medical and scientific community, capillary glycemia by Dr. Ph Derache, and the recent developments in microbiology based on molecular techniques by Prof. P.Y. Levy. At the end of the first day, it was possible to have a comprehensive overview on the importance of the connectivity, remote data management, and IT by Dr. M Boisson, and how to reduce preanalytical errors using RFID in the blood gas process.

The second day saw Nader Rifai report on recent advances in technology that revolutionized the research and discovery capabilities for scientific information, and discussed the experience with Clinical Chemistry in the dissemination of scientific information.

With the new French regulation, many presentations described the strategies for the implementation of the accreditation for POCT. An experience from APHM Marseille by Prof. H Portugal, and the second one by P Vernet, CHU St Antoine, APHP, before a lively round table discussed the new challenge posed by the compulsory accreditation for all French medical laboratories before end of 2016 under the coordination of Michel Ballereau and Anne Marie Gallot, the initiator of the French reform for medical laboratories.

The last session was organized by the AACC critical care and POCT division with three presentations J.A. Dubois who reported on POCT as a growing, connected market segment with increased wireless capabilities where POC communication standards ensure fulfillment of the critical user requirements of bidirectionality, device connection commonality, commercial software interoperability, security and QC/regulatory compliance. Prof. S Ehrmeyer presented CLIA'88 quality-management system model to ensure quality of POCT in comparison with the worldwide ISO 15189/22870 norms and J.Nichols described the changing US regulations with new development in proficiency testing and quality control based on risk management.

Since the movie "A Man and a woman," Deauville has been under an international spotlight, forever connecting the town to romanticism, and we can sing, "Chaba-daba-da" (theme music from the Claude Lelouch film "Un homme et une femme."). We enjoyed the gala dinner with the red carpet at the entrance and the interactive Quiz Movies. This congress will be also an opportunity to interact with colleagues, young scientists, friends, to meet new ones and to build long-term professional relationship. Thanks also to the corporate companies who supported this project: IL, Radiometer, Roche, and Siemens.

Photo: (From left to right) Michel Vaubourdolle (SFBC-Chair Committee on accreditation), Nader Rifai (Editor in chief, Clinical Chemistry), Greg Miller (AACC president), Ian Watson (EFLM president), Bernard Gouget (SFBC-EFLM representative)

What's in a Name?

by Michael Thomas,
Association for Clinical Biochemists (ACB) President

What's in a name? "That which we call a rose by any other name would smell as sweet", says Shakespeare's Juliet, implying in her words that the names we ascribe to objects have an element of arbitrariness and are a mere matter of convention. But is this really so? Is there more to it than mere convention? In 2005, the Association of Clinical Biochemists, based in the UK, became the Association for Clinical Biochemistry. This was a small change in name but a significant change in that it recognized the desires of the membership to promote a greater inclusivity towards all those with an interest in the specialty and within the wider discipline of medicine. It formally extended the membership to all individuals interested in clinical biochemistry, and as a consequence, many biomedical scientists and industrial colleagues are now members of the ACB.

More fitting for the Articles Mergers with first, the Association of Clinical Scientists in Immunology, and more recently the Association for Clinical Microbiology, has further broadened the range of the Association's membership outside the traditional boundaries of Clinical Biochemistry. Two years ago, my predecessor, Julian Barth, wrote in ACB News (No. 563, March 2010) that this "does not quite fit our present Association articles, which permit membership to any … health professional with an interest in clinical biochemistry in the UK or Ireland." And, "nor would our Association name fit the bill." Changes in the by-laws do now reflect that our members may have an "interest in clinical biochemistry and/or laboratory medicine." However, the Association's name stubbornly remains that of "Clinical Biochemistry" alone and fails to recognize the wider constituency of our membership. We recognize that it is time to reconsider the Association's name and ACB Council would endorse this after consultation with the membership. It is therefore our intention to canvass members through an electronic survey on a further change in name, and Laboratory Medicine Executive Officers will recommend that the Association's name becomes the "Association for Clinical Biochemistry and Laboratory Medicine." This title would be consistent with those of international bodies who have also embraced a wider membership such as the International Federation of Clinical Chemistry and Laboratory Medicine and the American Association for Clinical Chemistry and Laboratory Medicine, both of whom continue to use their trademark names and logos of IFCC and AACC, respectively. We believe it is essential to retain our accepted trademark of ACB. Having been known by this abbreviation for almost 60 years, it is recognized nationally and internationally and also sits well against the proposed change in name. "A rose is a rose is a rose," said Gertrude Stein, often interpreted as emphasising that things are what they are. But there are benefits for the ACB in changing our name at this time. A professional association such as ours has strength in numbers and in breadth. Moreover, a wider membership fits with the changing pattern of delivery of laboratory medicine away from the old disciplines to that of a more integrated service. I sincerely hope that members will participate in the electronic survey and they will be persuaded of the benefits of changing the name of the Association to encourage membership across all branches of laboratory medicine, without losing the trademark "ACB."

UK Biobank Opens Its Data to Researchers

The massive health data resource UK Biobank (www.ukbiobank.ac.uk) recruited 500,000 people aged between 40-69 years from 2006-2010 from across the United Kingdom to undergo various measures, providing blood, urine and saliva samples for future analysis, as well as detailed information about themselves. Now, the databank is opening its resources to researchers. Scientists from the UK and from overseas, hailing from academia, industry, charity, or government-funded projects, will be able to use data after confirmation that research is health-related and in the public interest. Information provided to researchers will be anonymized. Applications to use the resource can be made online.

News from the Croatian Society

by Dr. Jasenka Wagner, President of the CSMB committee for public relations

During the past year, Croatian Society of Medical Biochemists (CSMB) organised two national meetings and one international meeting. The first meeting, "22nd Symposium of the Croatian Society of Medical Biochemists," was held in Zagreb in June 2011. This meeting is organized annually with different topics covered each year. This year's topics were Novel markers of gastrointestinal diseases. About 200 participants attended the meeting, with abstracts from the symposium being published in Biochemia Medica (2011;21(2):A21-A30).

Recently organized for the first time (2010), but already becoming a successful tradition, "2nd Croatian Predictive Medicine Symposium with International Participation" was held in Zagreb, in November 2011. About 150 participants attended this meeting dedicated to the role of laboratory medicine in predictive medicine. This year's lectures were oncology based. The abstracts of the Symposium were published in Biochemia Medica (2012;22(1):A1-A16).

The traditional meeting in the frame of EFLM, "11th EFCC Continuous Postgraduate Course in Clinical Chemistry: New trends in Classification, Diagnosis and Management of Inflammation" in cooperation with Slovenian Association for Clinical Chemistry and Inter-University Center Dubrovnik CSMB was organized in October 2011 in Dubrovnik. Course proceedings were published in Biochemia Medica (2011;21(3)) as review articles. About 120 participants from Croatia and surrounding countries attended the Course.

Publishing activities of CSMB are related to CSMB's scientific journal *Biochemia Medica (BM)* (www.biochemia-medica.com). We are proud to announce that, since October 2011, BM is indexed in Medline. With its international Editorial and Advisory Board it continues to publish articles by Croatian and international authors dedicated to professionals from laboratory medicine and various fields of biomedicine that share the same interests. Papers are published in English with abstracts in English and Croatian. BM is indexed in Medline, SCIE, JCR, Thomson Reuters, EMBASE/Excerpta Medica, Scopus, CAS, EBSCO/Academic Search Complete and DOAJ. The journal's impact factor for 2010 was 1.085.

Task and Finish Group on Critical Results (TFG-CR) - 2012-2014

EFLM has established a new Task and Finish Group on Critical Results (TFG-CR) under the WG-PEQAS

Aim: To perform a European survey on what critical result management procedures and policies laboratories have and how critical values are established and used in European laboratories.

Deliverables: To publish at least one scientific paper about the subject and to give a presentation or poster at EuroMedLab or other EFLM and/or AACB-related conference or symposium.

Members: Éva Ajzner, Chair, County's Teaching Hospital, Central Laboratory, Nyíregyháza (HU), ajznereva@josa.hu; Kristin Moberg Aakre, Member, Laboratory of Clinical Biochemistry, Haukeland University Hospital, Bergen (NO), kristin.moberg.aakre@helse-bergen.no; Craig Campbell, Member, SEALS, Department of Clinical Chemistry, Prince of Wales Hospital, Sydney (AU), craig.campbell@sesiahs.health.nsw.gov.au; Andrea Rita Horvath, Advisor, SEALS, Department of Clinical Chemistry, Prince of Wales Hospital, Sydney (AU), rita.horvath@sesiahs.health.nsw.gov.au

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SFBC Promoting Accreditation ISO 15189 in Euro-Mediterranean Countries

by Michel Vaubourdolle, CHU St Antoine,
APHP France, chair SFBC committee on accreditation

Dr. Michel Vaubourdolle, supported by an IFCC visiting Lecturer program, was invited to Morocco, to speak on the ISO 15189 accreditation for medical labs. The 13th Arab Congress of Clinical Biology, joined with the 12th Moroccan Congress of Clinical Chemistry and Laboratory Medicine, designed as ArabMedLab 2012, was held May 2- 5, 2012, in Marrakech, Morocco. This meeting was organized by the Moroccan Society of Clinical Chemistry and Laboratory Medicine (SMCC) and the Arab Federation of Clinical Biology (AFCB), under the auspices of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

Marrakech was and is the hub of a great civilization that grew from a melting pot of people from the four corners of the world, drawn here by the prosperity of a capital that has not ceased to exert its influence across the world. African, Saharan, Muslims, Arab and other civilizations have blended harmoniously to produce an explosion of creativity and special appreciation of traditional arts, architecture, science, and the ways of life. With the 13 ArabMedLab Congress/12 SMCC, we got a good example of the creativity and of the dynamism of our Moroccan colleagues to explore and to drive the future of lab medicine.

The audience was important and representative of African and Mediterranean areas with 900 attendees and 40 countries represented. More than 60 speakers, recognized specialists, from many IFCC/EFLML countries as well as IFCC CPD, and SD representatives were present and contributed to 10 plenary sessions, 6 parallel sessions, and 7 industrial workshops.

Scientific topics concerned all biological specialties and actuality reviews, such as the value of laboratory medicine, pharmacogenomics, molecular genetics, biomarkers of Alzheimer disease, decision limits and reference intervals, vitamin B12 deficiency, cancer biomarkers, personalized medicine, hemophilia, vitamin D, highly contagious bacteria, quality management, viral hepatitis, autoimmune diseases, emerging antibiotic resistance. Some sessions were focused on African-Mediterranean aspects of the biological themes such as hemoglobinopathies in the Arab world.

The session "Proficiency Testing, Quality Management and Accreditation in the Arabic and Euro-Mediterranean Environment" was held Saturday May 5, 2012, in the morning. It was coordinated by Bernard Gouget (IFCC Treasurer, Paris, France) and Saif El Islam Slimani (President of CSB; Rabat, Morocco).

Various aspects and experiences about the accreditation process and quality assurance were presented. Fouad Harb (Damascus, Syria), Ghassan Shannan (Damascus, Syria) spoke on Quality management in the AFCB region, Present and future; The Road Map of quality management in Clinical Laboratories of Lebanon was done by Adel Mastori; Analysis of the Moroccan GBEA in comparison to the ISO 15189 was discussed by Nadia Charrat (LRAM; Rabat, Morocco); Anne Vassault (Paris, France) presented the Quality controls Tools for Clinical lab management in the AFCB region.

Comparisons between countries in the Arabic and Euro-Mediterranean areas were very interesting to discuss during a roundtable in the presence of Daniel Pierre, past president of ILAC and international accreditation bodies representatives.

In addition, this congress gives us the opportunity to meet the general secretary of the Marrakech University Hospital Mohammed VI and to initiate future collaborations between the University Hospital Mohammed VI and IFCC, SMCC, SFBC, and the French hospital organization.

Finally, this congress had also a convivial moment and met the IFCC executive board members in Marrakech for the board meeting and the International Francophone Federation of clinical biology and Lab medicine board members.

In conclusion, this meeting was very exciting and interesting, due to a real and useful mix between Arabic, Francophone, European and international delegates.

Invitation: 20th Meeting of Balkan Clinical Laboratory Federation to Be Held in Belgrade on September 18-22

by Prof. Dr. Nada Majkic-Singh, President, Society of Medical Biochemists of Serbia

The Society of Medical Biochemists of Belgrade has the pleasure of inviting you to the 20th Meeting of the Balkan Clinical Laboratory Federation to be held in Belgrade, on September 18-22, 2012, joined together with the 8th EFCC Symposium for the Balkan Region and 18th Congress of Medical Biochemists of Serbia.

This is the third time that the Society of Medical Biochemists of Serbia acts as the organizer of the BCLF Meetings. The Fourth Meeting of the Balkan Clinical Laboratory Federation was held in Budva in 1996, and the 11th BCLF 2003 Meeting was organized in Belgrade, under the auspices of the International Federation of Clinical Chemistry (IFCC) and the Forum of the European Societies of Clinical Chemistry (FESCC). More than 500 scientists from all over the world and all the Balkan countries were present. It has been generally agreed that the meeting fulfilled the expectations and was a success.

The Serbian capital Belgrade, the host of the Meetings, is an ancient city. No one knows when the first settlers inhabited the area of present-day Belgrade. During the prehistoric era, the city surroundings were already densely populated. In those times, land and river caravans traveling along some of the oldest trade routes were meeting on its territory.

The ancient peoples who lived on this land were changing by turns from the Illyrian tribe of Autariats, through Dacians, Celtic Scordians, to Thracian Sings, etc. Belgrade's many names include: Singidunum, Alba Bulgaricam, Nandorfejervar, Alban Andor, Wiessenburg, Griechisch Weissenburg, Alba Graeca, Castel bianco, and Beograd (Belgrade). It is believed that the first inhabitants of Belgrade were the Sings, one of the Thracian-Illyrian tribes. They are mentioned by Herodotus, the father of European history. The city's first name recorded in history was Singidunum, most probably of Celtic origin, and can be found in the works of ancient authors and antique inscriptions. It was derived from the name of the Thracian tribe of Sinngs and the Celtic word Dunum, meaning "town." In historic documents, the city appeared under the Slavic name Belograd or Beograd in the 9th century.

Belgrade lies at the mouth of two rivers, the Danube and the Sava, under the Mountains of Avala, the silent witnesses of a long and bloody history of the city that has always risen from ashes, like the phoenix, each time bigger and more beautiful.

The 20th BCLF Meeting in Belgrade will continue with its successful progress of the previous years, aiming to focus on the new data in the field of laboratory medicine. The intention is also to increase the participation of clinical chemists from all the Balkan countries, as well as from the neighboring states.

We hope that we will have the pleasure of your presence, and speaking on behalf of the Society of Medical Biochemists of Serbia, we look forward to your active participation in the works of the 20th Balkan Clinical Laboratory Federation Meeting and 8th Symposium for the Balkan Region, as well as the 18th Serbian National Congress of Medical Biochemistry and Laboratory Medicine.

European Commission's New Health in Europe: Information and Data Interface (HEIDI) Tool Includes Section for Rare Diseases

Heidi (Health in Europe: Information and Data Interface) is a recently developed internet-based wiki tool specifically designed for European health information and data. Emerging from two former EC Public Health Program projects (the Eugloreh report and EUPhix), Heidi offers articles and data on health status, diseases, determinants, health systems and policies, trends, institutional and policy aspects, and more.

There is a special section for rare diseases available via the Contents tab. Data can be accessed by employing either search or browse functions. The information contained in Heidi, presented in the form of texts, tables, graphs, charts, and maps, is provided by various health professionals. Experts are called upon to contribute their expertise by becoming editors for Heidi. It is hoped that this new information tool can help develop evidence-based policies to improve the health of Europeans.

Distribution Agreement Between Instrumentation Laboratory and Beckman Coulter Comes to an End

After over 20 years of successful collaboration, Instrumentation Laboratory (Bedford, MA, USA; www.instrumentationlaboratory.com) announced that their Strategic Alliance Cross-Distribution agreement with Beckman Coulter, Inc. (Brea, CA, USA; www.beckmancoulter.com) over their Hemostasis product line will be terminated. Beginning June 23, 2012, Instrumentation Laboratory will initiate 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.

"[Instrumentation Laboratory] has achieved significant growth in Hemostasis, culminating in the attainment of the number one market share position worldwide, thanks to our focus on quality and innovation," said Ramon Benet, CEO, Instrumentation Laboratory. "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."

Instrumentation Laboratories is currently the number one manufacturer of instruments and reagents for the Hemostasis market worldwide. Since the introduction of the first fully automated Hemostasis analyzer in 1985, the ACL 810, the company has continuously introduced hospital and specialty lab products, culminating in the release of the ACL TOP Family of Hemostasis Testing Systems. Along with Hemostasis systems, Instrumentation Laboratory's product lines also include Critical Care and information management systems.

Trovagene and Strand Life Sciences Collaborate on Urine-Based HPV Screening Test

Trovagene, Inc. (San Diego, CA, USA; www.trovagene.com), a developer of transrenal molecular diagnostics, and Strand Life Sciences Pvt Ltd. (Bangalore, India; www.strandls.com), which offers predictive systems modeling, data integration, and context management for research and laboratory professionals, announced they are collaborating on a urine-based *Human Papillomavirus* (HPV) test.

The companies entered into a Memorandum of Understanding (MOU) to license and validate Trovagene's proprietary *Human Papillomavirus* (HPV) urine test and High Risk HPV DNA Assay for clinical diagnostic and screening use in India and countries in the South Asian Association for Regional Cooperation (SAARC).

The companies will assess the accuracy of urine as a specimen for diagnostic purposes, as well as for determining stages of disease progression. If successful, the urine test will serve as a noninvasive alternative to standard cytology and PAP staining tests for the detection of HPV.

Strand Life Sciences also intends to explore and validate the clinical use of HPV DNA testing as a risk indicator and pathological cause of oral cancer in buccal swabs, biopsies, and saliva/sputum specimens.

Ventana to Commercialize Antibody Associated with Cancer Diagnostics

Ventana Medical Systems, Inc. (Ventana; Tucson, AZ, USA; www.ventana.com), a member of the Roche Group, has signed an exclusive license agreement with the German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) and University Hospital Heidelberg (Germany) to commercialize an immunohistochemistry (IHC) primary antibody that detects a mutated protein found in cancer patients.

The antibody, developed by researchers Andreas von Deimling, MD, Hanswalter Zentgraf, PhD, and David Capper, MD, detects the V600E BRAF mutation protein exhibited in many human cancers. It will assist researchers in the diagnosis and prognosis of major cancers including colorectal, thyroid, brain, and non-Hodgkin lymphoma.

The antibody is being developed both as an in vitro diagnostic (IVD) and for research use only (RUO). Ventana, which manufactures instruments and reagents for automating tissue processing and slide staining for cancer diagnostics, is developing the V600E BRAF mutation-specific antibody for IVD use on its Ventana BenchMark series of automated instruments.

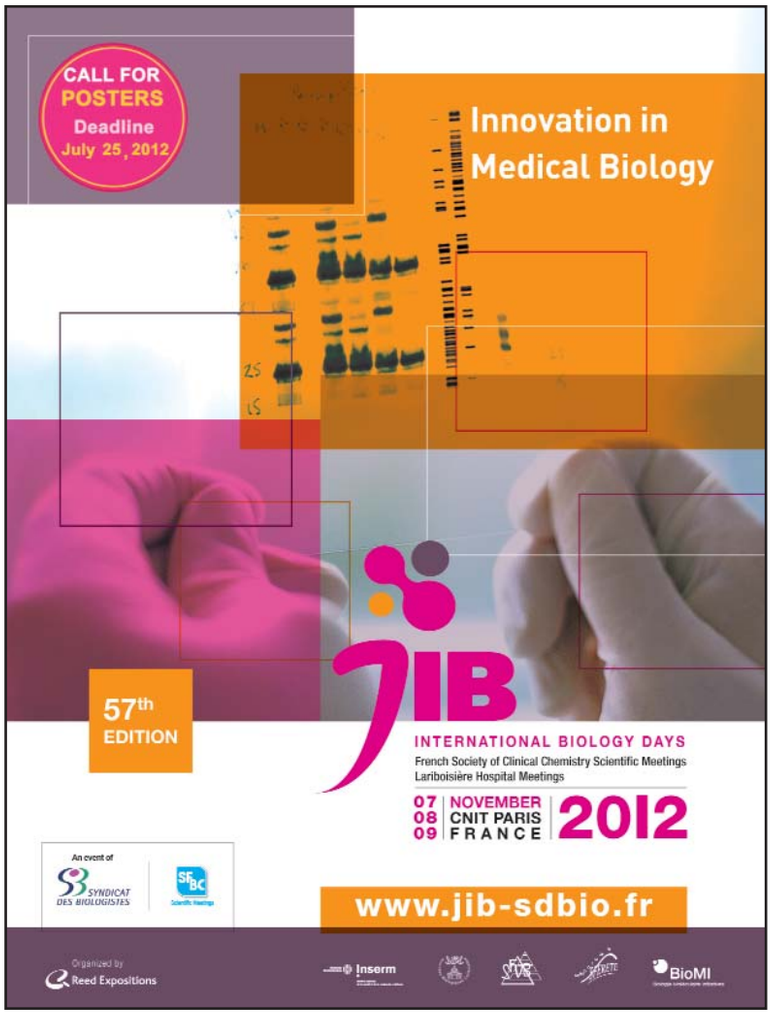
Spring Bioscience (Pleasanton, CA, USA; www.springbio.com), a subsidiary of Ventana, will commercialize a BRAF V600E RUO antibody to support research applications. The new IHC diagnostic will be added to Roche's existing BRAF diagnostics portfolio.

Roche Recognizes Med Fusion as a Molecular Center of Excellence

Roche Diagnostics (Roche; Basel, Switzerland; www.roche.com), has formed an alliance with Med Fusion LLC (Lewisville, Texas, USA; www.medfusionservices.com), an integrated laboratory and clinical trials service organization, designating the company as a Roche Molecular Center of Excellence (MCOE) for the next five years.

Established in 2002, Roche's MCOE program allows noncompeting regional laboratories across the United States to collaborate and capitalize on molecular testing instruments in order to advance test methodologies and technology. As a nationally recognized Roche MCOE, med fusion's molecular diagnostics laboratory will offer healthcare professionals and patients some of the latest and most advanced molecular technologies, including Roche's cobas 4800 BRAF V600 Mutation Test, a companion diagnostic that identifies patients who are eligible for treatment with the ZELBORAF (vemurafenib) drug for inoperable or metastatic melanoma, a deadly form of skin cancer.

Med Fusion is one of 35 labs in the United States and 3 in Texas that have received this accolade. According to Dr. Thomas Lohmann, chief medical officer of Med Fusion, the partnership with Roche will help the company provide healthcare professionals and patients with improved diagnostic services. Roche is an industry leader in pharmaceuticals and diagnostics, providing a broad range of products and services for the early detection, prevention, diagnosis, and treatment of diseases.



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ECI - European Congress of Immunology. Sep 5-8; Glasgow, Scotland; Web: http://eci-glasgow2012.com

Meditic Clinika 2012 – 4rd International Trade Fair for Medical Equipment and Technology. Sep 7-9; Palace grounds, Bengaluru; Web: www.meditec-clinika.com

24th European Congress of Pathology. Sep 8-13; Prague, Czech Republic; Web: www.esp-congress.org

CAP 2012 – The Pathologists' Meeting. Sep 9-12; San Diego, CA, USA; Web: www.cap.org

XIX Jornadas Bioquímicas del Noa. Sep 13-15; Catamarca, Argentina; Web: www.jornadasbioquimicasnoa2012.com

BCLF 2012 - 20th Meeting of the Balkan Clinical Laboratory Federation. Sep 18-22; Belgrade, Serbia; Web: www.bclf2012.org

EQAS 2012 - a 3-day Conference organized by the UK National External Quality Assessment Services for Endocrinology and Cardiac Markers. Sep 24-26; Edinburgh, UK; Web: www.eqas2012.org.uk

24th National Congress of the Turkish Biochemical Society (TBS). Sep 25-28; Konya, Turkey; Web: www.turkbiyokimyadernegi.org.tr

DGKL 2012- 9th Annual Congress of the German Joint Society for Clinical Chemistry and Laboratory Medicine. Sep 26-29; Mannheim, Germany; Web: www.dgkl2012.de/

IX National Congress of the Bulgarian Society of Clinical Laboratory. Sep 27-29; Sofia, Bulgaria; Web: www.aacb.asn.au

6th Santorini Conference Biologie Prospective "Systems Biology and Personalized Health - Science and Translation". Sep 30-Oct 2; Santorini, Greece; Web: www.santorini2012.org

OCTOBER 2012

Clinical Chemistry Conference on "Impact of Biomarkers on Cardiovascular Disease". Oct 1-2; Singapore, Republic of Singapore; Web: www.aacc.org/events

Promoting a Culture of Quality and Consistency in Critical and Point-of-Care Testing. 24th Internat. Oct 3-6; Prague, Czech Republic; Web: www.aacc.org

2nd Conference of the International Francophone Federation of Clinical Biology and Laboratory Medicine (FIFBCML). Oct 4-6; Beirut Lebanon; Web: www.sdbliban.org

ASHI - 38th Annual Meeting of the American Society for Histocompatibility and Immunogenetics. Oct 8-12; San Juan, Puerto rico; Web: www.ashi-hla.org

2nd EFCC- UEMS Congress, Laboratory Medicine at the Clinical Interface. Oct 10-13; Dubrovnik, Croatia; Web: www.dubrovnik2012.com

Analytica China. Oct 16-18; shanghai, China; Web: www.analyticachina.com

Vitamin D: minimum, maximum, optimum. Oct 19-20; Warsaw, Poland; Web: www.ifcc.org

ASRM 2012 - American Society for Reproductive Medicine 68th Annual Meeting. Oct 20-24; San Diego, CA, USA; Web: www.asrm.org

XI Ecuadorian and VII International Congress of Clinical Biochemistry. Oct 23-27; Cuenca, Ecuador; Email: mariapasquelc@yahoo.com

AMP 2012 - Association for Molecular Pathology. Oct 25-27; Long Beach, CA, USA; Web: www.amp.org

NOVEMBER 2012

India Lab Expo 2012. Nov 2-4; Chennai, India; Web: www.indialabexpo.com

ASHG 2012 - Annual Meeting of the American Society of Human Genetics. Nov 6-10; San Francisco, CA, USA; Web: www.ashg.org

JIB 2012 - International Medical Biology Event. Nov 7-9; Paris, France; www.jib-sdbio.fr

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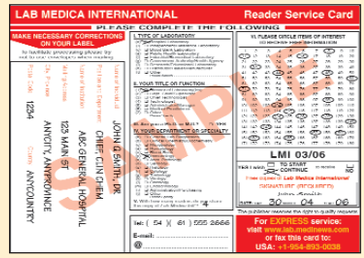

CaliLab 2012, La Fundación Bioquímica Argentina. Nov 7-10; Buenos Aires, Argentina; Web: www.fba.org.ar/calilab/

12th EFCC Continuous Postgraduate Course in Clinical Chemistry: New trends in Classification, Diagnosis and Management of Gastrointestinal Diseases. Nov 10-11; Dubrovnik, Croatia; Web: www.dubrovnik-course.org

Medica 2012. Nov 14-17; Dusseldorf, Germnay; Web: www.medica.de

International Conference of National Strategies for TORCH complex, Chlamydia Trachomatis, and Human. Nov 15-16; Kiev, Ukraine; Web: www.iecclm.org

AACB 50th Annual Scientific Conference of Australasian Association of Clinical Biochemists. Nov 15-18; Melbourne, Australia; Web: www.aacb.asn.au

India Lab Expo 2012. Nov 19-21; Chennai, India; Web: www.indialabexpo.com

DECEMBER 2012

WAO 2012 - World Allergy Organization, International Scientific Conference. Dec 6-9; Hyderabad, India; Web: www.worldallergy.org

JANUARY 2013

SLAS2013. Jan 12-16; Orlando, FL, USA; Web: www.slas2013.org

The Circulating Tumor Cells 2013. Jan 22-23; San Diego, CA, USA; Web: https://selectbiosciences.com

FEBRUARY 2013

2013 AAAAI Annual Meeting. Feb 22-26; San Antonio, TX, USA; Web: www.aaaai.org

MARCH 2013

ABRF 2013: Learning From Biomolecules: The Technology Behind the Story. Mar 2-5; Palm Springs, CA, USA; Web: http://conf.abrf.org

2013 Annual Meeting of the United States & Canadian Academy of Pathology. Mar 2-8; Baltimore, MD, USA; Web: www.uscap.org

Medical Fair India. Mar 8-10; New Delhi, India; Web: www.medica.de

52ND Anniversary Annual Meeting & ToxExpo – Society of Toxicology. Mar 10-14; San Antonio, TX, USA; Web: www.toxicology.org

PITTCON 2013. Mar 17-21; Philadelphia, PA, USA; Web: www.pittcon.org

Society for Endocrinology BES 2013 Meeting. Mar 18-21; Harrogate, UK; Web: www.endocrinology.org

APRIL 2013

58th Annual Meeting of the California Blood Bank Society (CBBS). Apr 23-27; Huntington Beach, CA, USA; Web: www.cbbsweb.org

23rd ECCMID. Apr 27-30; Berlin, Germany; Web: www.congrex.ch/eccmid2013.html

ECE 2013 – 13th European Congress of Endocrinology. Apr 27-May 1; Copenhagen, Denmark; Web: http://congresos.net

MAY 2013

22ND Annual Meeting & Clinical Congress of the American Association of Clinical Endocrinologists (AACE). May 1-5; Phoenix, AZ, USA; Web: www.aace.com/

113th General Meeting of the American Society for Microbiology. May 18-21; Dember. CL, USA; Web: www.asm.org/index.php/meetings/meeting-calendar.html

EuroMedLab 2013 - 20th IFCC-EFCC European Congress of Clinical Chemistry and Laboratory Medicine. May 19-23; Milano, Italy. Web: www.milan2013.org

Hospitalar 2013. May 21-24; Sao Paulo, Brazil; Web: www.hospitalar.com

JUNE 2013

European Human Genetics Conference 2013. Jun 8-11; Paris, France; Web: www.eshg.org

The International Society for Stem Cell Research (ISSCR). Jun 12-15; Boston, MA, USA; Web: www.global-cc-alliance.com

JULY 2013

AACC 2013 - Annual Meeting of the American Association for Clinical Chemistry. Jul 28-Aug 1; Houston, TX, USA; Web: www.aacc.org

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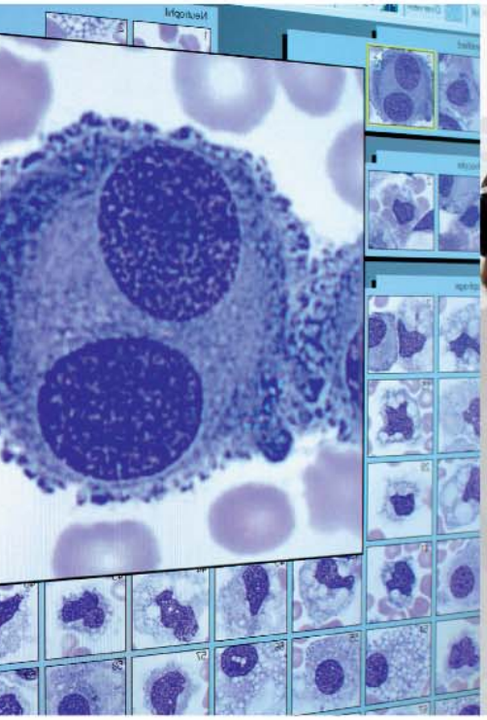

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