
DIAGNOSTICS & IMAGING WEEK

THE WEEKLY DIAGNOSTICS TECHNOLOGY NEWSPAPER

THURSDAY, AUGUST 7, 2008

VOL. 11, No. 32

PAGE 1 OF 12

FDA clears Pathwork test that better identifies type of tumor

By OMAR FORD

Diagnosics & Imaging Week Staff Writer

A test developed by **Pathwork Diagnostics** (Sunnyvale, California) that can help healthcare professionals determine what specific type of cancer cells are present in a malignant tumor has been cleared by the FDA.

The Pathwork Tissue of Origin Test uses a microarray to measure the expression pattern, comprising more than 1,500 genes, in the uncertain tumor and compares it to expression patterns of a panel of 15 known tumor types, representing 60 morphologies overall to help determine the tumor's origin.

"It took three years to develop the test," David Craford, VP of Commercial Operations for Pathwork told *Diagnosics & Imaging Week*. "This test represents a real milestone for expression-based molecular diagnostics. The feedback we've gotten is positive, and oncologists have
See Pathwork, Page 8

Watchful waiting preferable to intervention

Group urges against prostate cancer screening in older men

By AMANDA PEDERSEN

Diagnosics & Imaging Week Staff Writer

Sometimes a cure can have effects worse than the disease – and have faster, even deadlier, effect.

A prominent case in point: Men 75 or older should not be screened for prostate cancer, according to the U.S. Preventative Services Task Force (USPSTF), because there is evidence of more harm than benefit from carrying out this procedure and providing therapy based on a positive diagnosis.

The task force made this recommendation early this week, saying it is based on evidence that the benefits of prostate cancer treatment are "small to none" in older men.

Also, the group found that treatment based on routine screening causes "moderate-to-substantial" harm to men of all ages, such as erectile dysfunction, urinary incontinence,
See PSA, Page 9

Bureaucracy, corruption are a problem for diag firms

By MARK McCARTY

Diagnosics & Imaging Week Washington Editor

WASHINGTON – One of the sessions held at this year's annual meeting of the **American Association for Clinical Chemistry** (AACC; Washington), had more the feel of the symposium of old, with considerable audience participation.

The session, titled "Diagnostics for Disease Control in Developing Countries," was led by Mark Perkins, PhD, chief scientific officer with the **Foundation for Innovative New Diagnostics** (FIND; Geneva, Switzerland), led the discussion.

Perkins said FIND was launched by the **World Health Organization** (WHO; also Geneva) five years ago and "was established in order to run like a small company so it had the speed of a small company," giving it "the ability to make things happen." At its web site, FIND describes itself as "dedicated to the development of rapid, accurate and affordable diagnostic tests through public-private partnerships."
See AACC, Page 10

ThromboVision files for 510(k) okay of its T-Guide platelet test

By AMANDA PEDERSEN

Diagnosics & Imaging Week Staff Writer

A device that uses light-scattering technology to determine platelet aggregation in cardiac patients is now heading out to make its way through the regulatory process.

With its clinical trials of ThromboGuide (T-Guide) platelet aggregation system completed, **ThromboVision** (Houston), a diagnostics company, said it has filed a 510(k) application with the FDA for clearance of the system.

The T-Guide consists of a disposable test kit and a point-of-care base unit. According to ThromboVision, the system is designed to help physicians improve their cardiac patients' lives by providing additional information as they assess an individual patient's anti-platelet therapy used to prevent heart attacks, strokes and stent occlusions.

"In layman's terms, it allows us to measure the level of stickiness of platelets," Edward Teitel, MD, president/CEO of ThromboVision, told *Diagnosics & Imaging Week*.

Last year the company was awarded \$1.5 million from
See ThromboVision, Page 11

INSIDE: ADVISORY COMMITTEE MEMBERS' INTEREST CAPPED OUT AT \$50K.....2
NHS PROVIDES £10M TO FORM 3 NEW BIOMEDICAL RESEARCH UNITS.....3



To subscribe, please call DIAGNOSTICS & IMAGING WEEK™ Customer Service at (800) 688-2421; outside the U.S. and Canada, call (404) 262-5476.

Copyright © 2008 AHC Media LLC. Reproduction is strictly prohibited.

*Washington roundup***Advisory committee members' interest capped out at \$50K**By **MARK McCARTY****Diagnosics & Imaging Week Washington Editor**

WASHINGTON – The increased scrutiny of FDA advisory committees has the agency jumping to appease its many critics, and the agency held a conference call Monday to announce a set of guidelines to govern the appointment of advisory committee members. However, the voting process was also revised to address some concerns about how votes might be influenced.

Randall Lutter, PhD, the agency's associate commissioner for policy and planning, said on the call "we're announcing a package of improvements designed to enhance decision-making capability." Among the minor improvements is a faster posting of briefing materials he said would allow Internet viewers to find those materials "in two clicks, as opposed to the eight clicks you used to need." The advisory committee portion of the FDA site now has its own page, with only one click needed to find the calendar for advisory committee meetings.

The new voting procedure essentially calls for all panelists to vote simultaneously on approvability, conditions of approvability and so on. This is not an uncommon practice at present and FDA does not propose an electronic voting regime, but some of the agency's critics have cited sequential voting as an area of concern due to the potential for bias induced by more assertive members of a panel.

The guidances also include a set of rules to determine under what conditions an advisory committee should meet. According to Lutter, the guidance in question poses three questions, but the second requirement hints at what many have suspected about such meetings. This requirement states that a meeting will take place if the matter at hand is "so controversial that it would be highly beneficial to obtain the advice of an advisory committee."

Much of the impetus behind this move is that some advisory committees – perhaps most conspicuously the circulatory systems advisory committee – have been called upon numerous times, making life for panel members complicated.

Jill Warner, a policy analyst at the Office of Policy and Planning, said during the conference call, "the guidance on waiver . . . incorporates changes from public comments." She noted that FDA is "putting a cap of \$50,000 on personal financial interest," but candidates whose interests fall under that number must still be vetted.

Whether the new standards will create recruitment headaches is difficult to say, but Warner said "we certainly see recruitment . . . as an important goal and have stepped up recruitment to a significant degree." She said FDA has contacted 280 professional organizations for nominations to the various committees and has posted announcements in the *Federal Register* to further boost recruitment. "We've received 350 CVs [curricula vitae] at this point" as a result, she said.

As for how to deal with situations in which the panel might not have enough members present to constitute a voting quorum, Michael Orthwerth, PhD, director of the advisory committee on oversight and management staff at FDA, said that a quorum is achieved with the presence of one person more than half the standard membership, but "we can augment with special government employee members," so it's not an issue.

CMS proposes alternate quality test for labs

Clinical lab operators are sometimes no more happy than those making medical devices about the regulatory burden imposed by FDA and CMS, although those burdens are substantially different. So when the director of the division of lab services at the Centers for Medicare & Medicaid Services told attendees at this week's annual meeting of the **American Association for Clinical Chemistry** (Washington) that the agency would rethink its expecta-

See Washington, Page 11

DIAGNOSTICS & IMAGING WEEK™ (ISSN 1932-7757) is published weekly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BBI® and DIAGNOSTICS & IMAGING WEEK™ are trademarks of AHC Media LLC, a Thompson Publishing Group company. Copyright © 2008 AHC Media LLC. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media LLC.

ATLANTA NEWSROOM: Executive Editor: **Jim Stommen**. Managing Editor: **Holland Johnson**. National Editor: **Don Long**. Washington Editor: **Mark McCarty**. Staff Writers: **Omar Ford**, **Amanda Pedersen** and **Lynn Yoffee**. Senior Production Editor: **Rob Kimball**.

BUSINESS OFFICE: Senior Vice President: **Donald R. Johnston**. Senior Marketing Product Manager: **Chris Walker**. Marketing Coordinator: **Sonia Blanco**. Account Representatives: **Bob Sobel**, **Chris Wiley**.

REPRINTS: For photocopy rights or reprints, please call **Stephen Vance** at (404) 262-5511 or e-mail him at stephen.vance@ahcmedia.com.

SUBSCRIBER INFORMATION
Please call (800) 688-2421 to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call (404) 262-5476. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

EDITORIAL
Don Long, (404) 262-5539
Fax: (404) 814-0759

SVP/GROUP PUBLISHER
Donald R. Johnston, (404) 262-5439

INTERNET
www.ahcmedia.com

 **AHC Media LLC**

*International report***NHS provides £10 million to form 3 new biomedical research units****A *Diagnosics & Imaging Week* Staff Report**

The National Health Service in the UK has reported the formation of three new biomedical research units which it said will be at the forefront of a £10 million drive to prevent, diagnose and treat illnesses such as heart disease, asthma and obesity.

The new National Institute for Health Research (NIHR) biomedical research units – to be located in Liverpool, London and Nottingham – will focus on “translational research” that will take advances in basic medical research out of the laboratory and into the hospital clinic. The NHS said this means that patients will benefit more quickly from new scientific breakthroughs.

Each of the new units will receive £3.4 million over the next four years.

NHS said that the new units will complement the existing twelve NIHR biomedical research units in Bristol, Leeds, London, Nottingham, Oxford, Sheffield and Southampton, and the 12 NIHR biomedical research centers in London, Oxford, Cambridge, Liverpool, Manchester and Newcastle.

“People who suffer from illnesses such as heart disease, gastrointestinal infections and pancreatic disease will really benefit from these new NIHR biomedical research units,” said Public Health Minister Dawn Primarolo. “The new funding will enable high quality research to flourish in these small but excellent research groups and will strengthen our drive to put the UK at the forefront of vital health research, as well as enhancing the nation’s international reputation as a center for excellence.”

iCAD SecondLook now available in Europe

iCAD (Nashua, New Hampshire), a provider of computer-aided detection (CAD) solutions, reported that its SecondLook Digital CAD technology, customized for use with **Sectra’s** (Linköping, Sweden) MicroDose Mammography system, is now available throughout Europe.

“Adding the benefits of iCAD’s technology to Sectra’s digital mammography systems enhances the screening mammography experience exponentially for the radiologist,” said Dr. Jean-Claude Piguet from ImageRive, the official and exclusive institution of postgraduate studies for the **Universite de Geneve** in Switzerland.

He added: “Sectra’s Photon-Counting Technology provides a clearer, easier-to-read image due to high resolution, high DQE and low electronic noise. When coupled with iCAD’s SecondLook Digital CAD to identify areas of interest for closer consideration, the solution significantly improves workflow and increases the detection of cancer.”

iCAD has received CE mark marketing approval of cus-

tomized solution with Sectra’s mammography systems

“The availability of our CAD technology with Sectra solutions throughout Europe is a milestone in iCAD’s business strategy outside the U.S.,” said Ken Ferry, president/CEO of iCAD.

Sectra develops IT-systems and products for radiology, mammography and orthopedic departments.

CAD use in Italian cancer screening effort

About 26,000 residents within Italy’s Piemonte region will be involved in its Protèus project, described as the first program in the world to use CAD to screen patients for colon cancer, part of the Italian province’s cancer prevention efforts.

Protèus will feature the use of CAD-COLON, a diagnostic system developed as the result of more than 6 years of interdisciplinary medical and scientific research conducted by **im3D – Medical Imaging Lab** (Torino, Italy), together with its clinical and scientific partners.

The program is being launched in Torino and will allocate €4.7 million (\$7.5 million) over two years to test the CAD as a primary screening protocol.

Protèus is sponsored by the Region of Piemonte, im3D, the **University of Torino** (through its Interdepartmental Center for Molecular Biotechnology and the Department of Medical Surgery Disciplines – Radiology section), the Center for Epidemiology and Oncology Prevention and **CIS Piemonte**. The program emphasizes the use of technological innovation applied to prevention.

The experimental screening program is hoping to confirm the diagnostic performance levels already obtained within preliminary studies using CAD-COLON, which have primarily addressed its sensitivity and specificity, im3D said.

Verification of the methodology means that it can then be applied to large-scale screening projects as well as to other pathologies.

CompuMed gets Chinese okay for OsteoGram

CompuMed (Los Angeles), a provider of diagnostic software solutions, said it has received approval from China’s State Food and Drug Administration (SFDA) to market its OsteoGram system for screening, diagnosing and monitoring osteoporosis.

The approval enables CompuMed to sell the OsteoGram product as an approved clinical device in China and will allow the company to work with its Chinese OEMs to target a market with “substantial strategic importance.”

CEO Maurizio Vecchione said, “With this approval, we have passed all of the regulatory hurdles necessary to support our effort in the Chinese market, where the demographics are very favorable and the incidence of bone disease is very high.”

CompuMed noted that osteoporosis affects more than
See International, Page 7

*Financings roundup***CleveX raises private \$1.4 million; IDS secures data collection funds****A *Diagnosics & Imaging Week* Staff Report**

CleveX (Columbus, Ohio) reported that it has closed \$1.4 million in equity financing that will help accelerate its growth in commercializing tools to assist in the excision of cancerous and non-cancerous skin lesions.

The company said it raised the seven figure investment from a group of mid-western based investors. The lead investor, Plymouth Venture Partners, was joined by WPWIII Cap LP and The Esposito Group. Terms were not disclosed.

The company said the financing will help it fully commercialize ExiClip, its lead technology. ExiClip is a surgical tool that is designed to excise skin lesions and close the site significantly more efficiently than typical scalpel and suture procedures. The company said the technology also provides patients with an excellent cosmetic result. The device was cleared by the FDA in May 2007. The company said it will initiate the ExiClip pilot launch in September.

"We are very pleased to receive these investments. We can now move forward with our pilot launch and begin to bring key sales talent into the company," said CleveX President, Gary Smith. "CleveX is seeking an additional \$400k to close this round," he added.

In a letter to the shareholders of **Imaging Diagnostic Systems** (IDS; Fort Lauderdale, Florida), Linda Grable, a co-founder who returned to the company as interim CEO and chairman three months ago, revealed that she recently helped secure a tiered debenture for up to \$2 million to aid in the clinical collection of the PMA data and the submission of the PMA application for the company's CTLM diagnostic imaging device designed to detect breast cancer without radiation or compression.

Grable noted that over the past two years, IDS had installed upgraded CTLM systems, initiating a new study protocol utilizing a new intended use at 10 various clinical sites throughout the U.S. These sites are currently gathering cancer cases and non-cancer cases required to support the intended use hypothesis for the PMA application.

"We believe we are on schedule to complete the data collection and submit the PMA application to the FDA in its entirety by the end of this year," Grable said.

Grable also said she recently arranged a new sixth private equity credit agreement for \$15 million over a three-year period with Charlton Avenue, who has provided substantially all of the necessary funding for the company over the past eight years.

In other financing activity:

- **Michelson Diagnostics** (MDL, Kent, UK) received £600,000 (\$1.18 million) in a new funding round for its

Optical Coherence Technology (OCT) systems for cancer diagnosis.

The capital injection forms part of a new funding round of almost £600,000 into pioneering MDL, with Catapult Venture Managers investing a further £250,000, London Seed Capital a further £50,000 and the balance of the money coming from private investors.

The money will be used to complete development of its hand-held OCT probe for applications in cancer diagnosis and treatment, which uses OCT to provide real-time images of sub-surface tissue at near-cellular resolution without tissue removal - an optical biopsy.

- A group of **CardioNet** (Conshohocken, Pennsylvania) investors will sell 5 million shares of CardioNet stock for \$26.50 a share, the company said Friday. CardioNet will not receive any proceeds from the sale, which is expected to close Wednesday.

The selling stockholders have also granted the underwriters a 30-day over-allotment option to buy an additional 750,000 shares.

Citi is the sole book-running manager, Banc of America Securities and Leerink Swann are the co-lead managers and Cowen and Company and Thomas Weisel Partners are the co-managers for the offering.

According to CardioNet's filing with the Securities and Exchange Commission, a group of Sanderling funds are the largest participants in the offering, selling 869,565 shares out of nearly 2.6 million shares. H&Q funds will sell 503,240 shares out of about 1.4 million. The offering is expected to raise \$125,543,500 in proceeds to the selling stockholders, before expenses, according to the filing.

CardioNet, a wireless med-tech company with an initial focus on the diagnosis and monitoring of cardiac arrhythmias, said in the filing that it has incurred net losses from its inception through March 31, including net losses \$300,000 for the quarter ended March 31, 2008, and \$400,000 for the year ended Dec. 31, 2007.

The company said that it expects its operating expenses to increase as the company expands in a variety of areas: sales and marketing activities; designing, manufacturing and building its inventory of future generations of the CardioNet systems; hiring additional staff; investing in infrastructure; and incurring the added expenses associated with being a public company.

"With increasing expenses, we will need to continue to substantially increase our revenues to be profitable in the future," CardioNet said in the filing.

The company said its business is dependent upon doctors prescribing CardioNet's services. If it fails to obtain those prescriptions, its revenues could fail to grow and could decrease, the company said in the filing.

Thus far, a key barrier in this area has been a general reluctance by insurers to pay for these types of monitoring services, the result of insufficient data validating their worth. ■

*Deals roundup***ProUroCare, Artann Laboratories in prostate imaging agreements****A *Diagnosics & Imaging Week* Staff Report**

ProUroCare (Minneapolis) reported entering into two agreements with **Artann Laboratories** (Trenton, New Jersey) to complete development, conduct clinical trials and file for FDA clearance on the company's ProUroScan prostate imaging system.

ProUroCare will provide to Artann consideration in the form of cash and ProUroCare common stock, along with royalty payments based on the ProUroScan's worldwide net sales.

The agreements grant to each party license rights and expand the working relationship of the two companies to include development and licensing of future generations of the ProUroScan system.

Under the agreement, Artann will conduct and complete all remaining product development activities, clinical testing and evaluations, and make an FDA 510(k) submission. Artann also will supply ProUroCare with systems for pre-commercial testing and validations, marketing and clinical studies and facilitate transfer of the product to a third party manufacturing partner.

In the deal, Artann granted to ProUroCare an exclusive license to patent applications and trade secrets to mechanical imaging technology used in the diagnosis or treatment of urologic disorders of the prostate, kidney or liver. ProUroCare granted to Artann rights to its mechanical imaging patents for the breast field of use.

ProUroCare develops mechanical imaging technology applications for the detection and surveillance of prostate disease.

In other dealmaking news:

- **Bioheart** (Sunrise, Florida) reported that it has agreed to acquire **Medicalgorithmics** (Warsaw, Poland) and the rights to that company's PokcetECG, a real-time wireless beat-to-beat, heart monitor system for long-term, fully-automated ECG arrhythmia analysis. The device recently received CE mark approval for European marketing.

Terms of the transaction were not disclosed; the companies said they will conduct their due diligence reviews within the next 60-90 days.

"Similar in size to an MP3 player, patients find the PocketECG easy to use 24-hours-per-day in the comfort of their homes and when going about their normal activities," said Dr. Marek Dziubinski, co-founder and CTO at Medicalgorithmics.

The device connects to the patient via electrodes and wirelessly transmits data in real time 24-hours-a-day directly to the physician or a monitoring center for long-term monitoring over a period of days or weeks. Like other companies in this sector, the company says the intent is to reduce emergency hospital stays, improve care and reduce

costs.

"We believe the merger of these two companies would create important synergies in the diagnosis, monitoring and potential treatment of heart failure patients, specifically in the area of arrhythmias and A-Fib," said Howard Leonhardt, CEO/CTO and chairman of Bioheart. "The monitoring and management of patients experiencing arrhythmias and A-Fib represents one of the fastest-growing segments of the treatment market."

- **Veridex** (Raritan, New Jersey), a business of **Johnson & Johnson** (New Brunswick, New Jersey) developing *in vitro* diagnostic oncology product, reported closing its previously disclosed acquisition of the assets of **Immunicon** (Huntingdon Valley, Pennsylvania) and its wholly-owned subsidiaries for \$31 million, that deal first unveiled in June.

The assets, acquired just after Immunicon filed for Chapter 11 bankruptcy, include intellectual property, product inventory and clinical data, as well as all technologies related to the CellSearch System, the first diagnostic test to automate the detection and enumeration of circulating tumor cells (CTCs), cancer cells that detach from solid tumors and enter the blood stream. The system is currently cleared for the prognosis and monitoring of patients with metastatic breast, metastatic colorectal and metastatic prostate cancer.

Veridex also acquired all technologies related to Repeat-Free (RF) Poseidon Fluorescent In-Situ Hybridization (FISH) Probes, which it called the latest advance in FISH DNA probes.

- **VWR International** (West Chester, Pennsylvania), a laboratory supply company, reported acquiring **Spektrum-3D Kft** (Debrecen, Hungary), a private scientific laboratory supply distributor.

Spektrum-3D distributes laboratory chemicals, consumables, furniture, equipment and instrumentation to laboratories throughout Hungary, including customers in the pharmaceutical and chemical industries and scientific research institutes.

Manuel Brocke-Benz, senior VP and managing director of European operations for VWR, said, "This acquisition demonstrates our ongoing commitment to the Central and Eastern European markets and our intention to expand our product and service offerings globally. VWR started penetrating these markets a number of years ago through our export operations but have successfully developed a local supply chain in recent years to provide improved service to our valued customers."

- **Alliance Imaging** (Newport Beach, California), a national provider of outpatient diagnostic imaging services and radiation therapy services, reported that it has acquired Medical Outsourcing Services (MOS; Naperville, Illinois), a mobile provider of positron emission tomography/computed tomography (PET/CT).

See Deals, Page 8

Court report

SonoSite and GE settle first of 2 handheld ultrasound lawsuits

A *Diagnosics & Imaging Week* Staff Report

SonoSite (Bothell Washington), a developer of hand-carried ultrasound, on Friday reported the resolution of a lawsuit filed against the company last year by **General Electric** (GE; Fairfield, Connecticut) in federal district court in Madison, Wisconsin.

SonoSite said that following the trial court's summary judgment rulings on July 24, the parties agreed to dismiss the remaining claims, thereby resolving the entirety of the case in the district court and therefore not needing a trial. The parties have retained their rights to appeal the trial court's decisions, SonoSite said.

GE alleged that SonoSite had infringed six of its patents relating to ultrasound technology. SonoSite denied infringement, and it issued counterclaims, alleging that GE infringed four of its ultrasound patents and that GE's patents were invalid.

SonoSite said that Judge Barbara Crabb ruled in its favor on five of the six patents that GE had asserted. It said the court ruled that one of GE's patents is invalid and that SonoSite products do not infringe the other four GE patents. "The court also ruled in GE's favor on two of SonoSite's patents finding that GE did not infringe those two patents. At that time, the court did not rule on the two remaining SonoSite patents and one remaining GE patent," SonoSite said in a statement.

Kevin Goodwin, SonoSite president/CEO, said, "We have always believed that GE's allegations of patent infringement were baseless and without merit and the trial court's July rulings confirmed that. As with this first lawsuit, we strongly believe that there is no legal basis for a second lawsuit that GE filed against us this year in May. We will proceed firmly ahead to defend our legal rights."

GE filed the second patent lawsuit against SonoSite in the same federal district court in Madison, Wisconsin, on May 22, 2008, seeking to invalidate SonoSite's U.S. patent 5,722, 412 relating to digital ultrasound weighing less than 10 pounds. That case is scheduled for trial in June 2009, with Judge Crabb presiding.

In other legalities: **Qiagen** (Venlo, the Netherlands) and **Idaho Technology** (Salt Lake City) reported reaching a settlement agreement for rights to a suite of intellectual property relating to **Corbett Life Science's** (Sidney, Australia) Rotor-Gene instruments. The settlement preceded Qiagen's acquisition of Corbett, which was disclosed Friday. Financial terms were not disclosed.

The agreement covers Idaho Technology patents surrounding rapid polymerase chain reaction methods and instrumentation, the use of SYBR Green I in PCR reactions, melting curve analysis (rights obtained through **Roche Diagnostics** [Basel, Switzerland]), analysis methods of

DNA melting data, specifically high resolution melting (HRM), and others.

The companies also agreed to jointly file a stipulation of dismissal with prejudice with the District Court in Salt Lake City to end the pending legal proceedings.

The settlement follows Idaho Technology's January 2007 settlement with **Cepheid** (Sunnyvale, California) involving similar intellectual property and extends Idaho Technology's program, the company noted.

"We are pleased with this settlement which was a condition for our transaction with Corbett and which provides customers of Corbett cyclers and Qiagen the key freedom to operate elements required to develop, market and operate performance leading real-time PCR detection technologies based on Corbett's innovative Rotor-Gene solutions", said Peer Schatz, CEO of Qiagen.

"Idaho Technology is a company built on innovation; we are pleased to have reached a settlement with Qiagen/Corbett and we look forward to working with Qiagen. Protecting our intellectual property will continue to be exceedingly important to our business," said Randy Rasmussen, president of Idaho Technology. ■

Patent watch

Non-Invasive Monitoring Systems gets new U.S. Exer-Rest patent

A *Diagnosics & Imaging Week* Staff Report

Steven Mrha, COO for **Non-Invasive Monitoring Systems** (NIMS; North Bay Village, Florida), reported that the U.S. Patent Office has issued it Patent NO. 7,111,346, titled, "Reciprocating movement platform for the external addition of pulses of the fluid channels of a subject."

Mrha said, "This fourth patent, the first issued as U.S. patent 6,155,976 in 2000, encompasses 83 claims that further protect the value of the company's flagship products [Exer-Rest AT and Exer-Rest] for therapeutic and diagnostic applications that have already been published in peer-reviewed research studies, as well as for future products and applications."

Marvin Sackner, CEO/chairman of the company, and the technology's inventor, said, "This patent describes the means to achieve the horizontal movements of the acceleration therapeutics platform technology and adds new applications for its use. These include prevention and treatment of athletic injuries, exercise-induced asthma, post-exercise muscular cramping, as well as reduction and/or prevention of susceptibility of athletes to viral and bacterial infections.

"The patent claims include among others the means to treat and/or prevent cognitive deficits, learning deficits and/or behavioral abnormalities in early cognitive impairment."

The company said it expects to file an FDA application for approval by the fourth quarter of this year. ■

International

Continued from Page 3

200 million people worldwide and is “especially prevalent” in China, where the traditional diet lacks calcium. It said that, according to China’s most recent national census, about 100 million Chinese suffer from the disease in various stages.

The OsteoGram is a software-based bone density measurement system that can be used with digital X-ray equipment, as well as with older film-based machines. CompuMed said it provides an “accurate, low-cost alternative to DXA bone mineral density screening systems, which require dedicated and costly equipment, office space and staff.”

The company said OsteoGram’s benefits in terms of cost and efficiency “can help facilitate more widespread osteoporosis screening and treatment of at-risk patients.”

ExAblate trial under way in U.S.

InSightec (Tirat Carmel, Israel) reported that the first U.S. patient has been treated in the company’s pivotal trial to evaluate the safety and effectiveness of the non-invasive, radiation-free ExAblate magnetic resonance-guided focused ultrasound (MRgFUS) system as a pain-relieving treatment for patients with bone metastases who have failed an initial round of palliative radiation.

The ExAblate system was approved to treat women suffering from symptomatic uterine fibroids in 2004. More than 4,000 women have undergone treatment with ExAblate worldwide.

“Pain from tumors that have spread to the bone is the most common kind of pain for cancer patients,” said InSightec President/CEO Dr. Kobi Vortman. “Many patients are too weak to withstand invasive procedures to quell their pain if it persists or recurs after palliative radiation.”

He added, “We look forward to advancing the trial in hopes that ExAblate may provide a non-invasive, ionized radiation-free means to improve the quality of life of late-stage cancer patients.”

The company noted that bone is the third-most-common tissue to which cancer spreads, after the lungs and liver. Almost all patients with metastatic prostate cancer have skeletal metastases and in breast cancer, bone is the second-most-common site of metastatic spread, affecting 90% of patients with progressive breast cancer.

InSightec noted that most cancer patients suffer from pain, so controlling it and managing its symptoms are important treatment goals.

Using the ExAblate system, a physician uses MRI to visualize the patient’s anatomy and then aims focused ultrasound waves at the targeted tissue to thermally ablate, or destroy it. The MRI allows the physician to monitor and continuously adjust the treatment in real time.

The company noted that due to the high acoustic absorption and low thermal conductivity of the bone cor-

tex, it is possible to use a low level of energy and still achieve a localized heating effect while minimizing damage to adjacent tissue.

InSightec said it hopes to enroll patients with bone metastases who have failed palliative radiation therapy into the study, which is being conducted at 15 sites across the U.S. among them **Brigham & Women’s Hospital** (Boston), **Fox Chase Cancer Center** (Philadelphia), **Methodist Hospital** (Houston), **University of California, San Diego Medical Center** and **Weill Cornell Medical College** (New York).

The company is in the process of obtaining institutional review board approval from the remaining sites.

The ExAblate 2000 system received CE-mark certification for pain palliation of bone metastases in June. ■

PEOPLE IN PLACES

- **CDX Holdings** (Irving, Texas) said that George Poste, DVM, PhD, was named non-executive vice chairman and chief scientific advisor of CDX Holdings and non-executive chairman of CMDx. Poste has been a director of Caris Dx, and now CDX Holdings, since November of 2006. He also acts as senior technical advisor to Caris, Ltd., which owns a controlling stake in CDX Holdings. CDX Holdings is a newly-formed holding company that is the parent company of Caris Diagnostics (Caris Dx) and Caris Molecular Diagnostics (CMDx).

- **DiagnoCure** (Quebec) said that four colorectal cancer opinion leaders have agreed to serve on the advisory board of its subsidiary **DiagnoCure Oncology Laboratories**. The new advisory board members are Edith Mitchell, MD, clinical professor of medicine & medical oncology at Jefferson Kimmel Cancer Center; Stanley Hamilton, MD, professor and head, Division of Pathology & Laboratory Medicine, at M.D. Anderson Cancer Center; Daniel Sargent, PhD, professor of statistics and oncology and director of cancer statistics at Mayo Clinic; and Martin Weiser, MD, surgical oncologist at Memorial Sloan-Kettering Cancer Center. DiagnoCure is a developer of cancer diagnostic tests and a provider of laboratory services.

- **DxS** (Manchester, UK) reported the appointment of Ron Long as non-executive director. Long holds board positions including Medivir AB, and Procognia Israel Ltd. DxS is a molecular diagnostics company specializing in cancer treatment.

- **IRIS International** (Chatsworth, California) said that Edward Voboril has been elected to the company’s board, expanding the board to eight members. Voboril is currently chairman of the board of Analogic. Voboril retired this year as chairman of Greatbatch. IRIS makes automated in vitro diagnostics.

Pathwork

Continued from Page 1

said that they were happy [this helps] get them to a stronger diagnosis.”

In the *in vitro* diagnostics clinical validation study submitted to the FDA, the test demonstrated 89% positive agreement (akin to sensitivity) with available diagnoses and 99% negative agreement (akin to specificity).

The study consisted of the analysis of 545 metastatic, poorly differentiated and undifferentiated tumors that had been identified as one of the 15 tumor types on the panel using existing methods. The test demonstrated an average 94% overall concordance across four laboratories in a cross-laboratory comparison study of 60 metastatic, poorly differentiated and undifferentiated tissue specimens.

Microarray technology can simultaneously measure gene expression levels of large numbers of genes. Small DNA fragments are placed or arrayed on a slide and then RNA, which has been extracted from the tumor tissue and labeled with a fluorescent marker, is spread over this “microarray.”

Since RNA binds to its complementary DNA strand, the amount of binding indicates how active the gene being evaluated is. This can be determined by putting the array under a scanning microscope and measuring the intensity of the fluorescent light at each point on the array.

“The test is administered through a tissue biopsy,” Craford said. “After it is completed you get this report that gives the interpreting pathologist a score of the 15 common tumor type tissues.”

Pathwork’s software converts the scanned image data to gene expression measurements. The gene expression patterns then are compared with known gene expression patterns in the database that correspond to different tumor types.

“Knowing the primary tumor site with greater certainty enables more appropriate cancer treatment. The growing trend in cancer care is the use of therapies that target specific tissues and their genomic components, rather than relying on a one-size-fits-all treatment approach,” said Deborah Neff, President/CEO of Pathwork. “We believe the Pathwork Tissue of Origin Test will help provide more certainty in tumor diagnosis, which will enable more patients to realize the benefits of this new era in genomics-based diagnostics.”

The FDA-cleared test will be available as an *in vitro* diagnostic (IVD) kit, meaning that clinical laboratories can run the test themselves. The test is currently available as a service through Pathwork’s CLIA-certified laboratory.

The test also uses PathChip; a gene expression array customized designed for the company by **Affymetrix** (Santa Clara, Florida). PathChip is the first custom Affymetrix gene expression array to be cleared for diagnostic use.

“Together Affymetrix and Pathwork have developed

and now bring to market a very powerful tool to potentially improve cancer diagnostics and subsequent treatment planning and outcome,” said Kevin King, president of Affymetrix. “The Pathwork Tissue of Origin Test is supported by extensive analytical and clinical validation data. This not only expands the menu on our diagnostic platform, but opens the door for other gene expression-based diagnostic tests that are currently being developed by Affymetrix and our PbA partners on the GCSDx platform.”

FDA said that the Pathwork Tissue of Origin test is the second *in vitro* diagnostic multivariate index assay (IVD-MIA) device that it has cleared. The first such test was the MammaPrint, developed by **Agendia** (Amsterdam, the Netherlands). A genetic test cleared early last year, the MammaPrint is used to determine the likelihood of breast cancer returning within five to 10 years after a women’s initial.

In July 2007, the FDA issued a draft guidance document to address premarket pathways and postmarket requirements for IVDMIAs. IVDMIA tests combine the values of multiple variables to yield a single, patient-specific result.

“The clearance of the Pathwork test is another step in the continued integration of molecular-based medicine into standard practice,” said Daniel Schultz, MD, director of the FDA’s Center for Devices and Radiological Health. “In the past, scientists have classified different types of cancers based on the organs in which the tumors develop. With the help of microarray technology, they will be able to classify these types of cancers in a standardized non-reader dependent manner based on the patterns of gene activity in the tumor cells.”

Pathwork was founded in June of 2006 through an \$11 million financing. To date the company said it has received no other financings. ■

Deals

Continued from Page 5

MOS currently generates about \$22 million of annual net revenue and serves about 90 clients in Illinois, Indiana, Iowa, Michigan, Missouri, New Jersey, Ohio, Pennsylvania and Wisconsin.

The purchase price is expected to total about \$20 million in cash and assumed indebtedness.

Alliance had 500 diagnostic imaging and radiation therapy systems, including 314 MRI systems and 81 PET or PET/CT systems, and served more than 1,000 clients in 44 states as of March 31.

The company operated 88 fixed-site imaging centers (five in unconsolidated joint ventures), which includes systems installed in hospitals or other buildings on or near hospital campuses, medical groups’ offices, or medical buildings and retail sites.

It also operated 18 radiation therapy centers and stereotactic radiosurgery facilities (two radiation therapy centers are in unconsolidated joint ventures) as of March 31. ■

PSA

Continued from Page 1

bowl dysfunction, and death. These harms are especially important, the task force notes, because some men who are treated for prostate cancer would never have developed symptoms during their lifetime.

Even the screening process itself can cause pain and discomfort, such as those associated with prostate biopsy and the psychological effects of false positive results, the task force said.

For men younger than 75, the issue falls into a very grey area, it said. The task force said that for this age group, there is not enough evidence to recommend either for or against prostate cancer screening.

As for detection, the task force did find convincing evidence that prostate-specific antigen (PSA) screening can detect some cases of prostate cancer, which it called the most common non-skin cancer and the second leading cause of cancer death in men in the U.S.

A previous review of the issue – performed for the USPSTF in 2002 – found insufficient evidence that screening for prostate cancer improved health outcomes, including mortality, for men of all ages. However, that review also found little evidence concerning the possible downsides of the screening process or the natural history of prostate cancer cases detected with screening.

The task force also noted that even if prostate cancer screening is effective, the disease usually takes at least 10 years to result in the patient's death. Because a 75-year-old man has an average life expectancy of about 10 years, very few men over 75 would experience a mortality benefit from the screening.

Similarly, younger men with chronic medical problems and a life expectancy of fewer than 10 years are also unlikely to benefit from screening and treatment.

Given the slow growth of this type of cancer, there has been a growing debate in recent years over the management of prostate cancer with many experts recommending the "watchful waiting" approach over interventional strategies.

More recently, there has been considerable debate concerning the accuracy of the PSA test, shown to have a false positive rate of 70%. The USPSTF says, however, that the PSA test is more sensitive than the digital rectal examination for detecting prostate cancer.

The conventional PSA screening cut-point of 4.0 µg/L detects many cases of prostate cancer; but some early cases will be missed by this cut-point. Using a lower cut-point to define an abnormal PSA level detects more cases of cancer, the task force said.

Some newer tests are in development to make it easier for men to get screened for prostate cancer.

One example is a new test strip, similar to urine-based pregnancy tests, from **Gentag** (Washington) and **MacroArray Technologies** (Philadelphia). The compa-

nies have teamed up to design a wireless immunoassay incorporating Gentag's cell phone communication technology and MacroArray's urine diagnostic test for prostate cancer. Gentag CEO John Peters, MD, told *Diagnostics & Imaging Week* in June that FDA approval of the test is likely still two years away.

Variations of PSA screening, including the use of age-adjusted PSA cut-points, free PSA, PSA density, PSA velocity, PSA slope, and PSA doubling time, have been proposed to improve detection of "clinically important" prostate cancer cases, the USPSTF said. However, no evidence suggests that any of these testing strategies improves health outcomes, the task force noted.

The task force also urged doctors not to order the PSA test for men younger than 75 without first discussing with the patient the potential "but uncertain" benefits and the known harms of prostate cancer screening and treatment.

"Men should be informed of the gaps in the evidence and should be assisted in considering their personal preferences before deciding whether to be tested," the USPSTF said in a statement.

In addition to "watchful waiting," other management strategies for localized prostate cancer include active surveillance (periodic biochemical monitoring with conversion to curative treatment if disease progresses), radical prostatectomy, external-beam radiation therapy, and brachytherapy (or radioactive seed implantation therapy).

According to the task force, about 218,890 U.S. men were diagnosed with prostate cancer last year, and one of every six men in the U.S. will be diagnosed with the disease in his lifetime.

Roughly 27,350 men died of prostate cancer in the U.S. in 2006. ■

M E D - T E C H N E W S A N D N O T E S

Vermillion exploring alternatives

Vermillion (Fremont, California) reported hiring ThinkPanmure, an investment bank, to assist in identifying and evaluating alternatives intended to enhance the potential of the company's proteomic tests (OVAI and VASCLIR) and pipeline of biomarkers.

"We continuously evaluate our strategic options to identify and develop prospects for maximizing value for all stockholders and look forward to working with ThinkPanmure in this regard," said Gail Page, president/CEO of Vermillion. "While reviewing the various alternatives, we will continue to advance our commercialization strategies, namely building marketplace awareness for our women's health, oncology, and cardiac programs which include the OVAI and VASCLIR tests."

Vermillion makes diagnostic products for oncology, hematology, cardiology and women's health.

AACC

Continued from Page 1

After the members of the small gathering introduced themselves and their reasons for attending, Perkins said he was surprised at all the interest in tuberculosis (TB) in the room. He said FIND is “supposed to look at how we support development of new assays, but also look at delivery of those assays.”

Perkins said “there are a lot of assays” for malaria, but not as many for TB. He said there are currently roughly 50 companies making about 100 rapid assays for TB. “That’s the good news, but they perform pretty variably,” and the fact that their controls are not standardized creates a problem for clinics in the developing world.

“The end result is that countries and health workers in those countries are unsure of the results they’re getting,” Perkins said. Hence, health workers in developing nations who see negative test results in a patient who exhibits the usual symptoms of that disease find it “difficult not to treat unless they’re sure of the test.”

Perkins said the current emphasis at FIND is to get all the companies to agree to a single testing protocol. In one such effort, FIND has engaged industry in developing positive controls for malaria tests. “We’re developing malaria antigens that you can dry down and are stable for two years,” he said, noting that the objective is to create a lyophilized control that can be easily stored and readily reconstituted for testing.

But in the end, “the whole point is making sure that the healthcare provider can be sure of the test,” Perkins remarked.

Toward that end, one entity or another – unless industry wants to handle the task – has to come up with standards for verifying an assay’s accuracy. Perkins said WHO “has no regulatory aspirations, and neither do we,” but “we want to make controls available.”

One attendee said, “It’s critical when you develop an assay that you have access to genuine clinical samples” that reflect “the biodiversity that’s in the real world.” The current base of controls tends to rely on a fairly limited set, he said, and “you’ll have surprises,” he said.

“It would be nice to facilitate a collection of strains and clinical specimens” so that diagnostic makers can ensure the quality of the assays, but he warned: “That’s not a simple thing to do.”

As to whether FIND is positioned to develop such standards, Perkins said WHO put together 196 strains of TB from 81 nations in an effort to provide an exhaustive library of types for diagnostics makers to work with, but “for clinical specimens, that’s an expensive business.”

Another attendee remarked that aid organizations “have an abundant supply” of medical supplies and equipment, and that the problem is logistics within the

nation that is the object of the aid effort. He said industry is “often naïve about how to get its product in” to a developing nation, and is subject to “sheer bureaucratic B.S.” In most such nations, there is no federal agency or other central authority dedicated to ensuring that aid is placed where it is needed, and the lack of a designated responsible party almost seems to ensure that the donated items will sit in a warehouse or be sold by profiteers.

Perkins acknowledged “it’s a huge problem,” and even a company with substantial resources, like **Becton Dickinson** (Franklin Lakes, New Jersey) has difficulty just delivering needles and syringes.

“In the public sector, even in settings where there is a national ministry,” he said, “supply management is a huge headache.” However, he conceded that WHO does not have a ready solution to this dilemma. “WHO is not involved in supply chain issues,” he noted.

Another attendee said that donor organizations might have better luck bypassing federal government entities and going straight to the locations where supplies and equipment are most desperately needed.

“The bureaucracy, the corruption” in India is growing worse, he said, adding that he was frustrated that WHO will not deal with a community and insists on dealing with the nation’s ministry.

Perkins replied that he knows that “getting through the web of disinterested or corrupt parties is a challenge,” but said his experience is that engaging those at high levels of government, as frustrating as it can be, works better than starting at the bottom.

“We can’t necessarily solve problems of corruption, but we can’t give up,” he said.

Perkins said that while cost is a problem for poorer nations that are interested in obtaining diagnostics, compulsory licensing probably will not be much of a problem in most such nations. “The situation is quite different [from that of pharmaceuticals] because there is no such thing as a generic diagnostic.” He pointed out that “there’s a lot of know-how and art getting things to work,” and most nations simply do not have enough trained engineers and others to manufacture a diagnostic.

Perkins said the question of technological competence for China is somewhat different, but even though the level of education there would allow the manufacture of a knock-off diagnostic, there is little incentive to do so.

“They don’t obtain licenses from Roche” because much of what goes on in China is done via “home-brew” diagnostics, he said.

Perkins made the case that anyone in China who wants to make money manufacturing a patented diagnostic would find it easier to buy a license from the patent holder. In any case, patent piracy “hasn’t come up on the radar screen,” he said. ■

ThromboVision

Continued from Page 1

the Texas Emerging Technology Fund to foster commercialization of the T-Guide system, and in January it initiated clinical trials of the technology.

Clinical trial data were gathered through independent studies at four research facilities: **The Methodist Hospital Research Institute** (Houston); **University of Arizona** (Tucson); **Intermountain Medical Center** (Salt Lake City); and **Houston Institute for Clinical Research**. The principal investigators at the respective sites were Drs. Neal Kleiman, Marvin Slepian, Jeffrey Anderson, and Dale Halter.

"With nearly 50 million patients on medications like aspirin and clopidogrel [Plavix] to modify the aggregability of their platelets, we are anxious to be able to offer our technology to doctors who treat patients for heart attacks, strokes, and stents occlusion prevention," Teitel said.

He said ThromboVision's 510(k) application is the culmination of research that began at the **Utah Artificial Heart Institute** (Salt Lake City), **Brigham Young University** (Provo), the **University of Utah** (Salt Lake City) and **Thrombodyne** (Salt Lake City) in 1998 and was then supported by multiple grants from the National Institutes of Health.

"After obtaining the worldwide, exclusive rights to the technology, ThromboVision did a great deal of design and engineering work to advance it to this point," Teitel said. "We are hopeful that when the FDA reviews our data and other materials, they will respond positively."

Teitel told *D&IW* that the company anticipates the test will be cleared and on the market later this year.

"We're just excited to be able to bring a potential life-saving technology to the market in a way that's cost effective and simple to use," he said.

At least two other private device companies are also addressing the need for a simple point-of-care, CLIA-waived, rapid test for measuring platelet reactivity.

Accumetrics (San Diego) introduced the first simple system for measuring individual response to multiple antiplatelet agents, including aspirin, Plavix, ReoPro and Integrilin. It has the only FDA-cleared, CLIA-waived, point-of-care test that measures whether a drug has blocked a specific pathway to platelet activation by using a specific cartridge for each drug tested.

Another company, **Placor** (Plymouth, Minnesota), is testing the platelet reactivity using shear force, mimicking a stenotic artery, rather than using a specific agonist that tests for a certain pathway of inactivation.

The company's theory is that it is testing the actual ability of the platelet to aggregate, regardless of whether antiplatelet drugs are being used, eliminating the need to test for each drug prescribed to the patient. Placor's testing system requires only a fingerstick rather than a venipuncture, and the company expects FDA clearance and initial commercialization this quarter, followed by application for CLIA waiver. ■

Washington

Continued from Page 2

tions for lab quality control (QC), the news was at least not the object of lusty boos and catcalls.

Judy Yost, the director of the division of lab services at the Centers for Medicare & Medicaid Services, titled her talk "New Methods for Complying with QC," and started out by reminding lab operators that, as of last December, there were more than 200,000 labs operating in the U.S., describing that as "an astounding number."

While only about 36,000 of that total are subject to lab QC, the task of keeping track of them is still no cakewalk.

CMS has been rethinking lab QC, Yost said, adding, "we have a lot of reasons we thought new QC was necessary," including the advent of new technology "and so much more testing being done in point-of-care settings."

Yost said the idea of "equivalent QC" – which would not apply to waived settings – first appeared in the interpretive guidelines published by the agency in 2004, which she said was "a welcome addition" for many labs. At present, QC requirements include a verification of the manufacturer's performance specification as well as establishment of performance specifications for lab-developed, or home-brewed, tests.

Calibration is another feature of lab QC, as are daily quality control checks using two levels of external control materials. Those controls can be obtained from providers or made in-house, and can also be drawn from previously tested patient specimens.

CMS is offering three equivalent QC (EQC) options to the traditional QC regime. For instance, analytical equipment that has internal monitoring systems for all analytical components can scale back their QC tests with external controls to once per calendar month with two levels of controls if that system can go 10 consecutive days under daily without going out of spec. The other two options address systems with some internal analytic controls and those with none, all with the idea that tests can be scaled back so long as the lab can demonstrate that the systems behave in a stable fashion.

However, Yost noted that "labs will need more information from manufacturers" regarding the internal controls, and warned attendees that "one-size-fits-all won't work for all test systems." ■

Sign up for our free, weekly e-mail blog, **Perspectives**, commenting on today's med-tech.

Go to **www.MedicalDeviceDaily.com** and sign up.

PRODUCT BRIEFS

• A new diagnostic marker, called urine NGAL, for early detection of acute kidney injury (AKI) in hospitalized patients can distinguish AKI from other forms of kidney dysfunction and save lives by preventing kidney failure, according to research presented at a scientific workshop hosted by **Abbott Laboratories** (Abbott Park, Illinois) at the American Association for Clinical Chemistry annual meeting. AKI is a common and potentially devastating illness in hospitalized patients. Onset is rapid and can result from trauma, sepsis or administration of medications toxic to the kidneys. AKI can also present following cardiothoracic surgery or as a complication of diabetes and other chronic conditions. AKI quickly reduces the ability of the kidneys to filter waste and leads to renal failure. The study focused on a new diagnostic biomarker for acute AKI, called urine NGAL (neutrophil gelatinase-associated lipocalin). The protein is produced by the kidney tubules and appears in urine just two to four hours following AKI, up to 46 hours sooner than biomarkers detected by current testing methods. Abbott's diagnostic division specializes in *in vitro* diagnostics and offers a range of innovative instrument systems and tests for hospitals, reference labs, molecular labs, blood banks, physician offices and clinics.

• **Atherotech** (Birmingham, Alabama) said that its VAP cholesterol test is now included in Biophysical Corporation's newly released health assessment, BiophysicalCheck. This means that the VAP test, with its ability to identify far more areas of risk than the standard lipid panel, will now be available in Biophysical's biomarker-based health assessment. The BiophysicalCheck is based on the technology used in the company's test, the Biophysical250. This test has been called "The Ultimate Blood Test" by Scientific American and has been featured on highly-rated U.S. syndicated talk shows. The VAP test directly measures LDL and has been shown to identify a far greater number of patients with lipid abnormalities than the standard lipid panel (cholesterol and triglyceride test). The test also reports 15 separate components versus four in the standard cholesterol test. Atherotech is a cardio-diagnostic company.

• **Cepheid** (Sunnyvale, California) has introduced its GeneXpert Infinity-48 high-throughput system, as an addition to its GeneXpert family of molecular diagnostic testing systems. Cepheid says the GeneXpert system is a self-contained, integrated system that automates molecular analysis with minimal risk of contamination. The GeneXpert combines on-board sample preparation with real-time polymerase chain reaction amplification and detection functions for nucleic acid analysis. Cepheid is a molecular diagnostics company that makes systems for

genetic analysis in the clinical, industrial and biotreat markets.

• **Dormio Tech** (Chatsworth, California), a division of CHAD Therapeutics, said that it received FDA clearance to market the company's FloChannel diagnostic system, Dormio's first product for the large and rapidly growing sleep disorder market. Dormio Tech's FloChannel is a diagnostic device that independently monitors left and right nasal airflow. This allows the system to detect and measure nasal cycling (the periodic alternation in nasal airflow resistance between the two nasal cavities), as well as oral airflow and snoring, and provides constant baseline airflow volumetric sleep scoring. The patented device connects easily to standard sleep lab systems. CHAD Therapeutics makes products for the sleep disorder market.

• **ImaCor** (Uniondale, New York) reported receiving FDA clearance for its ClariTEE probe and Zura imaging system. The ClariTEE probe is a miniaturized transesophageal echocardiography probe which facilitates episodic monitoring of cardiac function. The ClariTEE is a single-use device that can remain indwelling for up to 72 hours, allowing intensivists and anesthesiologists to periodically assess cardiac preload and left ventricular systolic function over a prolonged period of time. ImaCor makes solutions for monitoring cardiac function in the critical care environment.

• **Nonin Medical** (Minneapolis) has entered the clinical testing phase with its technology to measure regional oxygen saturation. The most common application for this technology is the continuous monitoring of the regional blood oxygenation in the brain — cerebral oximetry. The advanced modular design of this new technology permits future expansion of functionality, while also permitting product and data integration into other monitoring systems. Nonin specializes in the development of physiological monitoring products.

• **Thermo Fisher Scientific** (Waltham, Massachusetts) showcased a range of solutions for clinical applications at the American Association for Clinical Chemistry's 2008 Annual Meeting. Among the technologies, products and capabilities featured to support Clinical Laboratory Excellence, were: MGC 240 Analyzer (compact bench-top analyzer offers a broad range of immunoassays with multiple channels of up to 24 two-reagent tests); PRIME Clinical Chemistry Analyzers (PRIME random access clinical chemistry analyzer); Quantitative Microsphere System (drugs-of-abuse screening and therapeutic drug management); NanoDrop 1000 Spectrophotometer (capable of carrying out full UV-Vis absorbance measurements with only 1 μ l of undiluted sample); Fluoro-Max Fluorescent Streptavidin-Coated Particles (streptavidin fluorescent particles are monodisperse particles prepared by unique and proprietary emulsion polymerization methods). Thermo Fisher Scientific offers products in two brands, Thermo Scientific and Fisher Scientific.