

Diagnostic Testing and Healthcare Industry News Update

January 26, 2010

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Who We Are

The Emmes Group is a strategic consulting, information and knowledge provider whose core competency is conceiving and implementing proprietary research-based investigations that fulfill clients' explicit needs.

What We Do

We specialize in obtaining vital market facts, judgments, preferences and perceptions -- without delay, and converting this information into applicable knowledge. We deliver unique understandings whose depth and breadth provides our clients with enhanced insights and wisdom.

Who We Support

The Emmes Group counsels and supports managers who are seeking greater understanding and desire better results. Our practice is concentrated on the essential characteristics of healthcare, including diagnostics, medical information management/technology, biotechnology, medical devices, and lab instruments.

Our Credentials

The methods, skill sets, and analyses we offer are based upon decades of first-hand experience and success, not only in research, but also in significant operational roles for industry leaders. Thus, in any project we undertake for you, we can foreshorten the learning curve and help you to be better informed.

Contact Us

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New, 2010 MDx Database: Essential Information On Over 30 Molecular Assays Performed By 1,000 Labs With Preferential Pricing For Early Subscribers

The Emmes Group, a leading provider of essential IVD market information and insights for over 25 years is pleased to announce the upcoming launch of its 2010 Molecular Testing Database -- a unique and powerful tool for assessing today's molecular diagnostic business.

Far more than any other business tool, the 2010 MDx database provides the most current and accurate picture of what is truly going on in molecular diagnostics in the United States.

Subscribers can easily access desired information -- testing volume, product used, test type (FDA-cleared, ASR or Homebrew), vendor platform (by individual model), tube type, sample extraction method, and likely to add (a given assay) -- by assay, by vendor, by test volume, and several other measures -- individually or in combination with virtually any set of designated criteria -- directly or online.

Molecular diagnostics is one of the fastest growing components of the IVD market. For anyone interested in obtaining a better understanding of the specifics of this segment, the Emmes 2010 MDx database is an invaluable management resource.

The database is easy to use, comprehensive, efficient and interconnected. It is extraordinarily useful for a wide range of business disciplines including, but not limited to, marketing, sales, product development, strategic planning, and competitive analysis.

The Emmes Molecular Testing Database provides a critical foundation whose friendly design encourages users to apply advanced analytics, resulting in better-informed and improved decision-making, and leading to superior business outcomes.

Some, but not necessarily all, the assays scheduled to be covered in the 2010 MDx include:

Chlamydia/Gonorrhea
MRSA
HPV
HIV Viral Load
Herpes (HSV)
HCV Viral Load
Herpes (HSV)
Factor V Leiden
Factor II/Protrombin
Enterovirus
C-Diff
Respiratory Viral Panel
Group A Strep
Group B Strep
CMV Cytomegalovirus
Bordetella
Influenza A/B
CF
Tuberculosis
Warfarin
MTHFR
EBV (Epstein-Barr)
HBV Viral Load
BCR/ABL
Fragile X
Her2Neu
VRE
C-Diff
Respiratory Virus
BK Virus
K-RAS
VZV (Varicella Zoster)
Van A

A profile of 1 of the 1,000 lab records that comprise the 2009 Emmes MDx Database – representative of the 2010 MDx database -- is **shown on the next page**. For further information and **detailed preferential pricing** for companies that subscribe before the end of February 2010 **please contact**:

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Emmes 2009 Molecular Testing Database

Lab: <input type="text" value="Tacoma General Hospital"/> Address: <input type="text" value="315 Martin Luther King Jr. Way"/> City: <input type="text" value="Tacoma"/> State: <input type="text" value="WA"/> Zip: <input type="text" value="98405"/> Telephone: <input type="text" value="253-403-1113"/> Name: <input type="text" value="Gwyn Peterson"/> Title: <input type="text" value="Microbiology Supervisor"/>	Type of Institution: <input type="text" value="Teaching Hospital"/> Labs Performing MDx Testing: <input type="text" value="Microbiology"/> <input type="text" value="Immunology"/> Interview Number: <input type="text" value="457"/> Number of Beds: <input type="text" value="521"/>	Month of Interview: <input type="text" value="March"/> Year of Interview: <input type="text" value="2009"/>
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Test	Perform	Annual Volume	Trend + - %	Commercial, ASR, Homebrew	Manufacturer/Platform	Will Change	Reason Why Considering Change	Will Likely Add
Chlamydia Gonorrhea	YES	19500	Same	Commercial	BD - Probe Tec	no	N/A	N/A
MRSA	YES	3120	Same	Commercial	Cepheid - SmartCycler	no	N/A	N/A
HPV	YES	11700	Same	Commercial	Qiagen - HC2	YES	Sample prep too cumbersome	N/A
HPV Genotyping	no							YES
HIV Viral Load	YES	120	Same	Commercial	Siemens - 340 bDNA	no	N/A	N/A
HIV Genotyping	no							no
HCY Viral Load	YES	660	Same	Commercial	Siemens - 340 bDNA	no	N/A	N/A
HCY Genotyping	YES	144	Same	ASR	Hologic - Invader	no	N/A	N/A
Herpes (HSV)	YES	780	Same	Commercial	Roche - LightCycler	no	N/A	N/A
Group A Strep	no							no
Group B Strep	YES	7800	Same	ASR	Gen-Probe	no	N/A	N/A
CMV	no							no
Bordetella	YES	1000	Same	Commercial	Roche - LightCycler	no	N/A	N/A
Influenza A/B	no							YES
Factor V Leiden	YES	300	Same	ASR	Hologic - Invader	no	N/A	N/A
Factor II Prothrombin	YES	300	Same	ASR	Hologic - Invader	no	N/A	N/A

Lab: Tacoma General Hospital **Emmes 2009 Molecular Testing Database** Type: Teaching Hospital
 City/State: Tacoma, WA Page: 2 Interview Number: 457

Test	Perform	Annual Volume	Trend + - %	Commercial, ASR, Homebrew	Manufacturer/Platform	Will Change	Reason Why Considering Change	Will Likely Add
CF	YES	120	Same	ASR	Hologic - Invader	no	N/A	N/A
Tuberculosis	YES	72	Same	ASR	Gen-Probe - TMA	no	N/A	N/A
Enterovirus	no							YES
MTHFR	no							no
EBV	no							no
HBV Viral Load	YES	180	Same	ASR	Roche - HBV	no	N/A	N/A
BCR/ABL (Chronic Myeloid Leukemia)	no							no
Fragile X	no							no
Hor2Neu	no							no
VRE	no							no
C. Diff	no							YES
Respiratory Virus	no							YES
BK Virus	no							no
K-RAS	no							no
VZV	no							no

Which Molecular Tests, if Any, Does Your Lab Send Out Rather Than Perform In-House

BK Virus	MTHFR	VZV	
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Other Molecular Tests Your Lab Would Like To Add To Its Test Menu <input type="text" value="Warfarin"/>	Any Molecular Tests You Perform For Which We Did Not Inquire <input type="text" value="Bladder Cancer"/>
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January 25, 2010

Abbott Submits New HIV Test to FDA for Expedited Review

An assay to aid in the early detection of HIV infection may soon be available in the United States. Abbott announced today it has submitted a Premarket Approval application for the *ARCHITECT* HIV Ag/Ab Combo assay to the U.S. Food and Drug Administration (FDA) for expedited review. Upon approval, the assay is expected to be the first test available in the United States to simultaneously detect the combined presence of HIV antigens (proteins produced by the HIV virus) and antibodies (proteins produced by the body to fight HIV antigens), which would allow for the early detection and ongoing monitoring of the virus.

Studies conducted by researchers in the United States, including the Centers for Disease Control and Prevention (CDC), show that antibody-only tests fail to identify up to 10 percent of HIV infections in some high-incidence populations. However, the detection of the HIV p24 antigen enables laboratories to diagnose HIV infection before HIV antibodies are able to be detected. A combined antibody and antigen test holds considerable promise for HIV screening and could assist in detecting infections before antibodies can be identified.

"The potential to diagnose HIV in the acute phase of the disease when antibodies are not yet present would be an important development in the fight against HIV," said Michael Warmuth, senior vice president, diagnostics, Abbott. "The earlier a patient can be diagnosed, the sooner the patient can be placed into care and the better chance there is to stop further spread of the virus."

The Abbott-developed *ARCHITECT* assay was approved for use in Europe in 2004, and is currently an investigational device in the United States. The U.S. submission comes as Abbott marks the 25th year since the company developed the first FDA approved test for HIV. This latest submission underscores Abbott's continued commitment and leadership in HIV diagnostics.

The *ARCHITECT* HIV Ag/Ab Combo assay is designed for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV1 group M and group O) and/or type 2 (HIV-2) in adult and pediatric serum and plasma. The assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. It is also intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection in pregnant women.

ARCHITECT HIV Ag/Ab Combo assay is not intended for use in screening blood, plasma or tissue donors. The effectiveness of *ARCHITECT* HIV Combo (Ag/Ab) for use in screening blood, plasma or tissue donors has not been established. The assay result

does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody.

The CDC estimates that there are 56,000 new cases of HIV in the United States annually. In 2008, UNAIDS estimated that 2.7 million people throughout the world are newly infected with HIV each year. Leading risk factors for HIV infection include male-to-male sexual contact, high-risk heterosexual contact and intravenous drug use.

January 11, 2010

Quest Introduces Molecular Blood Test for Aiding Colorectal Cancer Detection

A new blood test that identifies changes in DNA associated with colorectal cancer is now available in the U.S. through Quest Diagnostics Incorporated the world's leading cancer diagnostics company. The test is designed to aid the detection of colorectal cancer, the third leading cause of cancer-related deaths.

The new test is based on DNA methylation of the Septin9 gene, a proprietary biomarker associated with colorectal cancer that was identified by Epigenomics AG (Frankfurt, Prime Standard: ECX), a cancer molecular diagnostics company. Quest Diagnostics is the first commercial laboratory in the U.S. to offer a laboratory-developed test based on the Septin9 biomarker.

"Early detection rates are dismally low, largely because many patients find existing tests and procedures invasive or unpleasant," said Jon R. Cohen, M.D. senior vice president and chief medical officer, Quest Diagnostics. "Our ColoVantage(TM) test, which is based on Septin9, has yet to be clinically validated as a screening test. Rather, it may promote further evaluation in patients who have resisted testing in the past or as an adjunct to existing procedures."

Colorectal cancer treated in localized, early stages has a five-year survival rate of 90 percent. Yet, only 40 percent of cases are diagnosed in early stages, due to low screening rates.

Epigenomics has demonstrated in more than a half dozen peer-reviewed studies involving approximately 3,000 specimens of patients with diagnosed colorectal cancer and of healthy control subjects that methylated Septin9 in blood plasma indicates an increased likelihood of colorectal cancer. Epigenomics is sponsoring a multi-center clinical study named PRESEPT in collaboration with Quest Diagnostics and other organizations to evaluate the Septin9 biomarker's performance for colorectal cancer

screening in screening-guideline-eligible individuals who have not been diagnosed with colorectal cancer. Epigenomics expects to conclude the PRESEPT trial early this year with the release of preliminary data, and publish the detailed findings later in 2010.

Quest Diagnostics is a leader in colorectal cancer diagnostics. The company's InSure(R) fecal immunochemical test (FIT) is an FDA-cleared fecal occult blood test (FOBT) for use in screening for sources of lower gastrointestinal bleeding, based on laboratory testing of a stool-based specimen. The company also offers mutation testing to help predict if a patient with metastatic colorectal cancer will respond to certain therapies and genetic testing to aid in evaluating a patient's inherited predisposition to colorectal cancer. In addition, the company provides anatomic pathology testing services for colorectal cancer, such as biopsy testing of tissues identified through colonoscopy.

Colorectal cancer, which refers to cancer of the colon and rectum, is a major source of cancer death in the U.S. and worldwide. An estimated 106,000 new cases were diagnosed and 50,000 deaths from the disease occurred in the U.S. in 2009. According to the American Cancer Society (ACS), beginning at age 50, both men and women at average risk for developing colorectal cancer should be screened by one of several established tests. People with certain risk factors, such as a family history, may be indicated for earlier or more frequent testing. Such methods include colonoscopy, the screening gold standard, once every ten years, as well as flexible sigmoidoscopy, virtual colonoscopy and double-contrast barium enema every five years or FOBTs, including FITs, annually. Any positive test result of any non-colonoscopy methods should be followed up by colonoscopy.

January 6, 2010

Cepheid Receives FDA Clearance for 45 Minute Surveillance Test for *vanA*

Cepheid today announced it has received clearance from the U.S. Food & Drug Administration (FDA) to market Xpert(R) *vanA*, the first rapid and accurate test released in the United States for *vanA*, the antimicrobial resistance gene most commonly associated with vancomycin-resistant enterococci (VRE) -- one of the more serious healthcare-associated infections (HAI). The 45-minute test runs on Cepheid's GeneXpert(R) System, the world's leading HAI molecular testing platform.

"As encountered with other HAI-associated pathogens, the lack of a rapid and accurate test for *vanA* has impacted clinicians' efforts in the recognition, prevention and control of VRE. Xpert *vanA* should be a significant aid in helping to address this

clinical need with fast and accurate test results that can be available on a 24/7 basis," said John Bishop, Cepheid's Chief Executive Officer. "The availability of Xpert *vanA* adds an additional dimension to the most complete molecular portfolio of test products for management of HAIs on the market today."

The U.S. Centers for Disease Control and Prevention reports that 30 percent of enterococcal HAIs are due to VRE.(1) HAI infections have proven to increase patient length of stays, mortality rates and unnecessary use of antibiotics -- leading to dramatically higher costs for healthcare institutions.

Healthcare workers, after contact with asymptomatic colonized patients, may spread VRE to other patients within hospitals. VRE can also be spread directly to people after contacting surfaces that are contaminated with the pathogen.

"Many patients in the areas of oncology, hematology, nephrology, transplant and abdominal surgery units are at highest risk for contracting VRE. Therefore, it's imperative to prevent potential outbreaks by testing for *vanA* upon admission of high risk patients," said Dr. David Persing, MD, PhD, Chief Medical and Technology Officer at Cepheid. "Several recent studies have demonstrated that a policy of recognition, prevention and control of vancomycin-resistant organisms that colonize patients in healthcare settings can lead to a reduction in transmission rates. A rapid PCR test mitigates perceived drawbacks to preemptive isolation and maximizes medical value by delivering actionable results almost immediately."

Xpert *vanA* is Cepheid's ninth test to receive FDA clearance, and fifth in its expanding menu of industry-leading HAI products. Xpert *vanA* will be available for shipment this month.

January 14, 2010

Celera Grants A License to UCSF for the Development of *KIF6* Testing

Celera Corporation today announced that it has licensed its *KIF6* discoveries to the University of California on behalf of its San Francisco Campus. Through this agreement, the University of California, San Francisco (UCSF) will be the first laboratory in the United States in addition to Berkeley HeartLab, a subsidiary of Celera Corporation, to have access to the relevant intellectual property to develop and perform an in-house test for the *KIF6* gene variant previously reported by Celera and its collaborators. The *KIF6* gene encodes a kinesin-like protein 6 (*KIF6*). Published research studies have shown an association between *KIF6* and cardiovascular risk and

statin benefit

As a result of this agreement, it is expected that UCSF will be able to offer a more personalized treatment approach for those patients with cardiovascular disease. Under the terms of the agreement, UCSF will be allowed to develop and perform its own *KIF6* test for three years in California. Testing will be performed at UCSF's state-of-the-art Pharmacogenomics CLIA-certified laboratory under the supervision of Dr. Alan Wu, professor of medicine at UCSF and chief of the clinical chemistry laboratory at San Francisco General Hospital.

"We're pleased to partner with a prestigious institution like the University of California, San Francisco to provide access to our intellectual property so they can develop and offer a test for the *KIF6* gene variant," said Kathy Ordoñez, Chief Executive Officer of Celera. "This is consistent with Celera's strategy to make *KIF6* testing broadly available and our efforts to drive our new genetic discoveries into routine personalized care for patients with risk for cardiovascular disease."

January 20, 2010

Novel Treatment Cuts Recurrence of *C. difficile*

Patients who received a single infusion with the two monoclonal antibodies were significantly less likely to have a recurrence through 84 days of follow-up than those who received placebo (7% versus 25%, $P < 0.001$), according to Israel Lowy, MD, PhD, of Medarex in Princeton, N.J., and colleagues.

Adverse events occurred at similar rates in the two groups, the researchers reported in the Jan. 21 *New England Journal of Medicine*.

Medarex is a subsidiary of Bristol-Myers Squibb focused on developing fully human antibody-based therapies.

"The trial results are impressive," Lorraine Kyne, MD, MPH, of University College Dublin, wrote in an accompanying editorial.

Although monoclonal antibodies probably would not be used as first-line treatment, she said, "this novel nonantibiotic approach to secondary prevention is likely to offer hope to physicians and patients battling *C. difficile* infection."

Agreeing was Neil Fishman, MD, of the University of Pennsylvania, who called the findings "very encouraging and very exciting" in an interview.

However, he noted that the safety of the treatment would have to be established in a much higher number of patients.

The proper place for the antibody therapy in the management of *C. difficile* needs to be established in future studies as well, said Fishman, who is also chair of the antimicrobial resistance work group for the Infectious Diseases Society of America.

Whether it should be administered during a first episode or at first recurrence is an open question, he said, and the answer will depend both on phase III results and cost, which tends to be high for monoclonal antibody therapies.

Still, he said, "All disclaimers aside, I think this is a very significant, important study and an important new development in the management of *C. difficile*."

Lowy's group wrote in the journal that new therapies are needed to manage *C. difficile*, which is increasing in prevalence and severity.

Some 15% to 30% of patients will have a recurrence despite antibiotic treatment, which itself puts patients at risk for *C. difficile* diarrhea or colitis. Broad-spectrum antibiotics knock the infection down but do not allow for the re-establishment of normal bowel flora.

In addition, a hypervirulent strain -- called BI/NAP1/027 -- has emerged in several large, deadly outbreaks in the U.S., Canada, and Europe.

The two fully human, monoclonal antibodies evaluated by Lowy's group -- one each against *C. difficile* toxins A (CDA1) and B (CDB1) -- showed efficacy in a hamster model and safety in healthy people.

To further establish safety and efficacy, the researchers enrolled 200 patients with *C. difficile* infection at 30 sites in the U.S. and Canada and randomized half to receive the antibodies and half to placebo.

The antibodies were given together in a single infusion, both at a dose of 10 mg/kg. All patients were also receiving either metronidazole or vancomycin.

In the antibody group, all cases of recurrence within 84 days of infusion occurred in patients who had been hospitalized during their initial episode.

Echoing the primary finding, the rate of recurrence was significantly lower following the antibody infusion among the subgroup of patients who had had more than one previous episode of *C. difficile* infection (7% versus 38%, $P=0.006$).

The recurrence rate also tended to be lower in the antibody group among patients who had the epidemic BI/NAP1/027 strain (8% versus 32%), although the difference did not

reach statistical significance ($P=0.06$).

During the initial episode, the antibody treatment did not shorten the length of hospitalization or the time to resolution or severity of diarrhea compared with placebo. The antibodies were not immunogenic.

Safety from the monoclonal antibody infusion was not a concern. Adverse events during infusion or within the next two hours occurred in 15 patients in the antibody group and 10 in the placebo group. All were mild to moderate, with headache the most common.

During follow-up, at least one serious adverse event was reported by 18 patients in the antibody group and 28 in the placebo group, a difference that was not statistically significant ($P=0.09$).

There were 15 deaths during the study -- seven in the antibody group and eight in the placebo group. None was attributed to the study drug. Lowy stressed that larger studies are needed to confirm the findings.

January 7, 2010

Philips and biomérieux Announce Partnership To Develop And Market Next-Generation Handheld Diagnostic Solutions For Point-of-Care

Royal Philips Electronics and bioMérieux today announced that they have signed an agreement to jointly develop fully automated handheld diagnostic testing solutions for hospital use that can be deployed at the point-of-care – i.e. close to the patient. The collaboration aims to improve diagnosis and management of disease in critical care settings within hospitals (for example, Emergency Departments, Coronary Units and Intensive Care Units (ICUs)).

“Philips is convinced that point-of-care testing in hospital critical care settings will play a major part in improving patient outcomes and reducing healthcare costs. It is an excellent fit with our leading market position in critical care settings and our holistic care cycle approach to, for example, cardiac care,” said Steve Rusckowski, Executive Vice President and Chief Executive Officer, Philips Healthcare. “Their combined knowledge of medical technology, biomarker assays and clinical workflows, coupled with their joint understanding of the relevant markets, stakeholders and channels, puts Philips and bioMérieux in a commanding position to drive forward a paradigm change in critical care decision-making.”

“We are very pleased to be partnering with Philips, which has a strong tradition in innovating patient care, and our collaboration will result in superb products able to rapidly deliver high medical value results to clinicians,” said Stéphane Bancel, bioMérieux Chief Executive Officer. “We will be leveraging the strong synergies between our VIDAS® biology expertise and Philips’ unique engineering and technology capabilities. This new point-of-care testing device will allow us to enter a market that is growing at about 10% a year.”

This new alliance unites Philips’ existing strengths in medical technology, patient monitoring and healthcare IT, including solutions aimed at helping clinicians to make more informed decisions, with bioMérieux’s expertise in the development of biological assays and its extensive knowledge of cardiovascular and infectious disease markers. A product development program is underway and the first milestone is expected in 2010. As part of the agreement, bioMérieux will have access to Philips’ proprietary Magnotech technology for hospital-based point-of-care testing applications. Commercial solutions resulting from the partnership will be co-branded by Philips and bioMérieux, with bioMérieux being the exclusive distributor worldwide. The two companies intend to have products on the market by 2013.

In critical-care settings, such as Emergency Departments within hospitals, there is a persistent clinical need for diagnostic solutions that enable fast and accurate patient triage – for example, diagnosing acute coronary syndromes (e.g. a heart attack) to enable faster treatment and improve patient outcomes. The fully automated handheld testing devices that will be developed jointly by Philips and bioMérieux will be immunoassay-based and employ Philips’ new Magnotech biosensor platform. They are intended to assist clinicians in time-critical decision-making by reducing delays involved in laboratory-based testing. Philips’ Magnotech biosensor platform has been shown to have the potential to match the analytical performance of laboratory systems in terms of accuracy and sensitivity.

Philips and bioMérieux are already major players in supplying critical-care solutions for hospital environments, and the products resulting from the partnership will complement both companies’ offerings. Philips’ current portfolio includes a full range of diagnostic tools (e.g. medical imaging, ECG and vital function monitoring) to support healthcare providers in identifying high-risk cardiac patients during the early stages of disease. bioMérieux is already recognized among clinicians for its high medical value tests, which include the VIDAS range of cardiac emergency markers: Troponin I Ultra, Myoglobin, CK-MB, D-Dimer and NT-proBNP. The solutions co-developed with Philips will be complementary to VIDAS, giving clinicians the option of point-of-care testing without compromising on assay performance.

January 19, 2010

Beckman Coulter Genomics and Venter Institute Collaborate on Validation of the SPRIworks Fragment Library System I for the Illumina Genome Analyzer

Beckman Coulter, Inc. today announced a collaboration with the J. Craig Venter Institute (JCVI) on the validation of the SPRIworks Fragment Library System I for the Illumina* Genome Analyzer. The automated benchtop system prepares up to 10 DNA libraries in five hours with high reproducibility and consistency.

The SPRIworks Fragment Library System I, developed by Beckman Coulter Genomics, utilizes Solid Phase Reversible Immobilization (SPRI) paramagnetic bead-based technology. Through elimination of the column purification and gel electrophoresis-based size-selection steps, the library construction workflow is amenable to automation.

Holly Baden-Tillson, JCVI scientist and project manager said, "JCVI is very excited to be beta testing the SPRIworks Fragment Library System I. By implementing SPRIworks, we have significantly increased our throughput from six libraries to as many as 20 libraries in a working day, with very consistent library size and recovery. This enhanced productivity will also help us to decrease our library construction costs."

"The SPRIworks system was designed to simplify and automate next-generation sequencing workflows," said Patrick J. Finn Ph.D., director of research and development, Beckman Coulter Genomics. "This will enable users to prepare more samples for sequencing, and the customer to fully utilize the growing capacity of next-generation sequencing systems, increase operational efficiency and maximize sequencing capability. We're delighted to be working with JCVI during beta testing, and the performance data generated represents a major milestone in the development of the SPRIworks platform. We look forward to extending this collaboration with future SPRIworks applications."

"Simplifying a complex genomics process such as fragment library construction for next-generation sequencing provides another example of SPRI technology application to sequencing sample preparation," commented Julie Moore, director of marketing for Beckman Coulter Genomics. "Working in close collaboration with our customers and genomic research leaders such as the JCVI allows us to better understand the challenges faced by scientists in the sequencing community and to develop robust solutions to their needs."

January 20, 2010

OraSure, Roche Sign Agreement For Fully Automated Oral Fluid Drugs Of Abuse Assays

OraSure Technologies and Roche Diagnostics today announced that the companies have signed an agreement for the worldwide commercialization of homogeneous fully automated oral fluid drugs of abuse assays with OraSure's Intercept® oral specimen collection device. The oral fluid assays use Roche's KIMS (kinetic interaction of micro-particles in solution) technology and are being jointly developed under an agreement previously signed by the parties. The oral fluid assays are designed to run on various clinical chemistry automated analyzers, which is intended to allow oral fluid samples to be processed with the same efficiency as current fully automated urine-based drug tests.

"We are very pleased with our joint development effort with Roche and the finalization and execution of the commercialization agreement associated with these important drugs of abuse assays. This relationship leverages Roche's industry leadership in lab instrumentation and reagent chemistry and our leadership in oral fluid technology and sample collection devices," said Douglas A. Michels, President and CEO of OraSure Technologies. "We look forward to working with Roche to bring these new assays to market where they will have an immediate and positive impact on laboratory efficiency for drugs of abuse testing."

"We are very pleased to be collaborating with OraSure Technologies in the development and commercialization of fully automated oral fluid drugs of abuse assays," said Dirk Ehlers, Head of Roche Professional Diagnostics. "This partnership leverages the strengths and experience of both companies and will enable us to deliver on our global commitment to providing best-in-class high throughput oral fluid drug testing solutions."

The commercialization agreement is structured to take advantage of each party's respective distribution strengths, including OraSure's established market presence with oral fluid testing and Roche's established base of analyzers and broad marketing capabilities.

Developed and manufactured by OraSure Technologies, the Intercept® device is the only FDA-cleared in vitro diagnostic laboratory-based oral fluid testing system used for detecting commonly abused drugs such as marijuana, cocaine, opiates, PCP and amphetamines (including methamphetamine and ecstasy) and for detecting barbiturates, methadone and benzodiazepines. Intercept® is currently being used in workplace, drug treatment and criminal justice testing markets, as well as in public school systems.

A global leader in diagnostics, Roche has been providing testing solutions for the drugs of abuse market for more than 25 years. Roche offers a broad test menu, integrated analyzer platforms and automation solutions to help a wide variety of labs increase revenue, improve efficiency and enhance patient care.

January 18, 2010

AstraZeneca To Announce Tie-up With Dako To Develop Personalized Medicine Tests

AstraZeneca, the UK's second largest drug company, will work with Dako to develop tests which determine the most appropriate cancer treatment for patients.

The tie-up, which should be confirmed this week, is part of AstraZeneca's plan to focus more of its research and development (R&D) on personalised medicine, which involves tailoring drugs to particular genetic make-ups.

Personalised medicine has been heralded as the next stage of drug discovery, especially for cancer, because it allows doctors to determine the right medicine for the right patient at the right time. Ruth March, AstraZeneca's head of personalised healthcare, said the deal with Dako was the "first in a series we plan to do". At present, 10pc of AstraZeneca's R&D is personalised, but the company wants to increase that and infections is another therapeutic area where a diagnostic tie-up could be established.

Personalised healthcare has been dismissed by critics as too expensive for healthcare providers to be viable, but Ms March believes it could deliver savings, because medicines would be more targeted, relevant and therefore more efficient. AstraZeneca will use Dako's diagnostic tests to identify what patient conditions a drug works best under. At present, such results are not usually established until late in the testing process, but establishing the conditions earlier will allow drugs to be developed more effectively.

Personalised medicine is a potential avenue for the world's leading pharmaceutical companies to broaden their product pipelines, many of which are under growing pressure from generic rivals.

The financial terms of AstraZeneca's deal with Dako have not been disclosed but the Danish company is one of the world leaders in diagnostic products for cancer. Its technology identifies "molecular biomarkers" in a tumour.

Alan Barge, head of oncology development at AstraZeneca said: "The alliance heralds

the intentions of both companies to work closely together to develop new drugs linked to diagnostic tests that predict which patients are most likely to respond to treatment, ensuring that we are giving the right treatment, to the right patient, the first time.”

Lars Holmkvist, chief executive of Dako Denmark, said: “We believe it is important for pharmaceutical and diagnostic companies to combine their expertise in a strong collaborative approach to enable the development of diagnostic tests for use with drug therapies. Targeted treatment with personalised medicine is the future, and the outcome of this collaboration will be beneficial not only for cancer patients, but is also a significant contributive factor in cutting health care costs.”

January 14, 2010

bioMerieux Acquires Meikang Biotech, Chinese Rapid Test Manufacturer

A world leader in *in vitro* diagnostics, bioMerieux announced today the acquisition of the rapid test manufacturer, Meikang Biotech, and its large production site in Shanghai. This important milestone will reinforce bioMerieux's position in the Point of Care and rapid test markets for both emerging and developed countries. The acquisition highlights bioMerieux's continued business expansion in fast-growing emerging markets, giving the company fully-owned, integrated manufacturing and R&D capabilities in China.

"With this acquisition, we are gaining a strategic foothold in China, the country that should drive the most growth in the next 10 years, and significant assets to enhance our product offering for Point of Care, a segment with a double digit annual growth rate. We are now poised to become a major player in Point of Care with manual rapid tests including the QuickVue® range and the automated handheld device from our Philips partnership announced last week," said Stephane Bancel, bioMerieux Chief Executive Officer. "This also represents a significant step in the globalization of our company: bioMerieux will now have leaders based in three corporate hubs, in Marcy l'Etoile, France, Cambridge, USA and Shanghai, China."

Ideally located between downtown Shanghai and the international airport, Meikang Biotech's 2 hectare (4 1/2 acre) site houses R&D and commercial operations in addition to 9,000 m(2) of GMP and ISO certified manufacturing facilities, producing 30 million tests per year. Currently dedicated to rapid tests, production activities at this site will be expanded in the coming years to other products for global markets.

Founded in 1992, Meikang Biotech has 250 employees and contractors working at its site. The company has a wide range of rapid tests based on lateral flow immunoassay technology, including tests for infectious diseases, cardiovascular diseases and cancer. Many of these products are CE marked and some have received FDA 510k approval. 2009 revenues for Meikang Biotech are estimated at about euro 5 million.

By mid 2010, bioMerieux intends to establish its Greater China headquarters, as well as Asia-Pacific and corporate offices at the newly acquired site. From a commercial base in China, bioMerieux will move to a fully integrated corporate center of excellence with R&D, Manufacturing, Quality Assurance, Regulatory Affairs, Marketing and Logistics all based in Shanghai. bioMerieux also intends to set up a customer training center for Asia-Pacific and to use the site as a base for field support to customers and distributors in the region.

bioMerieux already has a solid base in China. Alain Merieux and Institut Merieux have been active there since 1978 and bioMerieux has had a Chinese subsidiary since 1992, with headquarters today in Shanghai and 5 regional offices. bioMerieux China has more than 100 employees and a large network of distributors. bioMerieux's product portfolio is well adapted to the Chinese market, where there are significant needs for infectious disease diagnostics. The Chinese *in vitro* diagnostics market is growing very rapidly, at 15-20% per year. As of September 2009, bioMerieux sales there had risen 26%. bioMerieux also has a number of ongoing collaborations with Chinese institutions and companies. These include an agreement with the Chinese Ministry of Health for healthcare-associated infection control, the first of its kind ever signed with a private company; a bioMerieux research team working in a joint unit at the Fudan University Cancer Hospital in Shanghai and a co-enterprise with Shanghai Kehua Bio-engineering for the production of immunoassay microplates.

January 14, 2010

Life Technologies To Acquire AcroMetrix

Life Technologies a provider of innovative life science solutions, today announced that it has signed a definitive agreement to acquire AcroMetrix, for an undisclosed amount.

AcroMetrix is a provider of molecular and serological diagnostic quality control products to clinical laboratories, blood screening centers and in-vitro diagnostic (IVD) manufacturers. Diagnostic controls allow a laboratory to achieve better standardization across systems and are more economically efficient to use than “homebrew” control reagents.

“With the growth of DNA and other molecular based tests, there is a growing need for high quality, independently provided controls to ensure the accuracy and integrity of laboratory test results,” said Gregory T. Lucier, Chairman and Chief Executive Officer of Life Technologies. “The acquisition of AcroMetrix builds on our substantial business of providing tools and technologies into the molecular diagnostics industry.” Life Technologies holds a significant portfolio of molecular diagnostics products that comprise more than \$300 million of the company’s revenue, including components such as magnetic beads, fluorescent dyes and specific antibodies, which can be custom designed for diagnostics manufacturers.

The company also provides the SPOT-Light(R) HER2 CISH Kit for assessment of breast cancer patients; the Dynachip(R) System for automated HLA antibody screening; and molecular diagnostic instruments such as the 3500 Dx Series Genetic Analyzer, cleared for diagnostic use in certain European countries, and the 7500 Fast Dx Real-Time PCR instrument. The 7500 Fast and 7500 Fast Dx instruments have received Emergency Use Authorization from the Food and Drug Administration for surveillance of the Influenza A (H1N1) virus and have been used by public health agencies worldwide.

“The addition of AcroMetrix will accelerate the expansion of our focused commercial channel for reaching molecular diagnostics customers, both with the current product portfolio and with assays in development,” said Mark Stevenson, Life Technologies’ President and Chief Operating Officer. “Our objective is to become the technology partner of choice to organizations worldwide that are building out their molecular diagnostic capabilities.”

“We’re pleased to add our superior line of products to Life Technologies’ comprehensive suite of offerings in the molecular diagnostics market,” said Michael J. Eck, President and Chief Executive Officer of AcroMetrix. “Our customers will now benefit from even greater investment in new molecular products designed to meet the needs of clinical laboratories.”

January 14, 2010

Biotheranostics Announces Commercial Agreement With Ferrer Incode To Market Theros Cancer Type ID

bioTheranostics, a bioMerieux company that discovers, develops and commercializes innovative molecular diagnostic tests in oncology, announced that the company has signed a three-year, exclusive agreement with Ferrer inCode to commercialize the bioTheranostics THEROS CancerTYPE ID® molecular cancer classifier in Spain, Portugal, Greece, and Venezuela. The agreement is effective immediately.

Under the terms of the agreement, Spain-based Ferrer inCode will market the THEROS CancerTYPE ID (CTID) molecular assay, while bioTheranostics will perform all sample testing in their CLIA-certified, CAP-accredited laboratory in San Diego, California. "The agreement with Ferrer inCode is a further demonstration of our commitment to make the THEROS CancerTYPE ID assay available to oncology professionals and patients worldwide through partnerships with leading, established diagnostic companies," said Richard Ding, bioTheranostics chief executive officer. "As with Lab21, our partner in the United Kingdom and Ireland since September of last year, we are confident that Ferrer inCode will provide the highest level of service to professionals and patients in the designated countries."

The CTID assay is a 92-gene molecular cancer classifier. It is particularly useful for oncologists and pathologists managing metastatic cancer patients whose primary tumor site (e.g., breast, lung, pancreas) is either "uncertain" or "unknown" following assessment with conventional diagnostics. The results of the CTID assay can guide physicians in selecting optimal therapies for these individuals and potentially improve treatment outcomes. Approximately three to five percent of cancers diagnosed worldwide each year are classified as "cancers of unknown primary origin" (aka CUP), and far more patients struggle with a differential diagnosis (i.e., two or more diagnostic options, each of which may lead to a different treatment path).

"We are thrilled that we can now offer the THEROS CancerTYPE ID assay to physicians in Spain, Portugal, Greece and Venezuela," said Alfredo Gracia, Ferrer inCode chief scientific officer. "As front runners in the field of personalized medicine, we have been asked by physicians to address one of their most significant unmet needs, which is the identification of the origin of tumors that are diagnosed via metastases or complications, in order to offer an appropriate therapeutic option to their patients. THEROS Cancer TYPE ID and bioTheranostics' capabilities give us an outstanding opportunity to broaden the scope of Ferrer inCode's services to the medical community."

bioTheranostics discovers, develops and commercializes molecular diagnostic tests for cancer patients. Leveraging its unique expertise in genomic profiling and proprietary algorithms, bioTheranostics provides innovative tests to the oncology community that help drive personalized treatment. The company operates a CLIA-certified, CAP-accredited diagnostic service laboratory in San Diego, California to perform its proprietary molecular diagnostic tests: THEROS CancerTYPE ID®, a molecular cancer classifier particularly helpful for patients diagnosed with metastatic cancer whose tumor origin is either as uncertain or unknown, or patients with their cancer origin not confirmable through conventional diagnostics; and the THEROS Breast Cancer Index®, which refines and improves risk stratification in patients with estrogen receptor (ER)-positive, lymph-node negative breast cancer.

January 14, 2010

Abbott Receives European Regulatory Approval for New Ovarian Cancer Diagnostic Test

A new diagnostic tool, which studies show can aid in determining the risk of whether a pelvic mass is benign or malignant, is now available in Europe. This simple blood test is expected to help in the assessment of epithelial ovarian cancer, the most lethal form of gynecological cancer. This important immunoassay, which will run on Abbott's ARCHITECT systems, is the first automated HE4 test available anywhere in the world.

Research has shown that this novel diagnostic marker, combined with other tests such as the CA125 assay, can aid in measuring the risk of epithelial ovarian cancer in pre- and post-menopausal women who have a pelvic mass.

According to the International Agency for Research on Cancer, the five-year survival rate of ovarian cancer patients is 46 percent. However, when the disease is diagnosed earlier, the survival rate increases to 94 percent.

"The ability of this test to help physicians predict whether a pelvic mass is benign or malignant is an important development for both patients and physicians," said Michael Warmuth, senior vice president, diagnostics, Abbott. "Abbott's ARCHITECT HE4 test will aid physicians in determining the most appropriate treatment for their patients."

Abbott partnered with Fujirebio Diagnostics, Inc. in the development of the assay. The test is now available in several European countries, as well as in some countries in Asia Pacific and Latin America. The ARCHITECT HE4 Assay was recently submitted to the FDA for 510(k) clearance.

Ovarian cancer is the leading cause of death from gynecological cancers and the fifth-leading cause of cancer death in women. An estimated one in 72 women will develop ovarian cancer in her lifetime. It accounts for 31 percent of cancers of the female genital organs. Women who are postmenopausal are at the greatest risk for ovarian cancer.

January 11, 2010

Sepsis and Septic Shock on the Rise, Affecting Younger Patients

bioMerieux, a world leader in the field of *in vitro* diagnostics, today released its results of a comprehensive survey of emergency department and critical care physicians. The vast majority of these doctors reported that sepsis and septic shock--the result of serious infections--is on the rise in U.S. hospitals, affecting increasingly younger patients. The surveyed doctors attributed the increase to the overuse of antibiotics, which is rendering these once wonder-drugs ineffective.

Sepsis, a usually fatal medical condition caused by the body's response to a severe infection of the blood and/or tissues, affects 5-10 percent of all hospital patients, leading to an increase of about \$5 billion in U.S. health-care costs annually. Nearly 300 emergency and critical care doctors were surveyed at two major medical conferences - the American College of Emergency Physicians Annual Conference, held in Boston in October 2009, and the American College of Chest Physicians Annual Meeting, held in San Diego in November 2009.

When asked if they have seen an increasing rate in sepsis in their hospitals during the last decade, the answer was unequivocally "yes." Seventy-six percent of the physicians surveyed said the incidence of sepsis is on the rise. In addition, nearly 60 percent said sepsis is affecting more patients than it did 10 years ago.

Sixty-three percent of doctors surveyed indicated that the No. 1 reason for younger patients becoming septic was an increase in multi-drug-resistant microorganisms, which is caused by the widespread overuse of antibiotics. In a recent study published by Roberts et al, examining the hospital and societal costs of antibiotic-resistant infections (ARIs) at a Chicago hospital, patients who suffered from these infections remained in the hospital between 6.4-12.7 days longer than those who were not infected and had a significantly increased risk of death - two-fold higher than in patients without ARIs, with an attributable mortality rate of 6.5 percent.

"Sepsis is often a life-threatening condition, compounded by multidrug-resistant organisms and patients who live longer with serious underlying co-morbidities," said Mark H. Oltermann, M.D., director of the Medical ICU at John Peter Smith Hospital in Fort Worth, Texas.

When asked if biomarkers, or telltale biochemical indicators of infection, are used to help diagnose severe infections that could lead to sepsis, the vast majority (nearly 70 percent) of the 281 surveyed doctors said yes. However, only 6 percent of these doctors reported using procalcitonin (PCT) as a biomarker to help them manage suspected sepsis patients. When asked to qualify the improvement that PCT testing

could bring to emergency and critical care patients, 51 percent said the test would dramatically improve the quality of care that patients with suspected sepsis would receive in U.S. hospitals.

"Sepsis is a disease that when diagnosed early and treated effectively, more lives can be saved than almost any other disease," Dr. Oltermann added. "It is critical that we add state-of-the art tools to our arsenal to help battle sepsis. PCT is one of those tools."

January 11, 2010

Quidel Corporation Announces Definitive Agreement to Acquire Diagnostic Hybrids

Quidel Corporation, a leading provider of rapid point-of-care diagnostic tests, announced today the signing of a definitive agreement to acquire privately held Diagnostic Hybrids, Inc. for approximately \$130 million in cash.

Diagnostic Hybrids, based in Athens, Ohio, is a market leader in manufacturing and commercializing direct fluorescent in vitro diagnostic assays used in hospital and reference laboratories for a variety of diseases, including viral respiratory infections, herpes, Chlamydia and other viral infections, and thyroid diseases. Diagnostic Hybrids leverages its antibody development and cell culture expertise to develop new products that address significant market opportunities. The company's direct sales force serves over 700 North American customers, and its products are sold via distributors outside the United States.

"This is an exciting acquisition for Quidel as it meets our criteria as a financially sound and strategic opportunity to grow our business. Diagnostic Hybrids and its products are highly regarded in the industry, the company has a leading market share, and its product development pipeline sets a continuing positive trajectory for its business," said Douglas Bryant, president and CEO of Quidel. "In the hospital segment, direct fluorescent assays fill a customer need that is not met by point-of-care lateral flow or molecular diagnostics assays. The combined company will offer the marketplace a continuum of diagnostic tests for triaging patients, confirming diagnoses and providing actionable results to improve patient care," Bryant continued.

Diagnostic Hybrids recognized \$38 million in revenue in 2008, reflecting a three-year compounded annual organic growth rate of 21%.

"Diagnostic Hybrids will broaden Quidel's current portfolio into complementary non-seasonal infectious and autoimmune diseases and help diversify our revenue base. Moreover, Diagnostic Hybrids has a solid track record of generating strong and profitable sales growth," said Bryant.

"Quidel is a synergistic and cultural fit for Diagnostic Hybrids and this transaction presents us with an excellent opportunity to have a larger presence in our markets and to leverage key aspects of our research and development teams to accelerate product development," said David Scholl, Ph.D., president and CEO of Diagnostic Hybrids. "Our combined organization will have greater channel strength and together we will provide our customers a full service offering of best-in-class diagnostic products."

Quidel plans to operate Diagnostic Hybrids as a separate subsidiary, and Dr. Scholl will remain as president of Diagnostic Hybrids and become a senior vice president of Quidel. The acquisition is subject to customary closing conditions including expiration of the waiting period under the Hart-Scott-Rodino Act, and is expected to close in the first quarter of 2010. William Blair & Company, L.L.C. acted as the exclusive financial advisor to Diagnostic Hybrids.

January 11, 2010

Quidel Corporation Announces Definitive Agreement Axis-Shield Granted US Patent For Active-B12 Test

Axis-Shield the international *in vitro* diagnostics company, today announces that it has been granted a US patent for its technology governing the specific detection of Active-B12, or holo-transcobalamin (holoTC), as a more effective way of determining vitamin B₁₂ deficiency. The newly granted patent lasts until 2024.

HoloTC is the biologically available form of vitamin B₁₂. In this specific form it is transported to body tissues and absorbed by cells. Deficiency of vitamin B₁₂ is now a major problem, particularly in elderly populations where the availability of the binding protein Intrinsic Factor, needed in the absorption of this important vitamin, has often been compromised by long-term use of drugs affecting gastric acidity. Vitamin B₁₂ plays an important role in creating red blood cells and keeping the nervous system healthy. It is also needed to absorb folic acid and helps to release energy. Vitamin B₁₂ deficiency should be suspected in all patients with unexplained anaemia and/or neurological symptoms. The elderly, neuropsychiatric and psychiatric patients, and those adhering to a vegetarian diet, are amongst the groups at risk.

Axis-Shield's test is available on the widely-placed AxSYM® analyser from Abbott Diagnostics. A manual ELISA test and an assay on Abbott's highest throughput ARCHITECT® system are in development. A recent symposium on Active-B12 held at the June Euromedlab/IFCC meeting in Innsbruck, Austria, attracted considerable interest and key opinion leaders argued that the assay should now be considered as a replacement for the routine measurement of total B₁₂.

Ian Gilham, CEO of Axis-Shield, commented: "Our global patent coverage for this important assay has been further strengthened with the approval of this US patent application, which highlights the unique approach of our specific detection of holoTC. We are currently seeking to make this analyte available on a wider range of instrument platforms and the strength of our intellectual property will be an important factor in achieving this goal."

January 4, 2010

Cepheid Receives FDA Emergency Use Authorization (EUA) for First 2009 H1N1 Influenza Assay for CLIA 'Moderate Complexity' Laboratories

Cepheid today announced it has been granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Xpert® Flu A Panel test. The test, which runs on Cepheid's GeneXpert® System, identifies the 2009 H1N1 influenza virus in less than one hour. The FDA has authorized Cepheid's Xpert Flu A Panel to be used in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform "moderate complexity" (not waived) testing, enabling the test to be performed in hospital near-patient settings.

"Accuracy combined with ease-of-use and the broad testing applicability of the GeneXpert® System offers a helpful unique diagnostic solution in helping to address this healthcare issue," said John Bishop, Cepheid's Chief Executive Officer. "Although PCR testing is now recognized as the new gold standard for detection of influenza virus infection, test availability for 2009 H1N1 has so far been limited to high-complexity laboratories and results are not typically available around the clock. Xpert Flu A Panel combines the convenience and ease-of-use of rapid testing with the performance of PCR, in a test format that maximizes medical value by providing results when they are most needed."

2009 H1N1 is a new influenza virus that was detected in the United States in April 2009. As such, children and younger adults are less likely than older people to have immunity to this virus, and illness may be more severe and widespread as a result.(1) In

June 2009, the World Health Organization (WHO) announced the spread of the novel 2009 H1N1 virus had reached pandemic phase 6, the highest level of pandemic alert designated by the organization.

"So far, 2009 H1N1 appears to be the predominant influenza strain this season," said Dr. Preveen Ramamoorthy, director of molecular diagnostics at National Jewish Health in Denver CO. "An easy-to-use, rapid PCR-based 2009 H1N1 test can assist clinicians in making real-time medical decisions that help hospitals significantly improve their patient management."

Cepheid will continue development of an expanded influenza panel product that it expects to test for Influenza A with strain identification for H1 seasonal and H3 seasonal influenza A subtypes, the 2009 H1N1 subtype, and Influenza B. For that product, Cepheid expects to submit a separate 510(k) in 2010.

The US Secretary of Health and Human Services has declared a public health emergency because of the outbreak of the pandemic flu virus. The FDA has issued emergency use authorizations to make diagnostic and therapeutic tools available to public health and medical personnel for use in the diagnosis of 2009 H1N1 influenza virus under certain circumstances.

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. The emergency use authorization authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved and uncleared medical products following a determination and declaration of emergency, provided certain criteria are met. The FDA can only grant emergency use authorization for the duration of the emergency, which is currently set to expire on April 26, 2010, unless it is terminated sooner or renewed. The FDA may also revoke an EUA prior to the termination of the emergency.

December 11, 2009

Positive Interim Analysis Supports Early Closure Of Heart Failure Trial

Roche and study investigators at the Massachusetts General Hospital have announced today that active enrollment into the Pro-BNP Outpatient Tailored Congestive Heart Failure Therapy (PROTECT) study (Clinical Trials.gov identifier: NCT00351390) has been stopped early based on a positive interim analysis.

PROTECT, a prospective randomized trial comparing a strategy of aggressive heart failure therapy guided by levels of a cardiac hormone— amino-terminal pro-B type natriuretic peptide (NT-proBNP)— versus standard heart failure treatment without NT-proBNP guidance has been enrolling subjects in the Heart Center at the Massachusetts General Hospital since 2006.

The positive interim analysis suggests a strategy of NT-proBNP guided heart failure care was independently associated with a significant reduction in total cardiovascular events, the primary endpoint of the study, which included relevant cardiac outcomes, such as worsening heart failure, heart failure hospitalization, and cardiovascular death.

Tests for NT-proBNP, a cardiac hormone that is released into the blood when the heart wall is stretched, are developed and marketed by Roche. NT-proBNP was approved by the US Food and Drug Administration (FDA) as an objective marker for the diagnosis and prognosis of heart failure as well as the risk assessment in patients with acute coronary syndrome.

Commenting on the trial's early suspension, lead investigator, Dr James Januzzi, Associate Professor of Medicine at Harvard Medical School and Director of the Cardiac Intensive Care Unit at the Massachusetts General Hospital said: "There are few reasons to stop a trial early, the most compelling of which is unequivocal success. In the case of PROTECT, the data from interim analysis of the study appear to indicate a significant difference between the treatment arms in favor of the NT-proBNP group."

Concentrations of NT-proBNP are known to be predictive of future risk in chronic heart failure. However, while therapies for heart failure that improve patient outcomes are known to lower NT-proBNP values, the strategy to actively "guide" heart failure therapy by combining standard clinical titration of medications together with a targeted strategy to lower NT-proBNP values (with the hope to reduce events further than heart failure therapy guided by clinical judgment alone) remains to be proven.

In the PROTECT study, patients with chronic systolic heart failure (left ventricular ejection fraction <40%) were randomized to one of two treatment approaches: a standard-of-care arm, where patients received aggressive guideline-compliant heart failure care, and an NT-proBNP arm, where patients were treated with similar aggressive clinical care, but investigators also aimed to decrease NT-proBNP concentrations to a level below 1,000 pg/mL, a value below which previous studies have shown the cardiovascular event risk in heart failure to be considerably lower.(2)

"The decision to stop the trial indicates strong potential for the guided therapy approach," Januzzi continued. "While previous studies have returned mixed results with respect to the approach of "guided therapy" with natriuretic peptide testing, the reduction in total cardiovascular events in the NT-proBNP arm suggests the important role of this cardiac hormone in the management of heart failure," he said.

The trial is now closed. Final patient visits will be carried out and final data will be collected to allow a full analysis. Final results of the study will be presented and published in 2010, once the analysis is complete.

Besides the primary endpoint of total cardiovascular events over a one year period, other endpoints in PROTECT will include effects of NT-proBNP guidance on quality of life, effect of NT-proBNP guided care on cardiac structure and function, and overall costs of care.

It is estimated that as many as five million Americans have heart failure, with 400,000-500,000 new cases/year; the diagnosis carries a mortality rate that exceeds many cancers. Heart failure ranks among the most costly chronic conditions in developed countries, with the burden being greatest among the elderly. Heart failure hospitalization represents a major burden on the health care system.

“Given this rapidly increasing incidence of heart failure, and relative shortage of novel therapies for diagnosis, a new strategy of care utilizing existing therapies including the intention to not only address symptoms, but also to lower NT-proBNP concentrations with the goal of reducing risk in parallel, would not only contribute to better patient outcomes but also likely reduce healthcare costs. We are excited to see the full results of the trial, and ascertain next steps for proceeding forwards with the concept of biomarker guided heart failure care,” concluded Dr Januzzi.

December 17, 2009

Molecular Basis of Colorectal Cancer Review Points to Key Advances

Every year in the United States, 160,000 cases of colorectal cancer are diagnosed, and 57,000 patients die of the disease, making it the second leading cause of death from cancer among adults, after lung cancer.

As researchers and clinicians fervently look for causes and cures for colorectal cancer -- simultaneously generating thousands of studies producing more and more promising results -- Dr. Sanford Markowitz, professor and researcher of cancer and genetics at Case Western Reserve University School of Medicine and oncologist at the Case Comprehensive Cancer Center at University Hospitals Case Medical Center, published his forward-looking view of the "Molecular Basis of Colorectal Cancer" in the Dec. 17, 2009 issue of the *New England Journal of Medicine*, with co-author, Dr. Monica Bertagnolli, from the Brigham and Women's Hospital, Harvard Medical School.

"Today's challenges are to understand the molecular basis of individual susceptibility to colorectal cancer and to determine factors that initiate the development of the tumor, drive its progression, and determine its responsiveness or resistance to antitumor agents," wrote Dr. Markowitz.

Key advances that the article singled out toward meeting these goals are:

Discoveries in DNA sequencing technology have made it possible to sequence the entire genome of a human cancer. Colorectal cancer provided the first example of the power of this technology. Sequencing of 18,000 (nearly all) of the known human genes in 35 colon cancers identified 140 as candidate cancer genes that were mutated in at least two colon cancers and that probably contributed to the cancer phenotype.

Biological pathways that are deregulated in colon cancer have been identified, and could now form the basis of new therapeutic agents. Although some high-frequency mutations are attractive targets for drug development, common signaling pathways downstream from these mutations may also be tractable as therapeutic targets.

Studies that aid in the understanding of colorectal cancer on a molecular level have provided important tools for genetic testing for high-risk familial forms of the disease, predictive markers for selecting patients for certain classes of drug therapies and molecular diagnostics for the noninvasive detection of early cancers.

Recent progress in molecular assays for the early detection of colorectal cancer indicates that understanding the genes and pathways that control the earliest steps of the disease, and individual susceptibility, can contribute to clinical management in the near term. For example, patients whose colon cancers have mutations in either RAS or BRAF genes are known not to benefit from treatment with the anti-colon cancer agent Cetuximab.

Moreover, patients with inherited mutations in tumor-suppressor genes, such as APC, MLH1, and MSH2 have a very high risk of colorectal cancer and require early and frequent surveillance for colon cancer and often prophylactic surgery.

Last, the development of molecular diagnostics for the early detection of colorectal cancer is emerging as an important translation of colon-cancer genetics into clinical practice. One example is the development of stool DNA tests to detect cancer-associated aberrant DNA methylation as a method for early detection of patients with colorectal cancer or advanced adenomas. Stool DNA testing for colorectal cancer has been added to the cancer-screening guidelines of the American Cancer Society.

Dr. Markowitz and Bertagnoli's concluding observations are optimistic ones that the considerable recent and ongoing advances in our knowledge of the molecular basis of

colorectal cancer will continue to result in markedly reducing the burden of this disease.

Dr. Markowitz reports being listed on patents licensed to Exact Sciences and LabCorp and is entitled to receive royalties on sales of products related to methylated vimentin DNA, in accordance with the policies of Case Western Reserve University. No other potential conflict of interest relevant to this article was reported.

December 9, 2009

QIAGEN Announces Closing Of The Acquisition Of SABiosciences

QIAGEN today announced the completion of its previously announced acquisition of SABiosciences Corporation, a privately-held developer and manufacturer of disease- and pathway-focused PCR assay panels based in Frederick, Maryland (USA).

"We are pleased to now have completed the transaction", said Peer M. Schatz, Chief Executive Officer of QIAGEN. "Together with our new colleagues we will initiate the integration process. We believe this process will be a quick and smooth one - given the high level of complementarities. I would like to use this opportunity to welcome our new employees to QIAGEN. Their competence will help us leverage the combined Company's value proposition in the field of biomarker discovery and validation for the development of future diagnostics and pharmaceuticals."

SABiosciences brings to QIAGEN a unique position in the design and commercialization of more than 100 PCR assay panels which allow for high-performance analysis of DNA, RNA, epigenetic and microRNA targets in biological pathways associated with specific diseases or with defined pathways. These assay panels may be operated on QIAGEN instruments in the future. QIAGEN expects that the combined offering will strengthen its position as a premium partner for the pharmaceutical industry and to yield content for its three molecular diagnostic segments: prevention, profiling and personalized healthcare.

QIAGEN had already disclosed its intention to expand the business of disease- and pathway-focused assay panels and to further grow SABiosciences' Frederick site as a Center of Excellence in biological content development. The proximity to QIAGEN's North American headquarters in Maryland is expected to contribute to a rapid and smooth integration.

Until further notice, customers in the U.S. can continue to order PCR assay panels

from SABiosciences' website at www.sabiosciences.com, while customers based outside the U.S. can order from their local distributors.

In the November 9 announcement of the acquisition, QIAGEN said it expects the transaction:

To add revenues of approximately US\$24 million in sales for 2010. The growth rate on these US\$24 million in revenues is expected above QIAGEN's average growth rate.

To incur one-time charges of approximately US\$0.02 in earnings per share (EPS) in the last quarter of 2009 which primarily relates to costs and expenses incurred in connection with the acquisition such as advisory fees as well as the write-off of certain assets.

To be neutral to EPS in 2010 on an adjusted basis excluding one-time charges, integration and restructuring costs, and amortization of acquisition related intangible assets, and to be significantly accretive to adjusted EPS in 2011.

The transaction was valued at approximately US\$90 million in cash subject to customary purchase price adjustments.

December 9, 2009

biomerieux Announces New Hospital Solution To Optimize Antibiotic Therapy Management

bioMerieux, a world leader in the field of in vitro diagnostics, announced the upcoming availability of ABxAlert® from ICNet International Ltd., a global clinical informatics company, at the 44th American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. ABxAlert is a web-enabled application to help hospital clinicians ensure patients with suspected or identified microbial infections receive the optimized antimicrobial therapy based on real-time data. The ABxAlert system is based on antibiotic, antifungal, and antiviral best practices as described in the Antibiotic Stewardship Position Paper published jointly in January 2007 by the Infectious Disease Society of America/Society for Healthcare Epidemiology of America (IDSA/SHEA).

Microbial strains--fungal, viral, and bacterial--vary dramatically around the globe. The strains can also vary regionally, from one hospital to another in the same city, or even from floor to floor in the same institution. This variety has a significant impact on appropriate antibiotic or antifungal selection. Institutional information about microbial drug sensitivity, called antibiogram data, is not always immediately available to the

hospital pharmacists or clinicians. An antibiotic that is effective against one strain of bacteria may not be effective against a slightly altered version of the same strain. The antibiogram information gap often results in patients receiving an antimicrobial treatment for an infection that is less than optimal.

The AbxAlert is a complement to ICNet, a web-enabled application that helps hospitals reduce medication costs through more expeditious and appropriate use of real-time microbiology diagnostic data management, surveillance and reporting. The use of the software can assist in decreasing the risk of spreading preventable infections through timelier root cause analysis once a problem has been identified.

In addition to prolonging illness and causing undue suffering, this "bug-drug" mismatch can contribute to the rising tide of antibiotic-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE). These resistant bacteria and other multi-drug resistant organisms are key contributors to the excessive burden of unnecessary medical costs brought on by lengthened hospital stays (6.4-12.7 days) and increased patient mortality (6.5%) within a single Chicago teaching hospital as reported in a recent study by Roberts et al.(1) published in *Clinical Infectious Diseases*. The goal of good clinical practice, often called "antimicrobial stewardship," is to treat patients with the appropriate antimicrobial drug as fast as possible in order to get them off of therapy as soon as the infection has been treated.

"Clinical pharmacists are critical consultants to physicians during the process of selecting the optimal antibiotic or antifungal therapy," said Herb Steward, executive vice president and general manager of bioMerieux North America. "ICNet's ABxAlert provides pharmacists with invaluable alerts when a potential bug-drug mismatch has occurred--this has a huge potential upside for improved patient outcomes and better antibiotic stewardship."

In January of 2009, bioMerieux and ICNet Systems, Inc. entered into an exclusive referral agreement for infection prevention and case management surveillance (HAI) software made by ICNet. The ABxAlert announcement is an extension of this agreement.
