

# Diagnostic Testing and Healthcare Industry News Update

August 1, 2012

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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***

For more information please contact Edward Weiner at **(508) 328-6800** or e-mail us at: **[EMMES@aol.com](mailto:EMMES@aol.com)**



# Diagnostic Testing and Healthcare Industry News Update

August 1, 2012

July 31, 2012

## Emmes Study: Considerable Percent of MDx Labs Are Using Culture/Non-Molecular Means For Key Tests

While molecular diagnostics has become a dominant platform and represents one of the fastest growing segments of the Dx market, a significant percent of laboratories that perform MDx testing are using culture, or other non-molecular methods to test for key analytes such as MRSA, HSV, Group A or B Strep, Flu A/B, TB, VRE and others.

The Emmes 2012 MDx database – a collection of comprehensive MDx testing data for over 30 analytes as performed by 1,000 labs across the US – provides detailed evidence of this trend. Below is an example of just one data view (of 43) from the Emmes database for one lab (of 1,000) that uses non-molecular methods:

Emmes 2012 MDx Testing Database										
Account: <input type="text" value="Henry Ford Hospital"/>					Type of Institution: <input type="text" value="Hospital"/>		Hospital Size: <input type="text" value="Large"/>			Month of Interview: <input type="text" value="March"/>
Address: <input type="text" value="2799 West Grand Blvd."/>					Labs Performing MDx Testing: <input type="text" value="Microbiology"/>					Year of Interview: <input type="text" value="2012"/>
City: <input type="text" value="Detroit"/>	State: <input type="text" value="MI"/>	Zip: <input type="text" value="48202"/>	Telephone: <input type="text" value="313-916-2335"/>		Annual MDx Test Vol.: <input type="text" value="77,220"/>		Interview Number: <input type="text" value="313"/>	Number of Beds: <input type="text" value="743"/>		
CULTURE/OTHER MEANS					MDx					
Test	Perform Culture	Annual Culture Volume	Culture Kit/ Method	Lab In Which Culture Testing is Performed	Perform MDX	Annual MDX Volume	MDX Extraction Kit/Method	MDX Platform	Lab In Which MDX Testing is Performed	
Bordetella	no				YES	260	Cepheid – Bordetella (ASR)	Cepheid - SmartCycler	Microbiology	
C. Diff	no				YES	780	BD - C-Diff	Cepheid - SmartCycler	Microbiology	
Group A Strep	YES	13,000	Culture Plate	Microbiology	no					
Group B Strep	YES	5,200	Culture Plate	Microbiology	no					
HSV	YES	2,400	Shell Vial	Microbiology	YES	780	Cepheid - HSV (ASR)	Cepheid - SmartCycler	Microbiology	
Influenza A/B	YES	1,040	Shell Vial	Microbiology	no					
MRSA	YES	52	Culture Plate	Microbiology	no					
SA	YES	1,040	Culture Plate	Microbiology	no					
TB	YES	4,680	Culture Plate	Microbiology	no					
Trichomoniasis	no				no					
VRE	YES	12	Culture Plate	Microbiology	no					

Below is another data view (basic display view – one of 43) of information in the 2012 MDx database. For further information, please contact:

**Edward Weiner**  
**E-Mail: ed\_weiner@emmesgroup.com**  
**Telephone: 508-328-6800**

Emmes 2012 MDx Testing Database																																																																																																																																																																																																																
Account: <b>Maine Medical Center</b>				Type of Institution: <b>Hospital</b>		Hospital Size: <b>Large</b>		Month of Interview: <b>March</b>																																																																																																																																																																																																								
Address: <b>301 A US Route 1</b>				Labs Performing MDx Testing: <b>Molecular Microbiology</b>		Interview Number: <b>326</b>		Year of Interview: <b>2012</b>																																																																																																																																																																																																								
City: <b>Scarborough</b>		State: <b>ME</b>	Zip: <b>04074</b>		Annual MDx Test Vol.: <b>50,120</b>		Number of Beds: <b>641</b>																																																																																																																																																																																																									
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July 30, 2012

## 23andMe, DNA Test Maker, Seeks FDA Approval For Personal Kits

Genetic test maker 23andMe is asking the Food and Drug Administration to approve its personalized DNA test in a move that, if successful, could boost acceptance of technology that is viewed skeptically by leading scientists who question its usefulness.

23andMe is part of a fledgling industry that allows consumers to peek into their genetic code for details about their ancestry and future health. The company's saliva-based kits have attracted scrutiny for claiming to help users detect whether they are likely to develop illnesses like breast cancer, heart disease and Alzheimer's.

The biology of how DNA variations actually lead to certain diseases is still poorly understood, and many geneticists say such tests are built on flimsy evidence.

For years, the Silicon Valley company has resisted government regulation, arguing that it simply provides consumers with information, not a medical service. But now company executives say they are seeking government approval — and the scientific credibility that comes with it.

"It's the next step for us to work with the FDA and actually say, 'this is clinically relevant information and consumers should work with their physicians on what to do with it,' " said CEO and co-founder Anne Wojcicki, who is married to Google co-founder Sergey Brin. Google and Brin have invested millions in the privately held company, which is based in Mountain View, Calif.

Wojcicki says the shift in strategy reflects the growing scope of the company's test kit, which now measures the risks of developing more than 115 different diseases.

23andMe said Monday it submitted an initial batch of seven health-related tests to the FDA for review. The company plans to submit 100 additional tests in separate installments before the end of the year. Tests involving family history and nonmedical traits will not be reviewed, since they don't fall under FDA oversight.

Even some of the harshest critics of the genetic testing industry say 23andMe is taking the right approach.

Dr. James Evans of University of North Carolina said he considers much of the information reported by 23andMe, "relatively useless," and "in the realm of entertainment." He believes patients benefit more from pursuing a healthy lifestyle than parsing the potential risks of developing various diseases.

But as test makers begin analyzing larger portions of genetic code, there are rare

cases when the findings may help doctors identify patients with a higher risk of treatable health problems, such as aneurysms or colon cancer.

"I think we've now entered an era where these direct-to-consumer offerings are beginning to have real medical relevance, and therefore I am in favor of them being done within some regulatory context," said Evans, a professor of genetics and medicine at UNC's Medical School. The move may also give 23andMe a competitive edge over rivals like deCODE Genetics and Navigenics, which market similar tests. Those companies did not respond to requests for comment Monday.

"We really want to take a leadership role in this industry," said 23andMe's chief legal officer, Ashley Gould. The company says more than 150,000 people worldwide have used its test, which sells for \$299 online.

The FDA already regulates a variety of genetic tests administered by health care providers, such as those given to pregnant women to detect cystic fibrosis in a developing fetus.

But it remains to be seen whether the FDA will endorse 23andMe's commercial approach, which sidesteps doctors by sending results directly to consumers. 23andMe and its peers believe there is a mainstream market for personalized genetic information, though it is still very much a niche field.

23andMe executives point out that they first contacted the FDA in 2007, before launching their product. The agency did not take an interest in the technology until 2010, when it issued letters to several testing companies, stating that their products are considered medical devices and must be approved as safe and effective.

Washington's pressure on the industry intensified a month later, when federal investigators issued a scathing report saying that companies like 23andMe produced misleading information of little to no use.

An undercover investigation by the Government Accountability Office found that four genetic testing companies delivered contradictory predictions based on the same person's DNA, which often contradicted the patient's actual medical history.

Proponents of genetic testing say 23andMe's bid for FDA approval is an important step in regulating an emerging application for genetic information.

"Many consumers are going to want to know this information, and you don't need a hospital to obtain it, so it's important to make sure it's well regulated," said Dr. Eric Lander, president and director of the Broad Institute, a genomic research center affiliated with Harvard University and the Massachusetts Institute of Technology. "I think 23andMe is taking a very forward-leaning step."

July 26, 2012

## FDA Clears Roche's Vitamin D Laboratory Test

Roche announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) for a fully automated vitamin D test for use on cobas modular platforms, further expanding the company's bone metabolism test menu.

Vitamin D is an important building block for human health and is mainly produced in the skin by exposure to sunlight. Vitamin D deficiency plays a major role in bone metabolism disorders, and in recent years studies have linked vitamin D deficiency with many other disease states, including cancer, cardiovascular disease and diabetes. "The demand for vitamin D testing in the U.S. is increasing rapidly, and having a large installed base of cobas analyzers will allow labs to easily respond to that demand and integrate the Roche test into their existing workflow," said Daniel O' Day, Chief Operating Officer of Roche Diagnostics. "Adding this test enables them to offer precise and accurate results to help clinicians assess vitamin D sufficiency in adult patients so they can provide optimal care."

An estimated one billion people suffer from vitamin D deficiency worldwide.

The Elecsys Vitamin D assay measures both vitamin D2 and D3, which is important for physicians who have patients taking different forms of vitamin D supplements. Test results are obtained using Roche's patented electrochemiluminescence (ECL) detection technology, which provides a broad measuring range and high precision at the low end of detection to aid in the assessment of severely deficient patients.

The test will be available for use on all of Roche's cobas modular analyzer platforms. Roche also has a vitamin D test available in Europe accepting the CE mark.

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July 25, 2012

## Cepheid Announces Release Of Updated Xpert BCR-ABL Monitor Test

Cepheid today announced the release of an updated Xpert<sup>®</sup> BCR-ABL Monitor test, now incorporating lot-specific standardization using the WHO (World Health Organization) BCR-ABL standards. The test is being released as a European CE-IVD Mark product under the European Directive on *In Vitro* Diagnostic Medical Devices. The test, which runs on Cepheid's GeneXpert<sup>®</sup> System, detects the BCR-ABL mRNA transcript in the peripheral blood of patients with Chronic Myelogenous Leukemia (CML) in about two hours.

“Our work in the CML area is the first of several initiatives we are developing as we extend the GeneXpert System test menu into a new line of molecular diagnostic oncology products,” said John Bishop, Cepheid’s Chief Executive Officer.

“The new lot-specific standardization translates to even greater clinical accuracy for physicians as they compare BCR-ABL values over time within the same patient, as well as comparability across geographic locations where testing is being performed.”

“We have used and endorsed Xpert BCR-ABL Monitor in our research efforts for several years,” commented Dr. Jerald Radich, head of the Molecular Oncology Lab at the Fred Hutchinson Cancer Research Center. “Lot-to-lot standardization to the WHO benchmark improves reliability and comparability between labs. This will facilitate both patient care and clinical research studies which rely on BCR-ABL testing as a benchmark of response.”

CML is a cancer of the myeloid lineage of leukocytes (white blood cells) that is characterized by the presence of the “Philadelphia Chromosome,” a reciprocal translocation of chromosomes 9 and 22 that results in the generation of the BCR-ABL fusion gene. The BCR-ABL protein functions as a constitutively activated tyrosine kinase that drives the proliferation of immature myeloid cells.

If untreated, CML progresses within several years from a chronic phase to accelerated phase or blast crisis, where survival is often measured in months. The introduction of the targeted Tyrosine Kinase Inhibitors (TKIs) imatinib, dasatinib, and nilotinib has had a profound impact on the survival of patients with CML.

Since their introduction, CML has been transformed into a chronic condition with a good long-term prognosis. Monitoring the levels of BCR-ABL mRNA transcript in the blood of CML patients on TKIs using real-time quantitative PCR has become standard of care in the management of CML. The goal of treatment is to reach a major molecular response (MMR), defined as a 3 log reduction (< 0.1%) in BCR-ABL mRNA levels from a standardized baseline as defined by the International Scale<sup>1,2</sup>.

In order to accurately assess treatment response, it is essential that variability in testing methodologies be tightly controlled. This has resulted in substantial efforts to standardize BCR-ABL molecular testing across laboratories by introducing an International Scale<sup>3,4</sup>.

Cepheid has now enhanced this validation effort by controlling variation between each lot of manufactured product. The updated Xpert BCR-ABL Monitor, with lot-specific standardization, is now available as a CE-IVD Mark product

July 9, 2012

## **BD Diagnostics Gets FDA Clearance To Market BD MAX MRSA Molecular Test In US**

BD Diagnostics, today announced it received FDA clearance to market the BD MAX™ MRSA molecular test in the United States.

The assay is performed on the fully-automated BD MAX™ System and is designed to rapidly and accurately identify patients colonized with methicillin-resistant *Staphylococcus aureus* (MRSA). Rapidly and accurately identifying patients enables infection control measures to be implemented faster to reduce transmission and help prevent infection in vulnerable patients.

"The BD MAX MRSA assay is an easy-to-use, cost-effective method to identify patients colonized with this deadly superbug, which may support better outcomes for the patient and a safer hospital environment," said Tom Polen, President, BD Diagnostics – Diagnostic Systems. "FDA clearance of the BD MAX MRSA test gives our customers a new level of automation to optimize MRSA surveillance testing."

According to the Institute for Healthcare Improvement, the total cost burden to the U.S. healthcare system from MRSA infections is estimated at more than \$2.5 billion annually. MRSA infections primarily occur in people who have been in hospitals or other healthcare settings. MRSA can spread among patients or healthcare workers via direct contact with colonized patients and/or hospital surfaces. Early identification of patients colonized with MRSA helps reduce the risk of transmission and infection, and helps to improve patient outcomes.

"BD MAX is an automated, bench-top molecular system designed to perform a broad range of molecular testing, offering unmatched flexibility and versatility," said Thomas Davis, M.D., Ph.D., Professor, Pathology and Laboratory Medicine at the Indiana University School of Medicine, and Pathologist with Wishard Health Services and Indiana University Health Laboratories.

"As the BD MAX assay portfolio continues to grow, the walk-away automation, standardized workflow and ease-of-use of the BD MAX System will allow laboratories to increase both the menu and efficiency of molecular testing to better meet the demands of clinicians."

The BD MAX MRSA assay is the second test cleared this year by the FDA on the BD MAX System. This milestone represents further confirmation of BD's commitment to rapidly expand its menu, enabling laboratories to offer a broad range of molecular tests that meet both their current and future clinical needs.

**July 31, 2012**

## **GenMark Advanced Liquid Logic To Develop an All-Digital Fully Integrated Diagnostic Platform**

GenMark Diagnostics, Inc., (NASDAQ: GNMK) and Advanced Liquid Logic, Inc. (ALL) announced today that they have executed definitive agreements pursuant to which GenMark and ALL will collaborate to develop an all-digital, fully integrated in-vitro diagnostic platform bringing together ALL's proprietary electrowetting technology and GenMark's proprietary electrochemical detection. The agreements follow from the Heads of Agreement entered into by GenMark and ALL on March 30, 2012.

GenMark Diagnostics is a leading provider of automated, multiplex molecular diagnostic testing systems that detect and measure DNA and RNA targets to diagnose disease and optimize patient treatment. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's eSensor® XT-8 system is designed to support a broad range of molecular diagnostic tests with a compact, easy-to-use workstation and self-contained, disposable test cartridges. GenMark currently markets three tests that are FDA cleared for IVD use: Cystic Fibrosis Genotyping Test, Warfarin Sensitivity Test, and Thrombophilia Risk Test. A Respiratory Viral Panel (RVP) has been submitted to the FDA for 510(k) clearance. A number of other tests, including HCV Genotyping and 2C19, versions of which are available for research use only, and KRAS, are in development for IVD use.

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**July 18, 2012**

## **Siemens Launches Next Generation Automation Solution 'Aptio' at AACC 2012**

Today, Siemens Healthcare Diagnostics launched Aptio™ Automation<sup>1</sup>, the company's next generation laboratory automation platform, at the 2012 AACC and ASCLS Annual Meetings and Clinical Lab Expo in Los Angeles. Aptio Automation promises to transform laboratory operations by combining Siemens' industry-leading workflow expertise with peak performance, adaptability and intelligent technology.

Increasingly, clinical laboratories are turning to automation to help them meet the growing demand for in vitro diagnostic testing in the face of a shrinking labor force. And, these trends are only expected to continue, as approximately 17 percent of laboratory professionals are anticipated to retire in the next five years.<sup>2</sup> By 2014, it's estimated that the United States alone will need 81,000 additional medical technologists and technicians to replace retiring staff, plus 68,000 more to fill newly

created positions.<sup>3</sup> Aptio Automation is an adaptable solution that allows for a phased implementation to accommodate both current and future needs of medium- to very high-volume laboratories.

William Bartlett, Ph.D., Joint Clinical Director of Diagnostics at the UK's NHS Tayside, one of the first laboratories to deploy Aptio Automation, said: "We chose Aptio Automation because it can handle increasing workloads while enabling us to use our staff better. We expect that the implementation of this new platform will allow us to provide a state-of-the-art service that aligns the lab function with Tayside's overall goals for organizational sustainability and improved patient outcomes.

"With every laboratory configured differently and floor space at a premium, Aptio Automation's circular track and modular design ensure it can adapt to nearly any lab or testing environment. It also offers connectivity to Siemens' portfolio of automation-ready analyzers, thus facilitating a multidisciplinary approach to testing. Further, Aptio Automation's point-in-space aspiration feature helps streamline workflow by reducing the need to aliquot (or divide) samples, and its puck-based system with RFID enables individual sample routing and tracking, along with STAT prioritization.

Additionally, Aptio Automation delivers comprehensive analytics via powerful, centralized information technology, while having the flexibility to provide pre- and post-analytical capabilities. Siemens' CentraLink™ Data Management System facilitates efficient sample flow, auto-verification, quick access to samples and proactive quality control (QC). Plus, the CentraLink System can be customized per end user, speeding up system access and supporting error reduction.

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**July 11, 2012**

## **Hologic And Gen-Probe Provide Update On Pending Transaction**

Hologic and Gen-Probe today provided an update regarding Hologic's previously announced acquisition of Gen-Probe. Gen-Probe has scheduled a Special Meeting of Stockholders for July 31, 2012 to vote on the pending transaction with Hologic. Gen-Probe stockholders of record as of June 29, 2012 are entitled to vote at the Special Meeting. The transaction is expected to close on or about August 1, 2012.

Hologic and Gen-Probe today announced that Carl Hull, Chairman and Chief Executive Officer of Gen-Probe, has entered into an agreement to continue his employment with the combined company for a minimum period of 15 months. Mr. Hull will serve as senior vice president and general manager of the combined company's Diagnostics

business, which will include Gen-Probe's current operations, as well as Hologic's Diagnostics segment. Additional members of the Gen-Probe management team are also being offered ongoing employment arrangements with Hologic.

The companies also confirmed that integration planning efforts are well underway and continue to proceed as planned. Integration planning teams at both companies have made significant progress in identifying critical integration issues, establishing objectives and targeted synergies for each area of the combined business, and developing a timeline to achieve certain synergies, which also includes other key milestone dates and events. Hologic expects to implement critical phases of this integration process immediately following closing with additional phases continuing over the next 24 months.

"We are making great progress toward completing the acquisition of Gen-Probe, which will strengthen our growing diagnostics portfolio and advance our presence in the overall molecular diagnostics market," said Rob Cascella CEO of Hologic. "The global outlook for diagnostics is compelling and as a combined company we expect to capitalize on the significant opportunities in the market. Hologic and Gen-Probe have a comprehensive and robust integration plan that we believe will position the combined company to deliver on the financial, operational and strategic benefits of this acquisition. I am confident the integration implementation will be efficiently executed upon the closing of the transaction and that our combined teams and product lines will create significant value for all of our stakeholders."

"As we move forward with the integration planning, I am confident that we will be able to achieve the expected benefits of this transaction," said Carl Hull, Chairman and Chief Executive Officer of Gen-Probe. "The combined company will have an impressive new product pipeline and broader research and development capabilities, with a strong sales force and talented employees that will position Hologic for continued success in the fast-growing molecular diagnostics market. I am committed to working with Rob and our combined teams and fully expect a smooth integration."

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**July 25, 2012**

## **IntelligentMDx's Automated Molecular Test Gets CE Mark For Detection And Differentiation Of HSV 1 & 2**

IntelligentMDx, has obtained CE-marking for its fourth automated, high-throughput molecular test designed and developed for the Abbott m2000 System. The IMDx HSV-1/2 for Abbott m2000 detects Herpes Simplex Virus (HSV) viral DNA and differentiates HSV-1 and HSV-2 in male and female genital or oral lesions and cerebral spinal fluid (CSF).

HSV is the most common cause of genital and oral lesions, but can also invade other human tissue, occasionally causing keratitis, encephalitis, meningitis, and neonatal sepsis.

“We are proud to play a role in easing the global burden of herpes virus infections through rapid and precise diagnostics,” says Dr Alice Jacobs, MD, chairman and CEO of IntelligentMDx. “Automated, high-throughput molecular diagnostics are becoming the method of choice for fast and reliable diagnosis of infections. The robust performance and automated nature of the IMDx HSV-1/2 for Abbott m2000 assay can aid in the diagnosis of patients and support faster treatment decisions.

”The IMDx HSV-1/2 for Abbott m2000 assay offers a fully automated method for accurate testing of up to 94 patient samples simultaneously in less than 6 hours. Minimal hands-on time is required as results are obtained using a direct swab taken from a symptomatic male or female patient. When compared against clinical samples classified for HSV-1 and HSV-2 using culture and a molecular reference method, the IMDx HSV-1/2 for Abbott m2000 demonstrated 100 per cent sensitivity and 97.2 per cent specificity for HSV-1 and 100 per cent sensitivity and 98.8 per cent specificity for HSV-2.

The IMDx HSV-1/2 for Abbott m2000 assay is part of a series of infectious disease diagnostic tests designed by IMDx for use on the Abbott m2000 system. The IMDx CE-marked test menu for use on the Abbott m2000 system includes real-time PCR assays for the detection of Group B Streptococcus, vancomycin resistant Enterococci (vanA/vanB) and toxigenic C. difficile. This assay is CE-marked and not available for sale in the US or Canada.

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**July 12, 2012**

## **Lab21 Among First to Offer FDA Approved Companion Diagnostic in the US**

Lab21 Limited, the global specialist in personalized medicine and clinical diagnostics is pleased to announce that its CLIA laboratory in Greenville, South Carolina, has been named as one of nine laboratories in the US to offer the first FDA approved companion diagnostic test to provide guidance for the use of Erbitux® (cetuximab).

Recent FDA approval of the Qiagen theascreen KRAS test, allows it to be used to determine whether patients with metastatic colorectal cancer are suitable for treatment with Erbitux. The test has been routinely used in Europe since 2008 and is the first KRAS assay to secure FDA approval.

The availability of this test gives healthcare providers an FDA approved test which provides fast, consistent and reliable data to determine optimal treatment for colorectal cancer patients who are candidates for EGFR-targeted inhibitor therapy.

Lab21 has been providing a KRAS analysis service using the assay from its CPA Accredited laboratory in Cambridge, UK for both Amgen and Merck Serono since 2008, and has performed in excess of 6000 tests during this time, including patient samples originating in a number of countries in Europe and the Middle East.

Michael Bolick, President of Lab21 Inc., commented: "Lab21 Inc. is delighted to have launched the thescreen KRAS assay as part of our initial portfolio of molecular diagnostic tests. As the only laboratory in Qiagen's launch group based in the South-eastern region of the US market, Lab21 is well positioned to be the first provider of this valuable service to the regional cancer community."

Mike Annable, Divisional Director – Clinical Laboratory, added: "Lab21 has significant clinical experience with the thescreen KRAS assay having been one of the first commercial labs to provide this validated assay in the UK. We have been able to leverage this experience during the laboratory validation of the assay for the US market and we are pleased that Erbitux patients can benefit from this experience."

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**June 25, 2012**

## **FDA Approves New Beckman Coulter Blood Test To Improve Prostate Cancer Detection**

Beckman Coulter announces Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) for the Prostate Health Index (*phi*), a simple, non-invasive blood test that is 2.5 times more specific in detecting prostate cancer<sup>1</sup> than PSA (prostate-specific antigen) in patients with PSA values in the 4-10 ng/mL range and is proven to reduce the number of prostate biopsies.<sup>2</sup>

Beckman Coulter's new test provides an answer to the current PSA testing controversy, where prostate cancer screening to save lives has been weighed against over-diagnosis and over-treatment. Last month, the U.S. Preventive Services Task Force (USPSTF) issued a statement indicating the need for "a better test and better treatment options."<sup>3</sup>

"Prostate Health Index is a better test because it provides more accurate information physicians and patients need for better decision-making," said William Catalona, M.D., director of the Clinical Prostate Cancer Program at Northwestern University in Chicago and founder of the Urological Research Foundation. "Now, patients and physicians

wondering what to do with an elevated PSA test result in the 4-10 ng/mL range have a new, non-invasive option. This represents an advance in the science of prostate cancer management."

The *phi* test is indicated for use in men with a PSA in the range of 4-10 ng/mL.<sup>4</sup> Typically, U.S. physicians recommend that men with a PSA in that range consider a prostate biopsy, however, an elevated PSA may be due to benign conditions other than cancer, which can lead to unnecessary biopsies. Prostate Health Index helps physicians distinguish prostate cancer from benign conditions. The results of *phi*'s multi-center clinical study showed a 31 percent reduction in unnecessary biopsies.<sup>1</sup>

Kevin Slawin, M.D., *phi* researcher and founder of the Vanguard Urologic Institute and the Texas Prostate Center at Memorial Hermann-Texas Medical Center added, "Now, with FDA approval in the U.S., *phi* can help physicians discriminate between prostate cancer and benign disease while reducing the number of negative prostate biopsies."

Separately, results from a recent health economic study of *phi* in the U.S. healthcare system suggests the test may help reduce costs associated with prostate cancer detection.<sup>2</sup>

"The Prostate Health Index is the result of years of collaboration with some of the world's leading prostate cancer researchers and medical institutions who have studied the scientific, clinical and economic benefits of *phi*," explained John Blackwood, vice president of Product Management, Beckman Coulter Diagnostics.

Available from Beckman Coulter in Europe since 2010, *phi* will be available in the U.S. in the third quarter of 2012 for use on the company's Access 2 and UniCel DxI immunoassay systems.

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**July 12, 2012**

## **FDA Approves Dako Assays as CDx for Genentech's Breast Cancer Treatment**

Dako announced late on Monday that the US Food and Drug Administration has approved its HercepTest and HER2 FISH pharmDx as companion diagnostics for Genentech's breast cancer drug Perjeta (pertuzumab). FDA also approved the drug.

Dako's assays will be used to identify patients with HER2-positive metastatic breast cancer who may be eligible for treatment with Perjeta and are available immediately.

"The role of HER2 in diagnosis and clinical decision making continues to evolve with the recent approval of Perjeta, a new targeted biologic therapy for patients with advanced HER2-positive breast cancer," David Hicks, director of surgical pathology at the University of Rochester Medical Center, said in a statement. "It is clear that optimal patient care depends now more than ever on the accurate, reliable, and reproducible assessment of the HER2 status for the full benefit of Perjeta to be derived by the appropriate patient population."

Dako, which is in the process of being acquired by Agilent Technologies for \$2.2 billion, and Genentech, a Roche company, announced in late 2011 a partnership to submit Dako's two assays for regulatory approval as companion diagnostics for Perjeta. In addition, the two companies are collaborating on a submission to FDA for the two assays as companion diagnostics for trastuzumab emtansine, an investigational drug candidate for patients with advanced HER2-positive breast cancer.

Dako, based in Denmark, also has similar companion diagnostic deals with Amgen, as well AstraZeneca, and Bristol-Myers Squibb to develop companion diagnostics.

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**June 19, 2012**

## **Epigenomics Licenses Septin9 Biomarker to Companion Dx Lab for Colorectal Cancer Test**

Epigenomics today announced Companion Dx Reference Labs has obtained the rights to establish and commercialize a colorectal cancer test using the methylated Septin9 biomarker.

Under the terms of the deal, Companion Dx will be able to use Epigenomics' biomarker to create a blood-based, laboratory developed test, while Epigenomics is entitled to double-digit royalties on sales of the test. Other terms of the agreement were not disclosed.

"The addition of Septin9 to our offering of cancer related products will allow us to more effectively serve the Texas cancer testing market," Steve Blum, CEO of Companion Dx, said in a statement. "Colorectal cancer is the second leading cause of cancer-related deaths in the US, and we believe that the blood-based method to detect colorectal cancer in the currently non-compliant patient population will improve participation in screening and therefore save more lives in Texas."

Houston-based Companion Dx is a molecular diagnostic reference laboratory offering pharmacogenomic assays and cancer companion diagnostics. Epigenomics has similar licensing agreements with Quest Diagnostics, ARUP

Laboratories, and Warnex Medical Laboratories for use of the Septin 9 biomarker to develop tests. Abbott has a license to develop and commercialize IVD test kits, while Qiagen and Sysmex have acquired options to do so.

Epigenomics is in the midst of filing a premarket approval submission with the US Food and Drug Administration for its Epi proColon blood-based colorectal cancer screening test, which is based on the Septin9 biomarker.

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**July 2, 2012**

## **Great Basin's TB ID/R Molecular Diagnostic Test Detects Mycobacterium Tuberculosis with 96 Percent Accuracy**

Great Basin Corporation, a privately-held molecular diagnostics company developing sample-to-result solutions, announced today that a study published in the July issue of the Journal of Clinical Microbiology demonstrates its TB ID/R assay to be 96 percent accurate in detecting rifampin-resistant Mycobacterium tuberculosis (TB). The assay is currently under development to provide rapid diagnosis and drug susceptibility information for TB.

More than 9.8 million cases of multidrug-resistant Mycobacterium tuberculosis (MDR TB) are reported worldwide each year, and more than half of those previously treated experience repeat infections. TB can be treated effectively if properly identified; however, mistreated or left untreated, can cause drug resistance and can be deadly. Many sources suggest that the main contributor in the delay of TB treatment is poor sensitivity of diagnostic tests.

"The need for improved point-of-care testing for drug resistance in MDR TB is acute, especially in the developing world," said Robert Jenison, CTO of Great Basin Corporation and study co-author. "A significant advantage of the TB ID/R assay is that more information can be added to it to detect additional TB resistance mechanisms, potentially allowing for diagnosis of MDR-TB, even extremely drug-resistant TB (XDR-TB). This diagnostic capability can improve management and treatment for greater numbers of infected patients, further reducing transmission risks."

The study was conducted by researchers from Great Basin Corporation and the Public Health Research Institute Tuberculosis Center at the University of Medicine and Dentistry of New Jersey.

"The data from this study further validates the versatility of Great Basin's technology as a platform for providing fast and accurate answers for some of the world's most vexing infectious diseases," said Ryan Ashton, CEO and president, Great Basin Corporation. "The progress we're seeing on the development of our TB ID/R test, in concert with our

recently-cleared C. diff assay and our product pipeline of staph and fungal detection solutions, means we're executing on our goal of delivering a robust menu of true sample-to-result and cost-effective molecular diagnostic solutions."

Great Basin's technology entails an integrated disposable cartridge containing all necessary reagents and an inexpensive bench-top analyzer that executes the assay, interprets the results and provides eye-visible detection to the clinician. This test is being automated in a manner consistent with the World Health Organization's ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and Robust, Equipment-free and Deliverable to end-users) goals for developing world point-of-care testing for drug-resistant TB.

The lead author of the study is Wanyuan Ao, senior scientist at Great Basin Corporation. In addition to Ao and Jenison, co-authors include Stephen Aldous, Evelyn Woodruff, Brian Hicke and Larry Rea of Great Basin; and Barry Kreiswirth of the Public Health Research Institute Tuberculosis Center, University of Medicine and Dentistry of New Jersey.

Great Basin Corporation is a privately held molecular diagnostics company that commercializes breakthrough chip-based technologies. The company is dedicated to the development of simple, yet powerful, sample-to-result technology and products that provide fast, multiple-pathogen diagnoses of infectious diseases. By providing more diagnostic data per sample, healthcare providers are able to treat patients with the right medication sooner, improving outcomes and reducing costs. The company's vision is to make molecular diagnostic testing so simple and cost-effective that every patient will be tested for every serious infection, reducing misdiagnoses and significantly limiting the spread of infectious disease.

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**July 9, 2012**

## **Luminex Corporation Announces Agreement to Acquire GenturaDx**

Luminex Corporation (NASDAQ: LMNX) today announced a definitive agreement to acquire privately-held, GenturaDx, a molecular diagnostics company focused on making nucleic acid testing both affordable and practical for any laboratory. GenturaDx is in late stage development of a fully integrated, highly automated, real-time PCR system that employs a single-use cassette for true sample-to-answer workflow. This new system will make rapid, high-quality molecular diagnostics accessible to hospitals and patients worldwide. The integration of Luminex's MultiCode-RTx chemistry with the GenturaDx instrument is expected to result in a market leading system for molecular diagnostic testing.

GenturaDx's patented cartridge design provides automated sample extraction, amplification and detection thereby improving testing throughput, while reducing hands on time, turnaround times and sample handling. The system's user-friendly design delivers the convenience of random access/batch format enabling customers to run a combination of available assays on up to 12 patients' samples simultaneously. The flexibility in throughput, rapid turnaround time and small footprint of the GenturaDx instrument will be unique in the industry when combined with its sample-to-answer workflow. Luminex anticipates commercial availability of a variety of assays for use with this system by early 2014.

"We are excited to have the opportunity to address the needs of a large market by expanding our instrument portfolio and integrating our MultiCode-RTx assays with this innovative platform," said Patrick J. Balthrop, president and CEO of Luminex. "This acquisition accelerates the development of integrated sample processing capabilities for our technology, and aligns with our mission to reduce healthcare costs and improve clinical outcomes by providing innovative and affordable solutions to today's clinical laboratories. The acquisition of GenturaDx builds on our strategic investments to date and positions the company to deliver ongoing growth by increasing our product portfolio, expanding our market opportunities and leveraging our leadership position."

"Our proprietary technology provides a unique and unmatched alternative to current sample automation for PCR technology," said Mark N.K. Bagnall, president and CEO of GenturaDx. "I am confident that Luminex will recognize significant strategic and economic benefit from this acquisition and am pleased that our expertise and technology will help to fuel continued growth of an established industry leader like Luminex."

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**July 16, 2012**

## **Acquisition of Navigenics Expands Life Technologies' Capabilities in Diagnostics**

Life Technologies today announced the acquisition of Navigenics, Inc. This acquisition represents Life Technologies' first step in executing against a strategy to build out its molecular diagnostics business through internal development, partnerships and select acquisitions.

"Genetic analysis is becoming increasingly accessible, cost-effective and a critical part of patient clinical management," said David Agus, M.D. co-founder of Navigenics, professor of Medicine and Engineering at the University of Southern California, and author of *The End of Illness*. "As a result, physicians have more complete and accurate

information about the patient than ever before, which is translating into more effective, individualized care programs for patients."

"The advent of personalized medicine will require a combination of technologies and informatics focused on delivering relevant information to the treating physician," said Ronnie Andrews, president of Medical Sciences at Life Technologies. "Navigenics has pioneered the synthesis and communication of complex genomic information, and we will now pivot the company's effort to date and focus on becoming a comprehensive provider of technology and informatics to pathologists and oncologists worldwide."

Navigenics' multidisciplinary expertise, including its technology infrastructure, user interfaces, online platforms, genomic support services, and an experienced team, will play a central role in the delivery of Life Technologies' molecular diagnostic model. The company's established CLIA-certified laboratory, licensed throughout the United States, will be employed for design and validation of new diagnostics assays. Life Technologies plans to develop and offer lab-developed tests as well as commercialized assays that have been approved by FDA and other regulatory authorities. Life will also continue to build partnerships with pharmaceutical companies for companion diagnostic development, including participating in clinical trials, which is enabled by the CLIA lab acquisition.

Navigenics' extensive clinical program provides Life Technologies with a leadership position in clinician and patient education and support, which will be leveraged by Life Technologies in building its diagnostics business. The platform includes a network of oncologists, pathologists, and genetic counselors, who will be available to support community-based physicians in the adoption of genetic medicine and assist them in understanding these innovative types of medical information.

"Since our founding in 2006, Navigenics has blazed a pioneering trail in bringing genomics to the everyday reality of physicians, patients, and health plans," said Vance Vanier, M.D., president and chief executive officer of Navigenics. "Life Technologies' entry into the clinical diagnostics market, coupled with the scope of their clinical vision, signals that personalized medicine is no longer a distant future promise, but today's reality. We are thrilled to be at the center of their powerful initiative, which will improve countless lives."

"Complex diseases like cancer require physicians to receive and interpret data from the genome, transcriptome and proteome. Life Technologies is the only company in the industry today with the breadth of technology to span the full continuum of diagnostic information necessary to effectively manage such diseases," said Gregory T. Lucier, chairman and chief executive officer of Life Technologies. "The Navigenics informatics platform allows us to now transform the data from our instrument systems into actionable information and deliver it in real time to physicians around the world."

As Life Technologies expands its molecular diagnostics business, its philosophical focus on clinically relevant, medically endorsed applications aligns with that of Navigenics. In compliance with existing policies and informed consent, all customer information will be protected and handled according to regulatory guidelines, in alignment with Navigenics' founding principle of protecting the privacy and security of its customers' genetic information. The Navigenics Health Compass set of genetic analysis services will honor existing commitments but not take in new business.

Life Technologies is also currently developing diagnostic tests across multiple platforms. In October 2011, Life Technologies announced a partnership to develop a companion diagnostic for GlaxoSmithKline's MAGE-A3 cancer immunotherapy. Life Technologies also has an assay development partnership with Gen-Probe, and recently announced collaborations with Boston Children's Hospital and the Hospital for Sick Children in Toronto to develop the company's next generation sequencers for clinical research in pediatric diseases.

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**July 16, 2012**

## **Testing Critical to Reducing HIV, FDA Approves Test for Home Use**

On July 3, 2012, the Food and Drug Administration (FDA) approved for marketing the first HIV test for home use. In the announcement that came a little more than a month after an advisory panel unanimously recommended it for approval, the FDA noted that the test is targeted to those individuals who might be reluctant to visit a doctor or clinic for testing. Although the test is not as accurate when used at home as it is when performed in a clinic or laboratory, the FDA felt that the potential benefit of increasing the number of people tested for HIV outweighs the drawbacks of possible errors when the test is performed at home. According to the CDC, testing for HIV is critical to preventing the spread of the virus and, along with appropriate medical care, can help prolong the lives of those infected.

In a recent *Vital Signs* report, the U.S. Centers for Disease Control and Prevention (CDC) emphasized that testing for HIV is critical to preventing the spread of the virus and, along with appropriate medical care, can help prolong the lives of those infected. The CDC estimates that there are 1.2 million people in the U.S. who have HIV, but up to 20% of them do not know that they are infected. Each year, 50,000 people become infected with HIV in this country. The CDC recommends that those at risk for infection, such as people who have more than one sexual partner, use injection (IV) drugs, or are men who have sex with other men, should get tested for HIV at least once a year. They also recommend that every person between the ages of 13 and 64 be tested at least one time for HIV.

Currently, a few different options are available for HIV screening. A sample can be collected at a clinic or doctor's office and then sent to a laboratory for testing, with results generally available within a day or so. Rapid tests may sometimes be performed on site in these settings and can provide results in about 20 minutes. Another type of test allows an individual to collect a sample at home and then send it to a laboratory for testing.

Now, an advisory panel of the Food and Drug Administration (FDA) has recommended that one HIV test be approved for marketing for home use. The kit would allow individuals to collect an oral sample and perform the test in the privacy of their homes, receiving the results in about 20 minutes. The panel expects the added convenience would encourage those who have been reluctant to get tested for various reasons to learn their HIV status.

The testing kit for the home test is the same as that used in many clinics and doctors' offices. It has two limitations. First, testing on oral fluid is less sensitive than testing on blood, meaning this test misses some cases of HIV that a blood test would detect. Secondly, research conducted by the manufacturer has shown that when the testing is performed by a lay person, some cases of HIV are missed compared to when it is performed by a trained health care professional. An FDA official estimated that performance of the test in a home setting using oral fluid might miss about 3,800 HIV cases annually.

In general, home tests can provide convenience and privacy, but mistakes can be made that lead to inaccurate results. Errors can range from storing the kit inappropriately to collecting the sample improperly to imprecise timing of the test—not waiting long enough or waiting too long before noting the result.

Nevertheless, the FDA panel felt that the potential benefit of increasing the number of people tested for HIV outweighs the drawbacks of a less-than-perfect test. FDA projections noted that the test has the potential to detect an additional 45,000 new HIV cases and prevent spread of more than 4,000 infections each year.

As with all positive HIV screening test results, supplemental testing is required before a diagnosis is established. There is concern that people who test positive at home outside of a health care setting will not have follow-up testing or seek necessary treatment. If the test is to be truly effective, those who test positive need to be motivated to seek help. Toward that end, the testing kit would include a number for a 24-hour hotline that would provide testing support and referrals for medical counseling.

July 16, 2012

## Coming Wave Of Companion Diagnostics: Who's Making A Splash

Experts have been incorrectly predicting the timing in the coming shift to personalized medicine for years now. Given the numerous claims of "personalized medicine is now," I will be more conservative and say I believe "we've hit an inflection point" in personalized medicine.

When Agilent decided to acquire Dako for \$2.2 Billion in May, many initially believed they drastically overpaid. Dako is very mature and paying more than 7x revenue seems a hefty ransom. Dako obviously provides an asset that Agilent wanted and not that many investors are thinking about: Existing relationships with Pharma.

Companion diagnostics (CDx), diagnostic tests that are linked to a particular drug/therapy, are a key to personalized medicine and I believe will see an acceleration in the coming years. Vision Gain estimates the global market for companion diagnostics to be \$1.5 billion growing at around 15%. This is one of the fastest sub-industries in hyper-growth molecular diagnostic market and I believe that growth rate can even be conservative. I believe companies well positioned for the shift to personalized medicine will be the ones with companion diagnostics franchises. Specifically, I believe IVD Kit manufacturers will see a shift in their contribution in revenue from laboratories and university medical centers to Pharma.

Not all companies can easily shift from a company that sells diagnostic kits and instruments to reference labs to being a major companion diagnostic player overnight. Typically companies need the right technology, relevance in the space, and have management with relationships in place.

The following list are the partnerships we could find since 2009 between pharmaceutical companies and diagnostic companies.

<b>Diagnostics Partner</b>	<b>Pharmaceutical Partner</b>	<b>Disease Area</b>	<b>Deal Date</b>
Foundation Medicine	Novartis (NVS)	Cancer-Multiple	12-Jun
PrimeraDx	Eli Lilly (LLY)	Cancer-Multiple	12-Jun
Genomic Health (GHDX)	OncoMed Pharmaceuticals	Cancer-Undisclosed	12-May
Dako	Genetech	Cancer-Breast	12-May
Roche/Ventana (RHHBF.PK)	Millennium/Takeda (TKPHF.PK)	Cancer-lymphoma	12-Apr
Roche/Ventana	Seattle Genetics (SGEN) and Millennium	Cancer-lymphoma	12-Apr

HTG Molecular Diagnostics	Sanofi (SNY)	Cancer-Undisclosed	12-Mar
Meso Scale Discovery	Bristol-Myers Squibb (BMY)	Neurology-Alzheimers	12-Mar
Abbott Molecular (ABT)	Merck & Co (MRK)	Cancer-Undisclosed	12-Mar
Myriad Genetics (MYGN)	Cephalon (CEPH)	Cancer-ovarian and breast	12-Mar
Biodesix Inc.	Kadmon Corporation	Cancer-Lung	12-Feb
Dako	Amgen (AMGN)	Cancer-Undisclosed	12-Feb
Siemens AG (SI)	GSK/ViiV (GSK)	Infection-HIV	12-Feb
Siemens AG	Tocagen	Cancer-Brain	12-Feb
Foundation Medicine	Sanofi	Cancer-Multiple	12-Jan
Roche/Ventana	Aeterna Zentaris Inc.	Cancer-Multiple	12-Jan
Xenon	Genetech	Pain	12-Jan
Roche/Ventana	Bayer (BAYZF.PK)	Cancer-Undisclosed	12-Jan
Roche/Ventana	Pfizer (PFE)	Cancer-Lung	12-Jan
Roche/Ventana	Syndax	Cancer-lung	12-Jan
Dako	Genetech	Cancer-Breast	11-Dec
MDx Health	Celldex (CLDX)	Cancer-Glioblastoma	11-Dec
Metamark Genetics	Johnson & Johnson (JNJ)/Janssen	Cancer-Undisclosed	11-Dec
Abbott Molecular	GSK	Cancer-Undisclosed	11-Nov
Dako	Bristol-Myers Squibb	Cancer-Undisclosed	11-Nov
Life Technologies (LIFE)	GSK	Cancer-Immunotherapy	11-Oct
Foundation Medicine	Johnson & Johnson	Cancer-Undisclosed	11-Oct
Qiagen (QGEN)	Eli Lilly	Cancer-Blood	11-Sep
Skyline Diagnostics	Clavis Pharma	Cancer-Blood	11-Sep
Qiagen	Pfizer	Cancer-Lung	11-Aug
Unilabs	Biogen Idec	Cancer-Blood	11-Jul
Skyline Diagnostics	Johnson & Johnson	Undisclosed	11-Jul
Roche Diagnostics	Merck	Cancer-Multiple	11-Jun
Roche Molecular Systems	Clovis Oncology (CLVS)	Cancer-Lung	11-Jun
Agendia	AstraZeneca (AZN)	Cancer-Colorectal	11-May
Myriad Genetics	BioMarin Pharmaceutical Inc (BMRN)	Cancer-ovarian and breast	11-Apr
MolecularMD	ARIAD Pharmaceuticals, Inc. (ARIA)	Cancer-Leukemia	11-Mar
Invivoscribe Technologies Inc	Novartis	Cancer-Leukemia	11-Feb

BioMerieux	Ipsen	Cancer-Multiple	11-Feb
OPKO Health (OPK)	Bristol-Myers Squibb	Neurology-Alzheimers	11-Jan
Biocartis	Johnson & Johnson's Janssen and Ortho-Clinical Diagnostics	Undisclosed	11-Jan
MDx Health (MDXHF.PK)	Pfizer	Cancer-ovarian and breast	11-Jan
Zinfandel	Takeda	Neurology-Alzheimers	11-Jan
Diagenic	Pfizer	Neurology-Alzheimers	10-Dec
Prometheus	Bayer Schering	Cancer-Undisclosed	10-Dec
Sanford-Burnham Medical Research Institute*	Takeda	Obesity	10-Dec
Roche	Astellas (ALPMF.PK)/OSI Pharmaceuticals (OSIPR.PK)	Cancer-Lung	10-Nov
Cepheid (CPHD)	Novartis	Cancer-Leukemia	10-Oct
Myriad Genetics	Abbott Laboratories	Cancer-Breast	10-Oct
MDx Health	GSK	Cancer-Undisclosed	10-Sep
Roche/Ventana	Transgene (TRGNF.PK)	Cancer-Lung	10-Sep
Accumetrics	Eli-Lilly & Daiichi Sankyo	Cardiovascular-Blood Clots	10-Jul
Lab Corp	Merck & Co	Infection-HCV	10-Jul
Pathwork Diagnostics	Novartis	Cancer-Undisclosed	10-Jul
Almac Diagnostics	Aeterna Zentaris Inc (AEZS)	Cancer-Ovarian	10-Jun
Saladax Biomedical	Bristol-Myers Squibb	Cancer-Undisclosed	10-Jun
BioMerieux	GSK	Cancer-Skin	10-May
Response Genetics (RGDX)	GSK	Cancer-Undisclosed	10-May
Almac Diagnostics	Merck	Cancer-Colorectal	10-Apr
Roche/Ventana	Clovis Oncology	Cancer-Pancreas	10-Apr
Abbott Molecular	GSK	Cancer-Skin	10-Mar
AgaMatrix	Sanofi -Aventis	Matebolic-Diabetes	10-Mar
Prometheus	Bayer Schering	Cancer-Undisclosed	10-Mar
Qiagen/DxS	Pfizer	Cancer-Glioblastoma	10-Feb
Roche	Merck & Co	Cancer-Undisclosed	10-Feb
Sequenom (SQNM)	Optherion	Ophthalmology-AMD	10-Feb
CMIC	Roche	Kidney Disease	10-Jan
Dako	Astra Zeneca	Cancer-Undisclosed	10-Jan
MDx Health	Roche	Cancer-Glioblastoma	10-Jan
Rules Based Medicine	Roche	Neurology-Undisclosed	9-Dec
BioMerieux	GSK	Cancer-Breast	9-Nov

Orion Genomics	Novartis	Cancer-Undisclosed	9-Oct
Almac Diagnostics	Eli Lilly	Cancer-Lung	9-Sep
Qiagen	Merck & Co	Cancer-Cervical	9-Sep
DxS/Qiagen	Bristol-Myers Squibb	Cancer-Colorectal	9-Sep
Abbott Molecular	Pfizer	Cancer-Lung	9-Aug
Dako	Roche	Cancer-Stomach	9-Aug
Abbott Molecular	GSK	Cancer-Lung	9-Jul
Asuragen	Biogen Idec (BIIB)	Cancer-Undisclosed	9-Jul
Enigma Diagnostics	GSK	Infection-Influenza	9-Jul
Qiagen/DxS	Astra Zeneca	Cancer-Lung	9-Jul
Celera (CRA)	Bayer Schering	Cancer-Undisclosed	9-Jun
Diagenic	Merz Pharmaceuticals	Neurology-Alzheimers	9-Jun
Almac Diagnostics	Pfizer	Cancer-Colorectal	9-May
Qiagen/DxS	Boehringer Ingelheim	Cancer-Lung	9-May
MDx Health	Merck	Cancer-Glioblastoma	9-Mar
Dako	OSI Pharmaceuticals	Cancer-Undisclosed	9-Jan
XDx	Bristol-Myers Squibb	Autoimmune-Lupus	9-Jan

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**July 30, 2012**

## **MolecularMD Submits PMA BCR-ABL T315I Mutation Test, A Companion Diagnostic to Ponatinib**

MolecularMD today announced that it has submitted PMA of the MolecularMD BCR-ABL T315I Mutation Test to the FDA. This test detects the T315I mutation in BCR-ABL RNA transcripts in blood using Sanger sequencing technology. The MolecularMD test can be used to identify patients with chronic myeloid leukemia (CML) and Philadelphia positive acute lymphoblastic leukemia (Ph+ ALL) who have the T315I mutation; the test is intended as a companion diagnostic to ponatinib. Ponatinib, a BCR-ABL inhibitor developed by ARIAD Pharmaceuticals, Inc., is being submitted for approval for the treatment of patients with resistant or intolerant CML or Ph+ ALL, including those with the T315I mutation. BCR-ABL mutation testing for the PACE trial, the pivotal phase 2 trial of ponatinib, was exclusively performed by MolecularMD.

MolecularMD's President, Dan Snyder, stated, "We have worked closely in partnership with ARIAD to perform all the mutation testing for the pivotal PACE trial of ponatinib and at the same time, complete the in vitro diagnostic test development and PMA submission. We are among the first partnerships to submit an NDA and a PMA to the FDA for simultaneous consideration, following the draft guidance set forth by the FDA in July 2011. We look forward to offering this companion diagnostic for use with ponatinib to identify CML and Ph+ ALL patients with the T315I mutation."

ABL tyrosine kinase inhibitors (TKIs) that block deregulated BCR-ABL activity have transformed the care of CML and Ph+ ALL patients over the past decade. While second-generation ABL TKIs have demonstrated potency against a number of imatinib-resistant forms of BCR-ABL, they are ineffective against the T315I mutant. Ponatinib has potent activity against native BCR-ABL and its mutants, including T315I.

The test service employs bidirectional Sanger sequencing to detect the T315I mutation in the predominant BCR-ABL transcripts that account for over 95% of gene fusion products in CML and Ph+ ALL cases. If approved, the Molecular MD BCR-ABL T315I Mutation Test would be the first BCR-ABL sequencing test approved by the FDA and the first service-based laboratory-developed test to be approved by the FDA as a companion diagnostic. Pending approval, the MolecularMD BCR-ABL T315I Mutation Test will facilitate identification of CML and Ph+ ALL patients who are candidates for ponatinib treatment.

Targeted cancer therapeutics account for approximately half of all cancer drug sales in the US or an estimated \$25 Billion. Molecular diagnostics are used to select patients most likely to respond to a targeted therapy, as well as to monitor and manage potential resistance to therapy. Increasingly, regulators are requiring that companion diagnostic tests, which define the appropriate patient population, accompany submissions for approval of new precision cancer medicines.

MolecularMD Corporation develops and commercializes specialty molecular diagnostics for oncology applications. Its tests are designed to allow appropriate selection, monitoring and management of patients treated with molecularly-targeted cancer therapies. MolecularMD incorporates gold-standard and innovative technologies in providing its partners with the highest quality results. Assays are designed to meet clinical trial needs, and MolecularMD has appropriate systems and standards in place to enable development of companion diagnostic tests in conjunction with partners' novel anticancer agents. A private company based in Portland, Oregon, MolecularMD was founded by Brian Druker, director of the Knight Cancer Center at Oregon Health & Science University, and Sheridan G. Snyder, entrepreneur and founder of Genzyme Corporation.