

GEN Clinical Research & Diagnostics

Changing the Face of Clinical Medicine

Novel Technologies Take Aim at the Astronomical Cost of Healthcare

K. John Morrow Jr., Ph.D.

The annual "American Association of Clinical Chemistry" meeting is the largest conference focusing on the needs of the clinical laboratory. This year the meeting expositions and presentations prominently featured multiplexing technologies and new strategies for developing biomarkers.

Hycor, a division of Agilent Technologies (www.agilent.com), offers allergy testing as an aid to diagnosing and treating allergic disease. "Allergic disorders are predicted to worsen as this century moves forward, due to modern living conditions and the swift industrialization of developing nations, adding to the current worldwide incidence of 400 million with allergic rhinitis and 300 million with asthma," said Mark Van Cleve, Ph.D., applications development manager.

The company offers allergy-evaluation systems, including a broad menu of allergy tests aimed at insects, animals, food, and occupational and environmental allergens, as well as autoimmune testing. The tests, which screen for allergen-specific IgE, have been cleared by the FDA for

quantitative detection.

The platform is based on Hycor's activated cellulose solid-phase technology and has demonstrated equivalence to the fluorescence-enzyme immunoassay. The portfolio includes an inventory of allergy tests which can be run on the Ultra-Sensitive EIA System and the Hytec 288 Plus system, which can handle a half million tests per year.

"This platform offers full walk-away automation for allergy testing," stated Dr. Van Cleve. "This highly sensitive technology offers clear benefits over the classic pin-prick allergy testing." He also stressed that, in addition to the improved sensitivity, there is a major improvement in patient safety. "When patients are inoculated with potential antigens in the traditional testing for allergens, there is always a risk of anaphylactic shock, which in its most extreme manifestation can lead to death," he added.

Hycor manufactures and markets allergy and autoimmune testing products widely used in clinical laboratories. The company also produces Kova urinalysis products that help standardize procedures to improve laboratory safety. "The company's move into an ultrasensitive, fully automat-



Water's Acquity UPLC (left) and TQD mass detector (right) are used to perform immuno-suppressant drug analyses with the firm's new Mass-Trak Immuno-suppressants XE RUO Kit.

ed allergy-testing system takes us into a place in the market where we haven't been," Dr. Van Cleve commented.

Immune Response

Invitrogen (www.invitrogen.com), a division of Life Technologies (www.lifetechnologies.com), announced the global availability of the PlexMark™ 3 renal biomarker panel assay, a new biomarker tool for use in preclinical kidney function research.

It is expected to assist in the development of more effective methods to monitor kidney health in transplantation protocols.

This new assay provides researchers with an alternative to the invasive and expensive biopsy procedure by measuring levels of cytokines, chemokines, and receptor levels in urine as proxies for monitoring immune function and response.

The PlexMark assay uses Luminex (www.luminexcorp.com) xMAP® multiplexing technology for bioassay analysis, while the biomarkers in the panel are licensed from Renovar (www.renovar.com).

Globally, more than 30,000 persons receive kidney transplants each year. These recipients must contend with the intrinsic rejection mechanism triggered by the graft and the cumulative cell and tissue damage caused by the immunosuppressive drugs. Given that kidney damage may already be advanced by the time a biopsy is performed, utilizing urine biomarkers and tracking therapies early in the course of rejection are essential for improving care for transplant patients.

Invitrogen also offers Dynabeads for in vitro diagnostic assays. These uniform magnetic beads are employed for a range of applications and are manufactured according to relevant regulatory requirements. The monodispersity and superparamagnetism of the Dynabeads allows optimal behavior in automated systems, according to Traci Moritz, senior manager for business development at Life Technologies. "Our experience with this technology has enabled us to build in lot-to-lot consistency in the broad range of the Dynabead product line," she said.

New product introductions include the MyOne product line, which employs a one-micron bead providing increased sur-

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News Molecular Diagnostics

MP Biomedical Gains Rights to Alzheimer's Blood Test

MP Biomedical (www.mpbio.com) obtained an exclusive, worldwide license to commercialize an Alzheimer's diagnostic based on discoveries made at the University of California, Los Angeles (UCLA). The UCLA team reported in May that they found a way to measure the amount of amyloid beta that is absorbed by immune cells in the blood. They suggested that if the immune system isn't adequately clearing amyloid beta, it may indicate Alzheimer's risk.

Genentech and Dako Collaborate on Companion Diagnostic for Herceptin

Genentech (www.gene.com) is collaborating with Dako (www.dako.com) on U.S. regulatory submissions of the latter's HercepTest™ and HER2 FISH pharmDx™ as companion diagnostics for Herceptin® in patients with advanced HER2-positive gastric cancer.

Herceptin is not yet licensed in the U.S. for the treatment of stomach cancer, but

in May the company reported positive data from the Phase III trial in this patient population.

Arup Licenses Epigenomics' mSEPT9 Biomarker to Develop Colorectal Cancer Test

Epigenomics (www.epigenomics.com) inked a nonexclusive licensing deal covering mSEPT9 (septin 9 DNA) biomarker with Arup Laboratories (www.aruplab.com). Arup will use the biomarker for the development and commercialization of a molecular-based laboratory test to help in the diagnosis of colorectal cancer from patients' blood samples.

Arup is the second company to license mSEPT9 for a molecular blood diagnostic for colorectal cancer. In February 2008 Epigenomics licensed the biomarker to Quest Diagnostics for development of a reference laboratory test in the U.S.

Rosetta Taps Warnex as Canadian Distributor

Warnex Medical Laboratories signed an exclusive distribution agreement in Canada

for three currently available tests from Rosetta Genomics (www.rosettagenomics.com). Samples will be sent from Canada to Rosetta Genomics' Philadelphia-based CLIA-certified laboratory for analysis.

Warnex will distribute miRview™ mets, which identifies the primary tumor site in patients presenting with metastatic cancer and those with cancer of unknown primary. miRview™ squamous, which differentiates squamous from nonsquamous, non-small-cell-lung cancer, is also included in the agreement. Finally, Warnex will distribute miRview™ meso, which distinguishes mesothelioma from other carcinomas in the lung.

Celera Partners with Aurora Health Care for Cardio Genetics

Celera (www.celera.com) is teaming up with Aurora Health Care to integrate genetic testing aimed at optimizing heart care for patients. Aurora and Celera have also agreed to research areas of mutual interest to validate additional genetic markers for cardiovascular disease risk and treatment.



Genetic
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News

Presents

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December 2–3, 2009
Sheraton Society Hill Hotel
Philadelphia

Meeting Schedule

December 2, 2009

7:00-9:00am	Continental Breakfast in Exhibit Hall
8:00-9:50am	Keynote—Lean and Green: Sustainability in Process R&D and Manufacturing <i>Tina Larson, Ph.D., Genentech</i>
9:50-11:25am	Achieving Higher Cell Densities in Disposable Bioreactors Through Energy-Intensive Techniques <i>Alvin W. Nienow, Ph.D., D.Sc., University of Birmingham</i>
9:25-10:00am	Bioprocessing title TBA <i>David Wood, Ph.D., Ohio State University</i>
10:00-10:55am	The Impact of Single-Use Systems (Disposables) on Cleaning Materials, Cost of Goods, and the Environment—A Case Study Involving mAb Production <i>Demetri Petrides, Intelligen</i>
10:35-11:05am	Networking Break in Exhibit Hall
11:05-11:40am	Water/Buffer Savings During Polishing Steps Based on Disposable Membrane Chromatography <i>Uwe Gottschalk, Ph.D., Sartorius Stedim Biotech</i>
11:40-12:10pm	Environmental Footprint and Sustainability of Bioprocesses <i>Beth Junker, Ph.D., Merck</i>
12:15-1:45pm	Lunch in Exhibit Hall
1:45-2:45pm	Roundtable: The Role of Sustainability in Biopharmaceutical Manufacturing Process and Facility Design <i>Panel of 4 moderated by Tina Larson, Ph.D., Genentech</i>
2:45-3:20pm	Balancing Sustainable Goals, Energy Use, and Budgets During Design of Biotech Lab Facilities <i>Paul Todd Merrill, Claysco</i>
3:20-3:55pm	Operational Cost-Saving Techniques Through Sub-2-Micron HPLC Column Technology Laboratories Track <i>Jeff Mazzeo, Waters</i>
3:55-4:30pm	Solvent-Sparing Techniques in Chromatography <i>Helmut Schulenberg-Schell, Agilent Technologies</i>
4:30-5:00pm	Networking Break in Exhibit Hall
5:00-5:35pm	Sustainable Procurement: Transforming Green Ideals into Smart Business Practices <i>Tom Russell, SciQuest</i>

December 3, 2009

7:00-9:00am	Continental Breakfast in Exhibit Hall
8:00-9:50am	Keynote—Disposable Biotechnology: The Time Has Arrived <i>Govind Rao, Ph.D., University of Maryland</i>
8:50-9:25am	Sustainable Design and Build for Biopharmaceutical Facilities <i>Mark Butler, IPS</i>
9:25-10:00am	Issues and Challenges for Facilities Managers in the Life Sciences <i>David P. Kaye, Facilities Management Solutions</i>
10:00-10:35am	Large Energy Reductions in Biopharmaceutical Facilities: Project Views <i>David Newman, Millipore</i>
10:35-11:05am	Networking Break in Exhibit Hall
11:05-11:40am	How Green Is Your Plant? Reducing the Carbon Footprint of Your Operations <i>Peter K. Walter, Ph.D., Hyde-Engineering + Consulting</i>
11:40-12:15pm	Bioprocessing title TBA <i>Cytovance Biologics</i>
12:15-1:45pm	Lunch in Exhibit Hall
1:45-2:20pm	Biocatalysis at Merck: An Enabling Green Technology <i>Gregory Hughes, Merck</i>
2:20-3:55pm	Adaptable Bioprocesses to Prepare Chiral Pharmaceutical Intermediates and Biopharmaceuticals <i>Ian Hotheringham, Ph.D., IIC Bio/Ingenza</i>
3:55-4:25pm	Networking Break in Exhibit Hall
4:25-4:50pm	Bioprocessing title TBA <i>Robert DiCosimo, DuPont</i>
4:50-5:25pm	Bioprocessing title TBA <i>Jon Stewart, U. Florida, Gainesville</i>



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Clinical Medicine

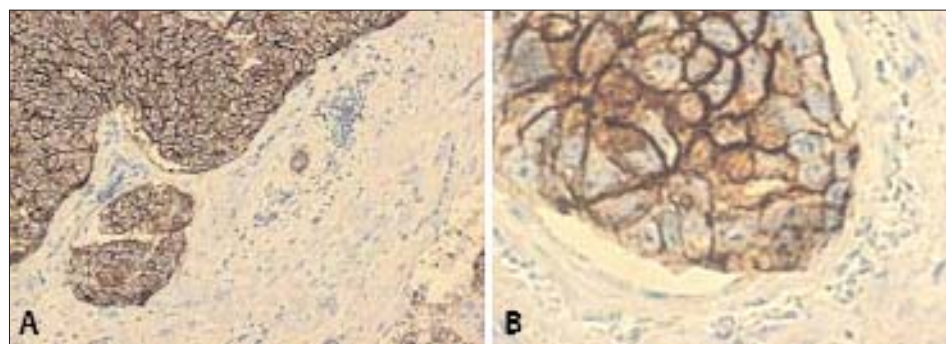
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face area, as well as Dynabeads Silane for use in molecular diagnostics. The scalability of the beads lends them to automation, noted Moritz.

New Kits Speed Mass Spec

Waters (www.waters.com) has addressed the demand for measuring levels of a whole family of immunosuppressive drugs, whose use has greatly expanded in recent years. According to Mark Bruns, Ph.D., senior

director for the clinical business operation, the company has introduced a new product for quantitative measurement of tacrolimus, sirolimus, everolimus, and Cyclosporin A. Known as the Waters® MassTrak™ Immunosuppressants XE RUO (Research Use Only) Kit, it provides laboratories an alternative to immunoassay test kits for research laboratory analyses. Included in the kit are reagents, internal standards, and an analytical column for performing up to



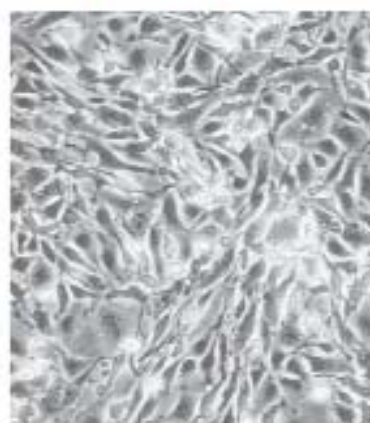
Dako's HercepTest is used for determination of HER2 protein overexpression. Assay performed according to manufacturer with sections from mirrored samples of HIBC of the human breast, treated with PAXgene Tissue from PreAnalytiX: x100 (A), x400 (B).

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Using a unique assay design, the HyCor Ultra-Sensitive EIA System from Agilent Technologies provides quantitative specific IgE detection with testing capacity sized for moderate- to higher-volume labs.

500 determinations per kit.

Dr. Bruns stated that the kit performs well in the presence of drug metabolites and addresses some of the analytical weaknesses of immunoassay technology. Currently, FDA-approved clinical tests include a kit to quantify the immunosuppressant tacrolimus in kidney and liver transplant patients by liquid chromatography-mass spectrometry (LC/MS/MS).

Vitamin D deficiency has received much attention in the scientific and lay press in recent years. Associations with an increased risk of osteoporosis, heart disease, diabetes, and other maladies have driven a 90% increase in testing for this condition since 2007. Whereas the mechanisms of the vitamin D protective effects are complex and not completely understood, one overriding explanation resides in the fact that it is a potent inhibitor of the proinflammatory response and slows the turnover of leukocytes.

A National Health and Nutrition Examination Survey caused researchers to conclude that low levels of vitamin D were associated with a generalized increase in mortality. Among many factors that may be responsible for vitamin D's apparent beneficial effect on all-cause mortality is its effect on telomeres and its potential effect on slowing aging.

Waters offers a new MassTrak system platform optimized for 25-Hydroxyvitamin D analysis for clinical research laboratories featuring a robotic liquid-handling system and Waters' Acquity TQD System for high-throughput measurement of total 25-Hydroxyvitamin, as well as 25-Hydroxyvitamin D2 and D3. The platform is

streamlined by a solid-phase extraction sample preparation step that minimizes solvent usage.

Another MassTrak product, the Amino Acid Analysis Solution, is offered as a comprehensive research tool for the analysis of physiological amino acids in urine and plasma. This product incorporates a Waters' Acquity UPLC system with pre-packaged reagents and consumables, for application in the clinical research laboratory. The platform permits the analysis of amino acids in approximately one-third the time of traditional amino-acid analysis, Dr. Bruns said.

Finally, in the realm of clinical toxicology, LC/MS/MS is now widely used in confirmation analysis, due to its greatly simplified pretreatment requirements. At the meeting, Waters exhibited the Acquity UPLC system and tandem mass spectrometry products for the research and clinical laboratory, with many facilities using the technique for a variety of applications including toxicology, therapeutic drug monitoring, and endocrinology.

Real-Time PCR with FDA Approval

Applied Biosystems (www.appliedbiosystems.com), also a division of Life Technologies, presented the 7500 Fast Dx Real-Time PCR Instrument, a flexible, medium-throughput device, designed to facilitate assay development on an in vitro diagnostic platform.

The instrument is devised to meet current health challenges to the identification of influenza strains, especially the strain associated with the recent outbreak of the H1N1 virus (swine flu), according to a Life Technologies official. The FDA has authorized the emergency use of a new CDC rRT-PCR detection panel for the swine flu with instructions that the assay be performed on an Applied Biosystems 7500 instrument.

The company has formed a special 24/7 task force to coordinate the company-wide response to requests for assistance with the outbreak. The task force provides health agencies with support, including instrument training, supply chain management, and monitoring regulatory compliance. The company has also accelerated the manufacture of components that will be used by laboratories to test for and identify influenza.

Other products of relevance to management of a possible H1N1 outbreak include the MagMAX™ viral RNA isolation kits, the SuperScript® III Platinum® One-Step qRT-PCR kit, TaqMan® influenza A detection kit, and several different capillary electrophoresis systems for determining the base-by-base sequence of viral samples.

Last September, the 7500 Fast Dx instrument received 510(k) clearance from the FDA for use with the CDC Human Influenza Virus Detection and Characterization Panel (rRT-PCR Flu Panel). Both products are required to be used together as a system for the detection of influenza.

Stabilizing Tissues

"Tissue over- and underfixing, crosslinking of biomolecules and lack of standardi-

zation can lead to loss of morphology and poor quality histological preparations," according to Lynne Rainen, Ph.D., scientific director at PreAnalytiX (www.preanalytix.com), a Qiagen/BD company. Dr. Rainen discussed her company's PAXgene tissue system, which is designed to overcome the drawbacks of conventional tissues processing.

The PAXgene tissue system's first step involves the use of a special container for

fixation and stabilization of the tissues under a standardized set of conditions. This allows the formalin-free preservation of nucleic acids along with the histomorphology of the tissues. Dr. Rainen argues that there are marked advantages to her company's technology.

"It provides details of the histology comparable to classic H&E staining, it is compatible with immunohistochemical applications, it preserves DNA for PCR-based appli-

cations, and it allows purification of all nucleic acids from one sample," she said.

Whereas standard fixation technologies may allow PCR amplification to take place, the company's studies have shown much better PCR response with the PAXgene system, Dr. Rainen noted. She said that the system is particularly effective at copurification of small RNAs.

"The excellent preservation of RNA sam-

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Molecular Diagnostics

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ing things back.” He added that pharmaceutical companies are focusing on companion diagnostics, “a new area that will help them refine and optimize drug sales.”

Bunger believes diagnostics will be pushed to the forefront with more emphasis on early and better testing, especially now with Dr. Francis Collins’ recent appointment as NIH director. “I think the field is poised for a great future,” noted Bunger.

He’s not alone in that assessment: the global market is estimated to reach \$6.35 billion by 2015 according to Global Industry Analysts.

The push to commercialize simple and cost-effective molecular tests for second-tier clinical labs is the incentive behind BioHelix’ (www.biohelix.com) IsoAmp® assays. “Our mission is to improve the quality of healthcare through development of simple molecular diagnostic tests for the near-patient setting, where rapid solutions are necessary for prompt medical intervention,” stated Huimin Kong, Ph.D., CSO. By combining its isothermal helicase-dependent amplification technology with an instrument-free detection device, these assays fulfill the company’s objective.

“Currently, only top-tier clinical labs (approximately 600 in the U.S.) perform molecular diagnostic tests, while there are about 5,000 to 6,000 second-tier labs that don’t due to high costs and complexity,” Dr. Kong explained. The IsoAmp Molecular Analyzer platform is targeted at these labs. With this product, a helicase enzyme unwinds DNA into single strands, eliminating the need for a thermocycler and providing a method for assay development, Dr. King said.

Amplicon detection is achieved via the BEST™ (biohelix express strip) cassette. This is an enclosed, disposable cassette that is cross-contamination proof, and available to detect a single amplicon (type I) or two amplicons (type II), reported Dr. Kong. Results are available in about ten minutes versus having a test done at a reference lab, which can take a few days, he added. “There is a need for conducting molecular diagnostics in near-patient settings or ultimately at the point of care.”

The company’s lead IsoAmp assay is for MRSA and is in beta testing. Additional assays in development include: *Staphylococcus aureus*, *Clostridium difficile*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, herpes simplex virus, and HIV (funded by NIH). The assay can also be used to detect genetic mutations such as SNPs that cause Factor V Leiden thrombophilia, Dr. Kong noted.

Prostate Cancer

Although high levels of prostate-specific antigen (PSA) can provide evidence of cancer, its use as a screening tool is controversial as normal prostate cells also shed this antigen into the blood. Prostate cancer gene 3 (PCA3) is being touted as a promising biomarker for prostate cancer. Gen-Probe (www.gen-probe.com) has developed a PCA3 test that is currently on the market in Europe, initial clinical trials are set to start this quarter in the U.S.

According to the company, this first-generation test is semiautomated and semi-quantitative and provides good clinical data. An endpoint assay, the PCA3 test uses chemiluminescence via the company’s

hybrid-protection assay technology. A specific DNA probe hybridizes with a nucleic-acid target to emit a chemiluminescent signal. This is followed by target capture and amplification.

A prototype of the second generation of this assay is being developed as a real-time assay, combining amplification and detection in one step. “You can measure the kinetics of the reaction and that’s how quantitation is achieved,” said Norman Nelson, Ph.D., director of biochemistry. Fluorescence also allows measuring multiple signals in one tube. It’s amenable to the types of probes needed with real-time assays.

“These are typically self-reporting probes, which are homogenous in that the fluorescence is quenched in a molecule with a stem-loop structure in the absence of target, but is unquenched in the presence of target.”

The multiplex format is more convenient, uses less reagent, and provides faster results, Dr. Nelson reported, adding that the biggest challenge when multiplexing nucleic acids is interference between oligonucleotides needed to build the test. “We solved this with a universal tag approach that’s unique to our methodology that makes amplification cleaner, with less interference.”



BioHelix’ IsoAmp Molecular Analyzer is an instrument-free molecular diagnostic platform for IsoAmp assays. It consists of isothermal nucleic acid amplification technology and a disposable detection device called the BEST™ Cassette.

This technology has the potential for use in other cancers and disease areas, as well as in other markets driven by nucleic acid molecular testing, Dr. Nelson said. “These tests are all about oligos, and that’s one of the things that’s so powerful about DNA chemistry—it’s exquisitely precise and to make it work for you, you have to design it properly.”

Collaborating with researchers at the University of Michigan, Metabolon (www.metabolon.com) has discovered a number of markers indicative of the aggressiveness of prostate cancer and involved in the transition of noninvasive cancer to invasive.

“One of these compounds is sarcosine, a small molecule that is a methyl glycine,” explained John Ryals, Ph.D., CEO. “Glycine is used within cells to monitor or buffer levels of ethyl-densyl methionine, the methyl donor for methylation of DNA and other methylation reactions. When that goes too high, glycine is converted to sarcosine, which is mechanistically involved in this transition”.

Researchers have found that sarcosine levels are substantially increased during progression to metastasis. This small molecule, and several other discovered markers, can be detected in urine to differentiate aggressive versus nonaggressive cancers. “That’s the holy grail of prostate cancer, because most prostate cancers are not aggressive and won’t metastasize,” added Dr. Ryals.

The company has a platform built around its Metabolizer™ data processor, which converts raw mass spec data into biomarker data. The biggest challenge in developing biomarkers, said Dr. Ryals, is obtaining source samples from existing studies. “Most of the time the studies aren’t designed in ways most efficient for discovering biomarkers, so you’re always trying

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to bridge an existing study to get the markers you want. In addition, banked samples are not always taken and stored the same way, causing large variation in analysis.”

Membranes for Plasma Separation

A new polymeric, 3-D membrane developed by **Pall Life Sciences** (www.pall.com) provides one-step plasma separation from whole blood for use in downstream diagnostic assays. The asymmetric structure of the membrane captures cellular components without lysis. This is in contrast to the standard membrane (glass fiber), which often shears cells, leading to contamination. “Our membrane works with small volumes of blood [from 5 to 100 microliters] but results in full plasma recovery,” stated Galina Fomovska,

Ph.D., senior principal scientist, molecular media R&D.

The membrane is available in three different grades, each optimized for various usage conditions, Dr. Fomovska said. GF is not treated and is for small blood applications, like finger sticks in microfluidic and lateral flow point-of-care devices. GX has low post-treatment to help minimize hemolysis and is also compatible with electrochemical analyte detection (good for up to 30 microliters). GR is for larger blood applications (up to 50 microliters) such as lateral flow immunochromatographic devices.

“We provide this separation membrane to people who are developing diagnostics—it’s designed for point-of-care use. We’re looking to move dependency away from the central lab and integrate our materials into a format that will allow testing for different analytes without having to centrifuge the plasma,” said Dr. Fomovska. She added that it is a “broad, universal enabler” that would also be of benefit for personalized medicine (e.g., glucose testing).

Drug-Induced Toxicity Biomarkers

Drug-induced toxicity is currently measured by histopathology and blood tests, and the time lag for clinical diagnosis is problematic. Researchers at **Compugen** (www.cgen.com) have developed a method to discover genetic biomarker signatures to predict the occurrence of drug-induced renal toxicity before it is detected by clinical

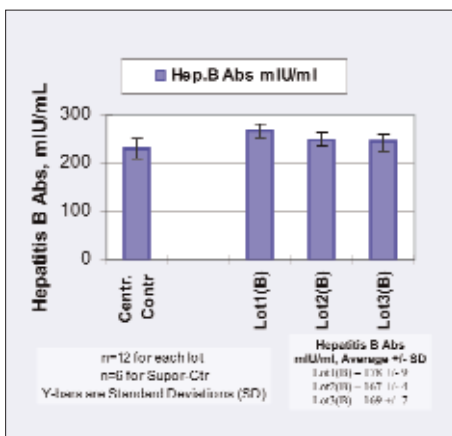
chemistry, offering an opportunity for early prediction.

Animal studies using rats treated with well-known renal toxins found a subset of four to six genes that were selected as a biomarker signature, indicating nephrotoxicity at day five. The four biomarker combination identified the nephrotoxic drugs following a one- to five-day exposure period, as opposed to a typical 28-day diagnostic timeline, according to the company. In addition, Compugen scientists reported that the biomarker combination successfully predicted the relative levels of toxicity of the compounds tested.

“These results represent the first applica-

tion of Compugen’s drug-induced toxicity biomarker discovery platform, which incorporates our rat-related predictive transcriptome and proteome,” explained Merav Beiman, Ph.D., head of molecular biology. He added that this database is substantially different in that the modeling of alternative splicing adds a large number of novel proteins and improves the quality of sequence prediction, contributing to the company’s ability to predict disease-related markers.

The platform is designed so that various components can be modified in order to use it for the discovery of novel preclinical biomarkers for other tissue toxicities such as cardio- or hepatotoxicities. **GEN**



Pall Life Sciences’ Vivid™ Plasma Separation Membrane GF can be used for hepatitis B antibody recovery from whole blood.

Clinical Medicine

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ples means that the system can be used for quantitative downstream measurements of message content in tissues, enabling molecular pathology testing at a level of accuracy not previously attainable,” Dr. Rainen concluded.

Nucleic-Acid Amplification

“Our one-step nucleic-acid amplification technology provides a rapid intraoperative method for assessing metastasis in breast cancer patients,” said Vishal Sikri, marketing manager for life sciences at **Sysmex America** (www.sysmex.com).

During cancer surgery lymph nodes may be sampled and metastases diagnosed through classical intraoperative methods (frozen section and imprint cytology). However, these types of intraoperative procedures may have a false-negative rate as high as 52%, based on peer-reviewed studies. In studies from Europe and Japan, a one-step nucleic-acid amplification technology has been applied in which multiple mRNA markers are measured.

The amplification step, known as RT-LAMP (loop-mediated isothermal amplification), is an isothermic nucleic-acid amplification technology that is thoroughly documented in the peer-reviewed literature. It can yield results in as little as 30 to 40 min-

utes, making it suitable for use in cancer surgery. Because it allows for a semiquantitative estimate of cancer-related genes, it is less subjective than the traditional methods of deciding degrees of malignancy.

Some of these markers, such as CK19 (cytokeratin 19), were greatly overexpressed in malignant lymph nodes, so much so that there was no overlap with the profiles of normal lymph nodes.

“The technology has been in clinical use in Europe for 2–3 years and in Japan for the last year,” Sikri stated. “It is currently not available for clinical use in the U.S.”

Rapid advances in clinical diagnostics are adding to a large portfolio of molecular applications. Faster, easier, and more accurate than technologies in place for years, the new face of clinical medicine promises to be cheaper and more user friendly.

Some, such as the serum-based assessment of allergic reactions, are safer and more accurate, whereas others, in the LAMP technology, are much faster and more accurate.

At a time when a noisy debate is in progress on the astronomical cost of healthcare, the new face of clinical medicine will provide better, more efficient healthcare at a more manageable price. **GEN**

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