

Diagnostic Testing and Healthcare Industry News Update

April 27, 2009

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Cepheid Announces European Release Of On-Demand Molecular Test for Simultaneous Detection Of Tuberculosis (TB) and Resistance to Rifampicin (RIF)

Cepheid today announced the release of Xpert(R) MTB/RIF as a CE IVD Mark product under the European Directive on *In Vitro* Diagnostic Medical Devices. For the first time, European clinicians will have access to a rapid test that can simultaneously identify *Mycobacterium tuberculosis* (MTB) and resistance to rifampicin (RIF), a common first-line drug for treatment of the disease and a reliable surrogate marker of strains that are multidrug-resistant (MDR-TB).

Xpert MTB/RIF is expected to enable clinicians to dramatically improve patient outcomes -- a situation possible only through on-demand, actionable test results that can help guide therapy decisions during an initial patient visit. The new test, developed in partnership with the Foundation for Innovative New Diagnostics, UMDNJ, and funded by NIAID, will leverage the power of Cepheid's GeneXpert(R) System to deliver a highly accurate diagnosis of the disease in less than two hours.

According to the World Health Organization (WHO), approximately two billion people are currently infected with MTB. An estimated nine million people develop active TB each year, and two million people lose their lives to the illness.

"With the documented re-emergence of TB and the development of drug-resistant strains, the need for accurate and rapid detection of tuberculosis is becoming increasingly acute," said John Bishop, Cepheid's Chief Executive Officer. "The GeneXpert System has a unique level of technical capability never before seen in molecular diagnostics -- and this capability is on full display with this test. Clinicians will now be able to obtain dependable test results in virtually any clinical setting not only for detection of TB, but simultaneous determination of whether or not it is a drug resistant strain. Xpert MTB/RIF should be a breakthrough technological leap forward in helping to ensure appropriate therapeutic management and in helping to halt transmission of this disease."

"I would also like to note that the Xpert MTB/RIF is Cepheid's first test released in the new Reagents on Board configuration. This new test configuration includes the packaging of liquid reagents along with the previously included dry reagents in the test cartridge. This added feature makes the procedure even easier to perform and further reduces hands-on time to about a minute. This new test configuration is also expected to form the foundation for Cepheid's projected future line of CLIA waived products."

Appropriate therapeutic management has been a significant factor in the development of drug resistant TB strains. Optimal management of the disease requires access to rapid detection, prevention, and treatment.

"Rapid diagnosis of rifampicin-resistant TB will have will have three main benefits, including earlier proper treatment, earlier interruption of the transmission chain-of resistant strains, and promote appropriate accommodation of patients infected with a resistant strain," said Dr. Sabine Rusch-Gerdes, Head of the National Reference Center for Mycobacteria, Borstel, Germany. "This will undoubtedly save more lives by reducing the time spent on inappropriate and ineffective patient treatment which ultimately promotes the development of further drug resistance."

According to data published by WHO, only 2 percent of multidrug-resistant (MDR) TB cases worldwide are being diagnosed and treated appropriately. This may leave MDR-TB patients untreated for weeks or months, leading to an increased likelihood of community transmission and eventual death of the patient.

"Multidrug-resistant TB is becoming increasingly prevalent throughout the world, making TB harder to treat with the usual regimen that includes rifampicin," said David H. Persing, M.D., Ph.D., Cepheid's Chief Medical and Technology Officer. "In my opinion, this new test is one of the most important diagnostic developments to have occurred in many years. It is the most technologically advanced test for TB ever developed, yet it is simple enough to perform anywhere testing is needed."

Currently, the most common testing method for TB is sputum microscopy, or the smear test, that has remained largely unchanged in its sophistication and sensitivity for over 100 years. The smear test has been proven to only detect around half of all active TB cases and is not capable of identifying drug resistance. As a result, TB is under-diagnosed today -- a major contributor to the 90,000 new TB cases and 10,000 deaths that occur annually in Europe alone. The Health Protection Agency recently announced that the number of TB cases reported in the United Kingdom is actually increasing, with a 2 percent rise in reported cases in 2008 when compared to 2007.

Patients who remain undetected are often co-mingled within general hospital populations, placing others at risk of infection. Due to their low accuracy, smear tests are followed up with culture tests, which offer more accurate results but take several weeks. To determine drug resistance, culture testing can take months to return a result.

"We designed this test so that it could be used by someone with minimal training," said UMDNJ's David Alland, M.D. who collaborated closely with Cepheid and FIND with support from the NIAID. "We're gratified to find that it requires less hands-on work than the acid fast smear, long a standard method to identify tuberculosis, but it is much more sensitive."

Sputum microscopy, which often delivers poor sensitivity in patients suffering from tuberculosis, is almost completely ineffective in those who also have HIV co-infection. The weakened immune system of an HIV-positive person is particularly susceptible to infection, resulting in one third of the 33 million HIV sufferers worldwide infected with TB. Left untreated, 90 percent of these people will die within months of first contracting the disease, reinforcing the urgent need for an accurate and rapid test.

The GeneXpert System is a closed, self-contained, fully-integrated and automated platform that represents a paradigm shift in the automation of molecular analysis, producing accurate results in a timely manner with minimal risk of contamination. The GeneXpert System is the only system to combine on-board sample preparation with real-time PCR (polymerase chain reaction) amplification and detection functions for fully integrated and automated nucleic acid analysis. The system is designed to purify, concentrate, detect and identify targeted nucleic acid sequences thereby delivering answers directly from unprocessed samples. Modular in design, the GeneXpert System has a variety of configurations to meet the broad range of testing demands of any clinical environment.

April 24, 2009

Perlegen Out-Licenses Genetic Diagnostics IP To Celera -- Patents and Cardiac Genetic Markers Key To The Development of New Celera Tests

Perlegen Sciences, which develops genetic tests that correlate genetic variation to predisposition to disease and drug response, announced today that it has entered a non-exclusive license agreement with Celera focused on a family of patents that covers methods of genetic analysis central to creating similar diagnostic products. The agreement grants Celera use of this Perlegen intellectual property as well as use of Perlegen's specific predictive genetic markers on chromosome 9p21 for coronary heart disease, to be included in products marketed by Celera.

Perlegen's genetic analysis intellectual property covers the combination of multi-loci markers to create diagnostic products for determining an individual's predisposition to multi-factorial disease or for ascertaining an appropriate course of treatment. It is

expected to allow Celera to detect genetic markers for multi-factorial traits and tightly linked haplotype blocks, facilitate optimal matching of patient cases and controls, and provide methods for managing the massive data sets that accompany these analyses.

“Perlegen is pleased to enter this agreement with Celera and support its mission of improving healthcare through modern diagnostic methods in genetics,” said Bryan Walser, M.D., CEO of Perlegen. “The important discoveries these patents represent, including the specific marker for coronary heart disease, should drive continued advances in genetic diagnostics as scientists across the field apply them to determine which genetic markers are present in an individual and combine those markers to help quantify actionable and specific health risks.”

“We believe access to these highly replicated markers, which complement our internal proprietary genetic discoveries in cardiovascular disease such as KIF6 and LPA, furthers Celera’s commitment to be a leading provider of genetic tests used routinely in personalizing disease management,” said Kathy Ordoñez, CEO of Celera. “These markers are expected to enhance our focus on cardiovascular disease while expanding our menu into diabetes and metabolic syndrome. We believe the additional pharmacogenomic aspects of these markers allow us the potential to personalize disease management that may further improve patient compliance with treatments for cardiovascular disease and diabetes.”

April 23, 2009

Declining System Sales Drag Cepheid Q1 Revenues Down 13 Percent

Cepheid reported on Thursday afternoon that its first-quarter revenue fell 13 percent year over year, largely due to a 45 percent drop in system sales. The firm brought in revenues of \$38.8 million for the three-month period ended March 31, compared to revenues of \$44.8 million in the first quarter of 2008.

System sales dropped to \$7.9 million from \$14.3 million year over year, while sales of reagents and disposables increased 4 percent to \$28.7 million from \$27.6 million. By industry, clinical system sales decreased 32 percent to \$4.8 million from \$7 million, while clinical reagent sales grew 79 percent to \$19 million from \$10.6 million in the first quarter of 2008.

Sales to industrial customers increased 3 percent, while sales to the biotech sector fell 37 percent and sales to partners decreased by 85 percent. The Sunnyvale, Calif.-based company said that it installed a total of 95 GeneXpert systems and 436 modules during the quarter, bringing its total installed base to 1,042 systems.

Cepheid CEO John Bishop said that the 79 percent increase that the company saw in clinical test sales partly offset the anticipated decline in biothreat and partner sales. Bishop said that the company has just submitted its *Clostridium difficile* assay to the US Food and Drug Administration, and that it plans to release its Xpert TB/RIF test for multi-drug resistant tuberculosis in Europe next week.

The firm's R&D expenses rose 5 percent to \$10.3 million from \$9.9 million, while SG&A spending increased 3 percent to \$12.1 million from \$11.7 million. Cepheid's net loss widened to \$7.4 million, or \$.13 per share, from \$1.9 million, or \$.03 per share, in the first quarter of 2008. Cepheid finished the quarter with \$26.8 million in cash and cash equivalents. The company reiterated its previous guidance for full-year 2009 of total revenue in the range of \$164 million to \$174 million and a net loss in the range of \$0.42 to \$0.47 per share.

April 2, 2009

Roche To Introduce New Lightcycler MRSA Advanced Test In the EU

Roche announced today that its new LightCycler test for the detection of methicillin-resistant *Staphylococcus aureus* (MRSA) is now available with the CE Mark, allowing it to be sold for clinical use in the European Union. The LightCycler MRSA Advanced Test is a qualitative in vitro diagnostic test for the direct detection of nasal colonization with methicillin-resistant *Staphylococcus aureus*. The test will aid in the prevention and control of MRSA infections in healthcare settings resulting in better patient care.

"As more guidelines recommend or require aggressive screening, it is important that healthcare professionals have access to fast, reliable products that can help improve medical outcomes," said Daniel O'Day Head of Roche Molecular Diagnostics. "This new test will aid infection control programs, and ultimately result in better patient care."

Healthcare-associated infections (HAIs) caused by MRSA have recently become an important issue for healthcare facilities worldwide due to high rates of infection, mortality, and high costs of treatment. In addition, community-associated MRSA (CA-MRSA) has spread in the past few years, feeding the pipeline of infection in hospitals, and underscoring the need for comprehensive infection control programs.

Dr. Reinhard Frodl, Laboratory Head of the Molecular Biology Department of Medizinisches Versorgungszentrum Dr. Gärtner & Kollegen in Ravensburg, Germany commented: "The test showed good sensitivity and specificity in our hands and we believe it will bring more efficient MRSA screening to hospitals across Europe because of its batching flexibility and easy handling."

The LightCycler MRSA Advanced Test is performed on Roche's LightCycler 2.0 Instrument with nasal swab specimens from patients suspected of colonization, using Roche's patented real-time polymerase chain reaction (PCR) technology. Provided in a convenient, ready-to-use format, and designed for flexible batch sizes, the LightCycler MRSA Advanced Test ensures safety and productivity of laboratory staff, flexible throughput, and accurate and reliable results.

Staphylococcus aureus is responsible for many serious infections and is one of the most frequently isolated bacteria from patients with healthcare-associated infections (HAI). Estimates suggest that 4 million HAIs and 37,000 deaths are attributable to these infections each year in the EU, and that 1 out of 10 patients in an EU hospital acquires an HAI. Antimicrobial resistance and HAIs, either combined or separately, constitutes a major infectious disease problem in the EU, and show signs of becoming more prevalent in the future.(i)

MRSA infections are a tremendous burden for healthcare systems and hospitals and are associated with significant healthcare costs. In 2004, the United Kingdom National Audit Office estimated that infections such as MRSA kill 5,000 people each year in the UK and hospital-associated infections cost the National Health Service around £1 billion a year.

With more than 6,600 LightCycler Instruments in the market today, the LightCycler® System is among the most widely utilized real-time amplification systems available. The LightCycler® 2.0 Instrument was the first system to introduce hybridization probes, true melting curve analysis, automated absolute quantification, and relative quantification with efficiency correction. Combining the power of the LightCycler 2.0 Instrument with the simple, flexible, and reliable design of the LightCycler MRSA Advanced Test provides a powerful tool to support healthcare institutions in their fight against MRSA.

March 30, 2009

Inverness Launches New FDA Cleared C. Diff Rapid Test

Inverness Medical Innovations, a global leader in enabling individuals to take charge of their health at home through the merger of rapid diagnostics and health management, announced today that it will begin marketing and distributing the new *C. DIFF QUIK CHEK COMPLETE* rapid test as an *in vitro* diagnostic aid for *Clostridium difficile* associated disease (CDAD).

This follows TECHLAB(R), Inc.'s recent clearance from the Federal Drug Administration (FDA) to manufacture the product for Inverness.

C. difficile is responsible for the most common form of hospital-acquired diarrhea and antibiotic-associated colitis. *C. difficile* is highly infectious and a significant danger to the health of immunocompromised or elderly patients. The infection can be life-threatening when not caught in time to allow for appropriate therapy to combat the disease and thereby reduce morbidity associated with CDAD.

The new rapid test yields results within 30 minutes and detects all strains of *C. difficile*, including the highly virulent strain BINAP1/027 that is causing outbreaks of increasing severity and mortality across Europe and North America. Collective scientific data suggests that the incidence of *C. difficile* infection (CDI) has recently increased in East Asia and the Middle East, further highlighting the disease as a global epidemic. In US Hospitals, current annual spending is estimated at \$40 million in testing aimed at diagnosing CDAD patients in order to provide appropriate therapy.

While primarily a hospital-acquired disease, *C. difficile* infection is increasingly occurring in community outpatient settings. This is causing a major problem for hospital and community care environments because the number of patients at risk for *C. difficile* infection is substantial. At present, the incidence of infection has reached epidemic proportions. Recently-released results from the "National Prevalence Study of Clostridium difficile in US Healthcare Facilities" indicate that the rate of infection, or colonization, is 6.5 to 20 times greater than previous estimates.

The *C. DIFF QUIK CHEK COMPLETE* test offered by Inverness Medical is the only device that simultaneously detects both *C. difficile* glutamate dehydrogenase (GDH) and *C. difficile* toxins A and B in one simple assay. It can be used for screening while also confirming the presence of toxigenic *C. difficile* strains. The test provides results in less than 30 minutes from fecal samples, enabling rapid diagnosis and initiation of appropriate patient management. With use of a *C. difficile* rapid test, patients can be effectively isolated at an earlier stage of illness, reducing the risk of cross contamination and widespread outbreaks.

The *C. difficile* antigen glutamate dehydrogenase (GDH) used in the test is common to all strains of *C. difficile* and has been identified as an excellent screening marker for the infection. The new *C. DIFF QUIK CHEK COMPLETE* test, developed and manufactured by TECHLAB(R), Inc. in Blacksburg, VA, provides a more complete picture of the patient's disease state within one single test format with quicker time to results and higher negative predictive value (*less false negative results*) when compared to alternative existing testing methods.

April 1, 2009

BG Medicine Commences Galectin-3 Assay Service for Clinical Research Related To CHF

BG Medicine Inc. (BGM), a developer of novel, biomarker-based diagnostic products, today announced the launch of the Galectin-3 Website (www.galectin-3.com) which will provide an array of research materials associated with galectin-3.

Galectins are a unique class of proteins with a relatively high affinity for specific carbohydrate compounds. Upon the tight specific binding between carbohydrate and protein, galectins display certain profound biological effects. Galectins were first described in 1994 and to date, 15 members have been identified.

Accruing evidence indicates that galectins are important immunoregulatory mediators and research in the role of galectins in health and disease is rapidly increasing resulting in a new article about galectins in the scientific literature approximately every 24hrs. In particular, Galectin-3 is attracting strong interest from the scientific community with regard to its role in cardiac disease and cancer.

Users of the galectin-3 website can easily navigate to informational resources such as PubMed, which provides access to galectin-3 citations from biomedical literature, certain full-text articles, and other web-based resources.

BG Medicine has developed a new optimized assay for measurement of galectin-3 in plasma or serum and anticipates clearance by the U.S. Food and Drug Administration and European authorities later in 2009 for clinical use.

BG Medicine also announced today the launch of a galectin-3 assay service for research purposes only. Researchers interested in submitting study samples for galectin-3 analysis can order such services from the galectin-3 website.

“Galectin-3 is one of the rare culprit biomarkers” said Pieter Muntendam, MD, President and CEO of BG Medicine. “Measurement in plasma provides important information about a disease process, while experimental research has demonstrated that administration of galectin-3 can actually induce the pathology.

Most biomarkers we know are bystander biomarkers – one cannot induce the condition by administering the biomarker. We expect that the availability of a robust assay will markedly accelerate our understanding of the role of galectin-3 in disease and how we can take advantage of this for improved treatment outcomes.

April 8, 2009

Siemens Introduces Two New RAPIDPoint 300 Blood Gas Analyzers

Siemens Healthcare introduces the RAPIDPoint 340 and 350 Blood Gas Analyzers for the low- to mid-volume critical care patient testing sites.

These two low-maintenance models are small, easy-to-use cartridge-based systems. The simplicity of these systems is ideal for operators in a variety of critical care testing sites including intensive care units, operating or emergency rooms, and the clinical laboratory.

The RAPIDPoint 340 analyzer measures pH and blood gas (oxygen and carbon dioxide).

The RAPIDPoint 350 analyzer also measures electrolytes sodium, potassium, calcium or chloride, and hematocrit. All patient test results are available in minutes with minimal operator involvement—an important feature for critical care environments where health care providers may need to make quick therapeutic decisions.

Both new systems use a small patient sample size of 75 uL to 120 uL, to accommodate all types of patients. In addition, the systems have the ability to interface with hospital and laboratory information systems.

Siemens' portfolio of blood gas analyzers fits the needs of all sizes and types of laboratories and critical care sites, offering the ability to deliver critical care test results near the bedside or in high-volume hospital environments.

Each analyzer has a high-level of test accuracy and ease-of-use features that offer simplicity for any type of operator.

The company's RAPIDComm Data Management and connectivity solution is available for use with many of Siemens' blood gas analyzers. This connectivity solution offers hospital-wide access, making it easier for health care providers to access patient test results throughout their institutions. The new RAPIDPoint 340 and 350 analyzers are currently available in the United States and Europe. The company anticipates introducing the systems to other countries in the future.

April 21, 2009

Celera Touts 6-Biomarker Immunodiagnostic Assay For Detecting Lung Cancer from Blood Serum

Celera Corporation today announced the presentation of data describing a novel mass spectrometry-based approach to identify and validate circulating protein biomarkers that detect non-small cell lung cancer (NSCLC). A key outcome of the study was the assembly of an immunoassay test for a panel of 6 biomarkers that detected lung cancer with 94% sensitivity and 93% specificity in a blinded analysis. In addition to detecting all stages of lung cancer studied and all major histological subtypes, the panel also accurately distinguished malignant cases from benign lung disease. The data will be presented from 8:00 a.m. to 12:00 p.m. MDT today as poster #3542 at the 100th Annual American Association for Cancer Research (AACR) Conference in Denver, CO.

“We believe these findings present an important development in our efforts to develop a robust method to detect lung cancer using a simple blood test,” said Steve Ruben, Ph.D., Vice President of Proteomics at Celera. “To this end, we have employed a novel mass spectrometry-based approach to finding biomarkers based on discovery from tumor tissues and tumor cell lines rather than from serum directly. This has allowed us to identify a collection of biomarkers which we have subsequently shown to be elevated in the blood of non-small cell lung cancer patients relative to appropriate controls.”

“We believe a test with this accuracy would have an opportunity to impact non-small cell lung cancer patient outcomes at many levels,” said Thomas White, Ph.D., Chief Scientific Officer at Celera. “For example, a test that precedes radiographic methods of detection, such as helical Computed Tomography, could reduce the number of patients requiring subsequent CT scans substantially, potentially reducing expensive workup and minimizing the morbidities associated with additional diagnostic procedures following a positive CT scan. We’re exploring the commercial opportunities for this program as we continue to validate these findings in a clinical setting.”

The study included 27 candidate biomarkers from approximately 500 proteins previously identified by mass spectrometry that were used to test serum specimens using ELISA (Enzyme Linked Immunosorbent Assay) methods in a pilot set of sera comprising 12 individuals with lung cancer and 12 healthy controls. Several of the selected markers have not previously been reported to show elevated expression in the blood of lung cancer patients. Markers that showed elevated disease expression in cancer patients were then validated in sera from 103 patients with NSCLC and 104 healthy controls who were matched for age, gender and smoking history. Cases comprised more prevalent histological types: adenocarcinoma (n=54), squamous cell (n=24) and large cell (n=11), and spanned all 4 stages of tumor progression. Additional control samples included 70 individuals with non-malignant lung disease, which included bronchitis, asthma, COPD, and benign pulmonary nodules.

The test panels that were configured detected lung cancer with higher sensitivity and specificity than previously reported. A blinded analysis was performed in which a logistic regression classifier was generated using a collection of serum samples (control, n=54; tumor, n=53). The performance of the classifier was then evaluated on a panel of blinded samples (control, n=50; tumor, n=50), and the 6-marker panel achieved 91% sensitivity at 91% specificity in correctly classifying cases and controls. This panel and others described in the study are expected to provide the flexibility to design tests with performance specifications suitable for a variety of diagnostic applications, such as screening individuals at risk for lung cancer and for monitoring of disease following diagnosis and treatment.

April 20, 2009

Roche Reports Diagnostic Division Results For Q1

Roche's Diagnostics Division, the world's leading supplier of in vitro diagnostics (IVDs), recorded first-quarter sales of 2.4 billion Swiss francs, an increase of 8% in local currencies (3% in Swiss francs, -4% in US dollars). This was well above the estimated 5% growth of the IVD market (4). All five business areas increased their sales in local currencies, with Professional Diagnostics and Tissue Diagnostics the biggest contributors to growth. The division launched nine major new IVDs in Europe as well as important additions to its DNA sequencing and cell analysis portfolios.

Roche Professional Diagnostics' sales rose 8% to 1,086 million Swiss francs. The immunoassay business gained further market share on sales growth of 18%. New placements of cobas 6000 analysers and recent additions to the immunoassay menu like the Elecsys anti-CCP assay (diagnosis of rheumatoid arthritis) were key growth drivers. Sales of decentralised solutions rose 4%, led by strong demand for portable testing systems like the CoaguChek coagulation monitors. In the EU and other markets recognising CE Mark certification the business area launched a highly sensitive test for cardiac troponin T (diagnosis of heart attack), a test for the inflammation marker interleukin 6 (as an aid in managing critically ill patients) and assays for the markers PIGF and sFlt-1, which together provide the first and only IVD for preeclampsia, a potentially life-threatening complication of pregnancy.

Roche Diabetes Care's combined sales of blood glucose (BG) monitoring and insulin delivery products rose 4% to 679 million Swiss francs. Sales of Roche's top-selling Accu-Chek Aviva BG system increased nearly 30%. Roche Diabetes Care has begun rolling out three major new BG monitoring systems in Europe: Accu-Chek Mobile (featuring strip-free technology), Accu-Chek Aviva Nano (for young, frequent testers) and Accu-Chek Active (for emerging markets). In addition, Accu-Chek Combo,

Europe's first interactive diabetes management system combining an insulin pump and a BG meter/remote control, was launched in its first markets.

Roche Molecular Diagnostics' sales rose 7% to 294 million Swiss francs. Automated real-time PCR platforms remained a growth driver. Sales of blood screening products increased 12%. Uptake of automated HIV and hepatitis B viral load tests remained strong, contributing to overall virology sales growth of 5%. The business area's LightCycler MRSA Advanced Test for improved screening for methicillin-resistant *Staphylococcus aureus* was CE Mark certified in March and commercially launched in Europe in April. In oncology, the TheraScreen K-RAS Test, which Roche began distributing in December 2008, is now validated for use on the LightCycler 480 II instrument, expanding platform options for laboratories.

Roche Applied Science's sales rose 6% to 196 million Swiss francs. Sales of DNA sequencing products and microarrays both showed high double-digit growth. Systems for sample preparation and real-time quantitative PCR analysis posted 4% growth despite price erosion in the market. In early April Roche complemented its existing cell analysis portfolio for research by acquiring innovatis AG, a leader in automated cell analysis solutions for biomanufacturing. Important launches included a new version of the xCELLigence cell analyser and new Titanium DNA sequencing reagent kits.

Roche Tissue Diagnostics' first-quarter sales totalled 106 million Swiss francs, up 55% compared with two months' sales in 2008 due to the timing of the Ventana acquisition. On a comparable basis, sales rose 14%, again outpacing the market. Advanced tissue staining (immunohistochemistry and in situ hybridisation) continued to be the main growth driver, delivering a robust double-digit sales increase. Last year's upgrades to the Symphony slide staining system contributed to double-digit growth in the high-volume primary staining market. In March the business area launched the INFORM EGFR DNA Probe in Europe for clinical use in oncology.

April 1, 2009

Cepheid Announces European Release of On-Demand Molecular Screening Test for Simultaneous Detection of Methicillin-Sensitive and Resistant *S. aureus*

Cepheid today announced the release of the Xpert MRSA/SA Nasal test as a European CE IVD Mark product under the European Directive on In Vitro Diagnostic Medical Devices. The test is designed for the simultaneous detection of nasal carriage of both Methicillin-resistant *Staphylococcus aureus* (MRSA: undefined, undefined, undefined%) and Methicillin-sensitive *Staphylococcus aureus* in less than one hour.

"With the addition of Xpert MRSA/SA Nasal, Cepheid now offers European clinicians the most comprehensive suite of on-demand molecular tests currently available to aid in the overall management of HAIs," said John Bishop, Cepheid's Chief Executive Officer. "This includes a broad line of diagnostic, surveillance, and pre-surgical screening tests for MRSA, SA, C. difficile, and vanA/vanB."

Staphylococcus aureus is widely recognized as one of the most common causes of HAIs worldwide. Surgical units are high-risk areas for potentially serious consequences of post-operative complications, including surgical site infections (SSIs). Cepheid's on-demand Xpert MRSA/SA Nasal test provides rapid determination of pre-operative carrier status by detecting MRSA and S. aureus, enabling clinicians to determine the best course of treatment for colonized patients.

"Determining pre-operative carrier status of S. aureus, including MRSA, can be helpful in targeting patient treatment, including decolonization, shown to reduce post operative SSIs," said Professor Jan Kluytmans, MD, Professor of Medical Microbiology and Infection Control, VUmc, Amsterdam. "This is particularly important given the high economic burden of S. aureus infection among patients admitted for elective surgery."

Conventional lab culture techniques require at least 24 hours to identify S. aureus. In contrast, rapid diagnostic tests can yield results at time of the initial preadmission screening visit, so clinicians can better counsel patients if results are positive, and can consider enhanced treatment approaches including decolonization to reduce the risk of post-surgical infectious complications.

Carriers of MRSA and S. aureus are at increased risk of developing post-operative SSIs. Studies have shown up to 80 percent of hospital-acquired S. aureus infections are caused by the patients' own flora, and colonized patients are up to nine times more likely to develop surgical site infections than non-carriers. As of April 1, the UK Department of Health has provided guidance that all NHS trusts must introduce MRSA screening for all elective surgery admissions. They must also extend screening to cover all emergency admissions no later than 2011.

Recent reports note that 29 million surgical procedures are performed each year in Europe and approximately 2.6 percent of these patients develop SSIs while recuperating in European hospitals. Once a patient has developed an SSI, their average length-of-stay is increased by 6.5 days and it costs three times as much to treat an infected person

April 20, 2009

RayBiotech and Satoris Announce Collaboration To Develop and Commercialize Early Alzheimer's Test

RayBiotech, Inc., a leading developer and supplier of multiplex protein detection arrays and array-based test kits, and Satoris, Inc., a molecular diagnostics company focused on developing blood-based tests for Alzheimer's disease, and, announced that they intend to cooperate in developing and commercializing an Alzheimer's detection blood test based on Satoris' proprietary plasma biomarkers.

Satoris researchers first reported the utility of Alzheimer's related biomarkers in the November, 2007 edition of the peer-reviewed scientific journal, Nature Medicine. In the reported study, researchers analyzed 259 stored blood samples, comparing those from individuals with presymptomatic to late-stage Alzheimer's disease with those from individuals without the disease. Using a technique known as signal profiling that was enabled by RayBiotech Cytokine Antibody Arrays, they were able to simultaneously measure the relative abundance of 120 known proteins found in plasma that function as chemical messengers between blood cells, brain cells, and cells of the immune system.

Among the 120 plasma markers measured in the Nature Medicine study, a panel of 18 exhibited an expression pattern that was statistically different in the Alzheimer's samples versus other samples. This panel of 18 biomarkers was used to predict the presence of the disease in a test sample set with nearly 90 percent accuracy.

In the collaboration with RayBiotech, the panel of 18 biomarkers will be applied to the proprietary RayBiotech Quantibody array platform. After validating performance of the resulting array-based test, it will initially be commercialized later this year as a research-use-only test, to support Alzheimer's research, and Alzheimer's drug development and clinical trials. RayBiotech will sell the test kit, while Satoris will use the array, together with proprietary bioinformatic analysis tools, to offer a testing service.

"RayBiotech is a recognized leader in the protein array field and we are pleased to be collaborating with them in the adaptation of our proprietary biomarkers to their platform," said Cris McReynolds, President & CEO of Satoris. "Their arrays have been integral to the discovery and validation of our Alzheimer's biomarkers, so it is natural that we utilize their platform and our markers in the configuration of a valuable Alzheimer's detection blood test."

"We are extremely excited and enthusiastic about working with Satoris, a leader in biomarker discovery for neurodegenerative diseases," says Dr. Ray (Ruo-Pan) Huang, Founder and President of RayBiotech, Inc. "We expect this blood test will be well received as a valuable tool in Alzheimer's research and, potentially, as a diagnostic test

as well." Dr. Huang also sees this as a model for future biomarker discoveries, "Using antibody-based approaches, more biomarkers can be identified, validated and put into clinical application faster and cheaper than with traditional methods based on mass spectrometry."

April 15, 2009

Prenatal Testing of Thyroid Is Debated

When women think about pregnancy, the thyroid gland is seldom the first thing that leaps to mind. Nestled in the neck, the gland makes hormones that govern metabolism, helping to regulate body weight, heart rate and a host of other factors. But if the thyroid malfunctions, it can produce too little or too much of these hormones. During pregnancy those conditions, known as hypothyroidism and hyperthyroidism, respectively, may lead to miscarriage, premature birth and pre-eclampsia — and in the case of hypothyroidism, impaired intelligence in the child.

A decade and a half of research has now brought the cumulative evidence of these risks to a critical mass. Clinical guidelines call for vigilant monitoring and treatment of patients to keep thyroid reserves normal and to safely guide women through pregnancy and early motherhood.

But because thyroid problems can easily go undiagnosed, the hazards have also set off a debate over whether every woman who is pregnant or planning to be should have a blood test to check her thyroid. That test measures for thyroid-stimulating hormone, or T.S.H., which spurs the gland's hormone production.

Most doctors' groups have not endorsed universal prenatal thyroid screening, citing uncertainties over whether it would yield health benefits justifying the expense of testing in roughly 6.4 million pregnancies each year and educating doctors to read results that are tricky to interpret.

But the big unanswered question — and crux of the debate — is whether treatment would help women with a mild, common form of thyroid deficiency, called subclinical hypothyroidism. For now, medical societies advise testing only high-risk women.

As a matter of policy, Dr. Kenneth D. Burman, the president of the American Thyroid Association, agrees with that stance for now. Yet like more and more endocrinologists, he offers T.S.H. pregnancy testing in his practice, at Washington Hospital Center in Washington.

"Every patient I see who's considering getting pregnant or is pregnant gets a thyroid function test," he said. "And I think that's the right thing to do."

He and others say they expect more and more doctors and medical societies to

support universal screening after weighing all the evidence. The thyroid association is holding a symposium this Thursday and Friday in Washington to discuss the most recent research. Symptoms of a wayward thyroid can be subtle, and pregnancy can mask them. Fatigue, weight gain and dry skin — all typical in pregnant women — can also result from hypothyroidism, said Dr. Alex Stagnaro-Green, an endocrinologist at Touro University College of Medicine in Hackensack, N.J.

The opposite condition, hyperthyroidism, affects roughly 2 in 1,000 pregnancies. But again, its symptoms — poor sleep, weight loss and nervousness after childbirth — could result from other postpartum conditions.

Hypothyroidism, which usually arises from underlying autoimmune disease, is the more frequent and worrisome concern. As many as 10 to 20 percent of reproductive-age women test positive for antibodies that attack the thyroid gland and may eventually destroy it. Their risk of miscarriage is doubled.

Three to five out of 1,000 women of childbearing age suffer from overt hypothyroidism, in which thyroid hormone, or T4, is low and T.S.H. is abnormally high. But the most common thyroid dysfunction is subclinical hypothyroidism, in which T4 is normal but T.S.H. is slightly elevated. That condition affects 2 to 3 percent of women but often goes undiagnosed when it causes no obvious symptoms.

Hypothyroidism may harm fetal brain development. Ten years ago, researchers in Maine analyzed blood samples from 25,216 pregnant women and identified 62 with hypothyroidism. Their children, by then 7 to 9 years old, were given intelligence tests. Nineteen percent of the children born to women with an untreated underactive thyroid had an I.Q. of 85 or lower, compared with 5 percent of those whose mothers had a healthy thyroid. “At about 85 or below, that’s where you begin to have trouble in school and in life in general,” said Dr. James E. Haddow, a pediatrician at Brown University who was an author of the study. But if mothers had their hypothyroidism treated, their children’s intelligence was not impaired.

In reaction, the American Association of Clinical Endocrinologists endorsed routine T.S.H. testing in all women considering pregnancy. But other organizations, including the American College of Obstetricians and Gynecologists, have said wide-scale screening is premature until more data prove that treating subclinical hypothyroidism would prevent adverse effects in women and their offspring.

Studies do suggest that T4-replacement therapy is protective. But few large clinical trials have rigorously tested this intervention in mildly thyroid-deficient women. So far, promising results have come from one major, well-designed Italian study that showed miscarriage and preterm delivery rates dropped sharply when thyroid hormone pills were given to pregnant women who tested positive for thyroid antibodies.

Experts are now looking to the outcomes of two other major clinical trials under way in Wales and the United States. Both aim to confirm the I.Q. effects and the ability to avert them by studying pregnant women with underactive thyroids who receive hormone therapy or no treatment. Pregnancy is such a critical time that “to expose a baby to a medication without known benefit may not be the best thing, unless we truly know that it’s helpful,” said Dr. Catherine Spong, the chief of pregnancy and perinatology at the National Institute of Child Health and Human Development, which is sponsoring the American trial.

That study will track 1,170 expecting mothers, including women with subclinical hypothyroidism, and their children will undergo I.Q. testing at age 5. Results are expected in 2015.

Advocates of routine testing see no need to wait for more answers, though. Dr. Terry F. Davies, an endocrinologist at the Mount Sinai School of Medicine in New York, finds the evidence “overwhelming” that a shortage of maternal thyroid hormone harms intellectual function in babies. “Once you believe that,” he said, “it would seem to me illogical not to be sure that all women have normal thyroid function during pregnancy.”

And Dr. Haddow said universal prenatal testing could be justified on the grounds of benefiting a woman’s general health. In the Maine study, 58 percent of the pregnant women who had hypothyroidism but did not know it eventually did have it diagnosed, but it took an average of five years. Pregnancy is “an optimal time” for T.S.H. testing, he said.

Most medical societies endorse only selective screening. Two years ago, the Endocrine Society released recommendations for testing T.S.H. in women at high risk for thyroid disorders, including anyone with symptoms of a goiter or sluggish thyroid, or a family history of thyroid problems, as well as those with Type 1 diabetes or autoimmune disease or previous miscarriage or premature delivery.

But research since then has revealed flaws in that strategy. “The problem is, it’s not good enough,” Dr. Stagnaro-Green said. A British study found that such testing missed 30 percent of those with hypothyroidism and 69 percent of those with hyperthyroidism. For now, until there is confirmation that treatment truly helps, Dr. Stagnaro-Green said he still favored selective thyroid screening. But he added, “My belief is that data will be forthcoming that will push us towards universal screening.”

April 14, 2009

Hospital Acquired C. difficile Often Spurred On By Antibiotics -- CMS May Withhold Reimbursement To Hospitals If Their Infection Rate Is Deemed Excessive

Earlier this year, Harold and Freda Mitchell of Como, Miss., both came down with a serious stomach bug. At first, doctors did not know what was wrong, but the gastrointestinal symptoms became so severe that Mrs. Mitchell, 66, was hospitalized for two weeks. Her husband, a manufacturing supervisor, missed 20 days of work.

A local doctor who had worked in a Veterans Affairs hospital recognized the signs of Clostridium difficile, a contagious and potentially deadly bacterium. Although the illness is difficult to track, health officials estimate that in the United States the bacteria cause 350,000 infections each year in hospitals alone, with tens of thousands more occurring in nursing homes. While the majority of cases are found in health care settings, 20 percent or more may occur in the community. The illness kills an estimated 15,000 to 20,000 people annually.

“It’s been the worst thing I’ve ever tried to get through in my life,” said Mrs. Mitchell, who remains weakened by the ordeal. “I really did think I was going to die.”

What is so frightening about C. difficile is that it is often spurred by antibiotics. The drugs wipe out the targeted illness, like a urinary tract or upper respiratory infection, but they also kill off large portions of the healthy bacteria that normally live in the digestive tract. If a person comes into contact with C. difficile, or already has it, the disruption to the beneficial bacteria creates an opportunity for the harmful bacteria to flourish.

The public health community has been sounding the alarm for years about the overuse of antibiotics and the emergence of “superbugs” — bacteria that have developed immunity to a wide number of antibiotics. But the C. difficile problem shows that the threat is not generalized or hypothetical, but immediate and personal.

“One of the things that we counsel consumers about is to make sure that an antibiotic is really necessary,” said Dr. Dale N. Gerding, an infectious disease specialist at the Stritch School of Medicine at Loyola University in Chicago. “There are many good reasons for taking an antibiotic, but an illness like sinusitis or bronchitis winds up being treated with antibiotics even though it will go away by itself anyway.”

Even appropriate use of antibiotics can put a person at risk. Dr. Gerding said his own adult son came down with a C. difficile infection after taking antibiotics for tonsillitis.

The typical treatment for *C. difficile* is another course of antibiotics, typically the drug vancomycin. But the situation can quickly turn tragic. The Centers for Disease Control and Prevention has reported on several cases of pregnant and postpartum women who developed life-threatening *C. difficile* infections after being treated for minor infections. In some instances, a *C. difficile* infection can be treated only by emergency surgery to remove the patient's colon. Doctors say many patients report that they continue to suffer from regular bouts of diarrhea even after the infection is gone. About 20 percent of patients with the infection suffer a relapse, and *C. difficile* support groups have emerged on the Internet.

In the case of the Mitchell family, Mr. Mitchell had been taking antibiotics for another health problem, and the treatment apparently led to his *C. difficile* infection. Mrs. Mitchell probably contracted the illness from her husband. The spores from *C. difficile* are hardy, and contaminated surfaces must be scrubbed down with bleach to eradicate the germ. Doctors say Mrs. Mitchell's illness is unusual because most people are protected by their own bacterial flora and wouldn't be vulnerable to *C. difficile* if they had not been taking antibiotics, even after close exposure. The risk of contracting *C. difficile* outside the health care setting remains low, at about 7 cases per 100,000 people, studies show.

C. difficile is not a new illness, but it appears to be spreading at an alarming rate. The rate of *C. difficile* infection among hospital patients doubled from 2001 to 2005, according to an April 2008 report from the C.D.C.

The rise in *C. difficile* cases around the world is linked with the growing use of all antibiotics, particularly a class of drugs called fluoroquinolones, which came into widespread use around 2001. The use of acid-suppressing drugs, including proton pump inhibitors like Prilosec, also may be a risk factor, although studies have been contradictory.

In addition to becoming more common, *C. difficile* is also becoming more deadly. Several years ago, the mortality rate from a *C. difficile* infection was around 1 to 2 percent. But today, various studies estimate that the death rate is 6 percent. The reason is that a hypervirulent strain has emerged that emits higher levels of toxins than earlier strains.

Many patients are far more familiar with another superbug, methicillin-resistant *Staphylococcus aureus*, or MRSA, which can cause a severe and potentially deadly skin infection. MRSA started off primarily as a hospital-based infection but has become increasingly common in the community.

Hospitals may become more motivated to control *C. difficile* if the Centers for Medicare and Medicaid Services decides to withhold reimbursement for cases of hospital-acquired *C. difficile* infections. The system already withholds reimbursement for certain other preventable hospital infections.

In addition to careful use of antibiotics, patients and hospital visitors should always be vigilant about hand washing, and visitors should not sit on a patient's hospital bed or use a patient's restroom if it can be avoided. Patients should always report severe diarrhea symptoms to a doctor, particularly if they have taken antibiotics recently.

"Up until about 2002, this was a very mild disorder and very few people ever died from it," said Dr. Perry Hookman, a gastroenterologist and associate professor of medicine at the Miller School of Medicine at the University of Miami. "But in the past few years the bugs have become hypervirulent, more severe and now it's a global threat."

April 13, 2009

MicroRNA-based Molecular Diagnostics to Mark Prometheus' Entry into Oncology Market

Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostic company, and Rosetta Genomics Ltd. (NASDAQ: ROSG), an innovative molecular diagnostic company, today announced the execution of a license and collaboration agreement under which Rosetta shall grant Prometheus U.S. rights to three recently introduced, microRNA-based cancer diagnostic tests: miRview mets, miRview squamous and miRview meso.

The terms of the license agreement provide for payments to Rosetta, either as milestones or research and development funding, as well as royalty payments on net sales in the U.S. Under the terms of a separate stock purchase agreement, Prometheus will also make an equity investment in Rosetta of \$8 million at \$4.00 per ordinary share, representing an approximate 41% premium over the closing price of Rosetta stock over three business days. The license and collaboration agreement and the stock purchase agreement are expected to close before the end of April 2009 and are subject to customary closing conditions.

In addition, Prometheus and Rosetta have agreed to collaborate to develop two new microRNA-based gastroenterology tests, which may result in additional, success-based milestones and royalty payments to Rosetta. Funding for development of these gastroenterology tests will be provided by Prometheus.

"Prometheus has established its position as a leader in the gastroenterology market by building an integrated portfolio of diagnostic and pharmaceutical products as well as a highly trained and efficient sales force," said Joseph M. Limber, President and Chief Executive Officer of Prometheus. "Leveraging our core strengths, we intend to apply this business model to oncology, where there is an unmet need to guide the use of a

growing number of targeted therapies. We believe these three molecular diagnostic tests can help oncologists personalize therapy and are ideally suited to lead our entry into the oncology market, while complementing our emerging internal oncology diagnostics program."

"We believe that with this agreement Rosetta has proven the great commercial value of its first three products, and has established itself as a leader in the development of novel, molecular diagnostic products based on microRNAs. We are delighted to enter into this comprehensive partnership with Prometheus," said Amir Avniel, President and Chief Executive Officer of Rosetta Genomics. "With Prometheus these tests now will be available across the U.S., and will be supported by an organization with a proven ability in diagnostic testing services and in launching new products."

April 6, 2009

Study Of 130,000 Women Demonstrates That HPV Molecular Test Clearly Outperforms Pap Smear

A new DNA test for the virus that causes cervical cancer does so much better than current methods that some gynecologists hope it will eventually replace the Pap smear in wealthy countries and cruder tests in poor ones. Not only could the new test for human papillomavirus, or HPV, save lives; scientists say that women over 30 could drop annual Pap smears and instead have the DNA test just once every 3, 5 or even 10 years, depending on which expert is asked.

Their optimism is based on an eight-year study of 130,000 women in India financed by the Bill and Melinda Gates Foundation and published last week in The New England Journal of Medicine. It is the first to show that a single screening with the DNA test beats all other methods at preventing advanced cancer and death. The study is "another nail in the coffin" for Pap smears, which will "soon be of mainly historical interest," said Dr. Paul D. Blumenthal, a professor of gynecology at Stanford who has tested screening techniques in Africa and Asia and was not involved in the study. But whether the new test is adopted will depend on many factors, including hesitation by gynecologists to abandon Pap smears, which have been remarkably effective. Cervical cancer was a leading cause of death for American women in the 1950s; it now kills fewer than 4,000 a year.

In poor and middle-income countries, where the cancer kills more than 250,000 women a year, cost is a factor, but the test's maker, Qiagen, with financing from the Gates Foundation, has developed a \$5 version and the price could go lower with enough orders, the company said.

“The implications of the findings of this trial are immediate and global,” Dr. Mark Schiffman of the National Cancer Institute wrote in an editorial accompanying the study. “International experts in cervical cancer prevention should now adopt HPV testing.”

At the moment, there are huge gaps in how rich and poor countries screen. In the West, women get smears named for their inventor, Dr. Georgios Papanikolaou. Cells are scraped from the cervix and sent to a laboratory, where they are stained and inspected under a microscope by a pathologist looking for abnormalities. Results may take several days. The DNA screen also needs a cervical scraping, but it is mixed with re-agents and read by a machine.

In poor countries, most women get no routine screening. Pain sends them to a hospital, by which time it is often too late.

But in some countries, women get “visualization,” pioneered in the last decade, also with Gates Foundation support: a health worker looks at the cervix with a flashlight and swabs it with vinegar. Spots that turn white may be precancerous lesions, and are immediately frozen off. Diagnosis and treatment take only one visit. Pap smears fail in the third world because there are too few trained pathologists and because women told to return often cannot.

The Indian study, begun in 1999, divided 131,746 healthy women ages 30 to 59 from 497 villages into four groups. One group, the control, got typical rural clinic care: advice to go to a hospital if they wanted screening. The second got Pap smears, the third got flashlight-vinegar visualization, and the fourth got a DNA test, then made by Digene, which is now owned by Qiagen. The company did not pay for or donate to the study, its authors said.

After eight years, the visualization group had about the same rates of advanced cancer and death as the control group. The Pap-smear group had about three-fourths the rates, and the DNA test had about half. Significantly, none of the women who were negative on their DNA test died of cervical cancer. “So if you have a negative test, you’re good to go for several years,” Dr. Blumenthal said.

The study’s chief author, Dr. Rengaswamy Sankaranarayanan of the International Agency for Research on Cancer in Lyon, France, said, “With this test, you could start screening women at 30 and do it once every 10 years.”

Asked whether that advice would apply in the United States, Debbie Saslow, director of gynecologic cancer for the American Cancer Society, replied, “Absolutely no.” “A negative test would mean a woman’s chances of developing cancer are small, but not zero,” she added. “But if he’d said five years, I wouldn’t have a strong reaction.”

Since 1987, she said, the cancer society and the American College of Obstetricians and Gynecologists have recommended Pap smears only every three years after initial negative ones. In 2002, they recommended the HPV test too, and evidence is mounting that the Pap smear can be dropped.

“But we haven’t been able to get doctors to go along,” Dr. Saslow said. “The average gynecologist, especially the older ones, says, ‘Women come in for their Pap smear, and that’s how we get them in here to get other care.’ We’re totally overscreening, but when you’ve been telling everyone for 40 years to get an annual Pap smear, it’s hard to change.” Dr. Sankaranarayanan said most European countries screen every three to five years, and many do not start before age 30.

Cervical cancer is caused by a few of the 150 strains of the human papillomavirus. Women pick strains up as soon as they start having intercourse, but more than 90 percent of cases clear up spontaneously within two years. Early DNA tests would find these, but lead to useless overtreatment. So in women ages 20 to 30, doctors often order repeat Pap tests, which is expensive but may catch the tiny minority of cancers that develop in less than 15 years.

“The U.S. has high resources and low risk-tolerance,” Dr. Schiffman explained, while countries like India have little money and are forced to tolerate risk.

Dr. Jan Agosti, the Gates Foundation officer overseeing its third world screening, said Qiagen’s new \$5 test — which proved itself in a two-year study in China — runs on batteries without water or refrigeration, and takes less than three hours. In countries where women are “shyer about pelvic exams,” she added, it even works “acceptably well” on vaginal swabs they can take themselves.

April 7, 2009

Adavance Developing New Test To Detect MRSA Bacteria Directly, Without Requiring DNA Be Amplified

A sensitive new diagnostic test for methicillin-resistant *Staphylococcus aureus* (MRSA)—a drug-resistant bacterium that can run rampant in hospitals—could help broaden access to fast, cheap testing. The test, being developed by Adavance Technologies, a startup in San Diego, is simpler to perform than existing molecular diagnostics, potentially making it accessible to hospitals without sophisticated labs. Researchers hope that this will enhance surveillance efforts and help stem hospital-centered outbreaks.

MRSA, a variant of the bacterium that causes most staph infections, is commonly found in hospitals, where it can be passed between healthcare workers and patients-- often those with weak immune systems; it accounts for more than half of hospital-acquired infections in the United States. Not everyone who is infected with MRSA shows symptoms, making it difficult to determine who carries the potentially deadly bug.

In an effort to stop hospital outbreaks, a growing number of states require that hospitals test patients for MRSA before admitting them, or are considering legislation that would require them to do so. The entire Veterans Administration health system now requires patient screening, and the practice has been in place in Australia and some European countries for years.

To identify whether a patient is infected with MRSA, hospitals either culture bacteria collected from nasal and other samples, which can take several days, or perform newer molecular tests, which are much more expensive. Only about 35 percent of hospitals in the United States are certified to perform the newer type of testing. The others must send samples out for analysis, which can also take time. "If you're going to isolate patients, the faster you can know who is colonized, the better," says Phil Polgreen, director of the Infectious Disease Society of America's Emerging Infections Network and an epidemiologist at the University of Iowa, in Iowa City. "With the culture studies, you don't know a patient's status for a few days. In that time, the infection could have spread."

In states where hospital screening is required, patients must be quarantined until test results are in--a move that is both costly to hospitals and potentially dangerous for patients. Some studies also suggest that patients in isolation receive less attention from staff.

Adavance is developing a new test that can detect MRSA bacteria directly, without requiring that the DNA be amplified, as is done in existing molecular tests. The central technology is a gold electrode coated with a proprietary marker that binds to the drug-resistant bacteria. As current flows through the electrode, it attracts negatively charged DNA, generating an easily detectable change in the surface charge of the electrode.

Randy White, Adavance's chief executive officer, says that in laboratory experiments, the test is 10 times more sensitive than existing tests, and it's able to detect as few as 12,000 copies of bacterial DNA. He says that the company is now planning to test clinical samples from patients. Adavance expects to launch the MRSA test in 2011, with an estimated price tag of \$60 per test.

"It certainly sounds interesting," says Carol Chenoweth, an epidemiologist at the University of Michigan Health System, in Ann Arbor. "But its success will depend on how well it functions in comparison to other tests out there, how much it costs, and how much technician time it requires to perform."

Despite a growing interest in hospital surveillance, it's not yet clear how effective patient testing is in reducing infection rates. Two conflicting studies were released last year: a large Swiss study found that surveillance had no effect, while a second U.S. study found that it significantly decreased infection rates.

"I think the main benefit can be found in settings where there is outbreak occurring, either hospital-wide or in a unit," says Daniel Diekema, a physician and epidemiologist who's also at the University of Iowa. "Rapid tests provide an advantage in that setting because they give an answer in two to four hours, rather than 24 to 48 hours, during which time you'd have to decide whether to keep a patient isolated."

If Adavance can simplify the screening process even further, it may have a market among physicians' offices. In addition to hospital-related strains, new strains of MRSA are emerging in community settings, such as gyms and day-care facilities. "The real mounting need is in the community," says Stuart Levy, director of the Center for Adaptation Genetics and Drug Resistance at Tufts University School of Medicine, in Boston. "What you want is quick diagnostics you can do when you see the patient."

But not everyone agrees that high-tech solutions are the best approach to controlling MRSA and other dangerous bugs that are springing up across the world. Diekema suggests that other drug-resistant bacteria are spreading more rapidly than MRSA, including strains of gram-negative bacteria, some of which can cause severe pneumonia. He says that simpler preventative measures that can stop the spread of all bacteria, such as increased hand washing, may be more effective.

April 1, 2009

Too Many Patients Must Go Back to Hospital, NEJM Study Finds

The nation spends billions of dollars a year on patients' return visits to the hospital — many of which are readmissions that could be prevented with better follow-up care, according to a study published Wednesday in The New England Journal of Medicine. As many as a fifth all Medicare patients are readmitted within a month of being discharged, according to the study, and a third are rehospitalized within 90 days.

Half the patients who returned to the hospital within 30 days of undergoing treatment other than surgery apparently did not see a doctor before they came back.

The high rate of hospital readmissions is "one of the fruits of an increasingly fragmented health care system," said Dr. Stephen F. Jencks, a former Medicare official

who is an author of the study, which analyzed Medicare claims information for 2003 and 2004. He estimated that the cost of the unplanned return trips was \$17 billion in 2004 alone. Policy analysts say that while high return rates have long been a problem, controlling those costs is increasingly urgent.

“Given the current financial situation, this is no longer something we can ignore,” said Dr. Anne-Marie J. Audet, a policy expert for the nonprofit Commonwealth Fund, a health research foundation that helped pay for the recent study.

The Obama administration, as it seeks money to provide health care for more Americans, has already identified hospital readmissions as a source of potential cost-cutting. The president’s budget calls for \$26 billion in savings from readmissions over 10 years, which includes lowering payments to hospitals with high numbers of patients who are readmitted.

Many elderly patients who leave the hospital with a chronic illness like heart failure or diabetes are left to cope largely on their own. They often do not receive clear instructions on what medications they should be taking, and they frequently have difficulties making doctor appointments to continue their treatment outside the hospital.

“When you get out of the hospital, you need to have an active interaction with the health system,” said Dr. Audet of the Commonwealth Fund, which also provided a grant to the nonprofit Institute for Healthcare Improvement to work with states to try to reduce the number of times patients come back to the hospital. “The patient has to be seen.”

Some hospitals have already shown they can reduce readmissions by taking seemingly simple steps to make sure patients get necessary follow-up care when they go home or to a nursing facility.

At Geisinger Health System, a network in Pennsylvania that has been a leader in improving the quality of hospital care, doctors say they are taking varied approaches to reducing readmissions rates, depending on why the patient was initially hospitalized. With surgery patients, for example, Geisinger has focused on educating people before they come to the hospital about what they are likely to experience and what they should expect when they leave. The effort could reduce readmission rates by as much as 20 percent, said Dr. Ronald A. Paulus, a senior executive at the health system. Geisinger’s early findings, he said, indicate that if patients “are not ready by the time they come in, it’s too late.”

Geisinger has also found it effective to alert the patients’ doctor about the hospital visit, including a brief summary of the patient’s discharge plan that is sent the doctor within 72 hours of the patient’s departure. That kind of simple step, Dr. Paulus noted, does not require an overhaul of the current system.

Successful measures elsewhere have included working more closely with patients or their caregivers to better manage conditions like diabetes, said Dr. Eric A. Coleman, one of the study's authors and a policy expert at the University of Colorado at Denver. Coaching patients to be more diligent about taking their medicine and recognizing when their condition is deteriorating, he said, helps people stay out of the hospital. But Dr. Coleman also said doctors needed to take more responsibility for their patients' continuing care. "Physicians haven't really been stepping up to the plate and taking on this accountability," he said, although he says several professional societies are expected this spring to clarify the doctors' roles.

Many policy analysts add that insurers like Medicare must change the way they pay hospitals and doctors — rewarding medical providers that are able to help patients get and stay better. Under the current system, reducing the number of returning patients can work against the financial interests of a hospital needing to fill empty beds. About one in four of the nation's hospitals derive 25 percent of their admissions from return visits by patients, according to the study.

"Reducing admissions in a hospital is quite punitive in today's environment," said Dr. Amy E. Boutwell, a policy expert at the Institute for Healthcare Improvement. The institute is working with states including Massachusetts, Washington and Michigan to determine how to change the payment system to encourage hospitals to work more closely with doctors and others to prevent needless round trips.

April 1, 2009

McKesson Announces Advanced Diagnostics Management Solution to Simplify Molecular and Genetic Test Selection and Reimbursement

McKesson today announced the availability of its Advanced Diagnostics Management (ADM) solution that intelligently connects payors, clinical laboratories and providers to help physicians order the most appropriate tests for the right cost at the point of care. ADM expands the RelayHealth network to allow providers to gain electronic access to labs' test catalogs and health plans' rules for eligibility, automatic pre-authorization, network coverage, and price estimation.

The burgeoning \$4 billion U.S. molecular and genetic testing market is expected to double by 2012, representing a third of all diagnostic testing costs, according to industry sources. These new tests enable earlier diagnosis of disease as well as safer, more effective, tailored treatments for patients. However, the advent of personalized medicine is clinically challenging and financially complex for payors, labs, providers,

and patients. With little information on the comparative effectiveness and cost of specific tests, and the labs that perform them, physicians may select tests that are unproven, unnecessary, and not covered by insurance, resulting in suboptimal care and costly payments for patients. In turn, selecting the wrong test increases administrative and medical costs for insurers, while labs suffer reimbursement hassle, delays, and denials.

Designed to address these issues, McKesson's Advanced Diagnostics Management solution provides payors and labs with a patent pending collection of advanced web-based services that enable informed test selection, electronic routing, and automatic authorization against centralized rules for coverage and orders. By connecting to clinical laboratories and payors, providers can inform their patients instantly on how much a test will cost, whether their health insurance will cover it, and which labs are best qualified to perform the test.

McKesson's powerful breadth of technology and clinical content, combined with its RelayHealth connectivity solutions across the payor, provider and diagnostic facility markets, uniquely position the company to deliver its Advanced Diagnostic Management solution. Evidence-based test decisions are supported by InterQual® Molecular Diagnostics Criteria, the industry's first point-of-service, evidence-based clinical criteria for molecular and genetic testing. The new InterQual criteria cover more than 270 high volume molecular and genetic tests in the areas of infectious disease, oncology, and inherited diseases. The new offerings also incorporate InterQual Imaging Criteria.

Early customers include labs and regional health systems such as John Muir Health, and major payors such as MVP Health Plan. Blue Cross and Blue Shield of Massachusetts (BCBSMA), New England's largest health plan, is also deploying the new solution to provider partners who frequently order genetic tests or inquire about the coverage offered by the patient's health plan. "We anticipate having the ability to automate information about new genetic and molecular diagnostics tests will help clinicians be better informed about the value of and indications for such tests, and to guide better diagnostic choices leading to optimal utilization decisions," said Barry Zallen, MD, medical director, Medical Innovation and Leadership, BCBSMA. "We also expect their new technology will offer a pathway for automating authorizations. Our goal is to achieve better care for our members with a lower administrative burden and lower cost."

Scott Liff, vice president, chief operating officer, MuirLab, added, "By having clean order requests, we don't inconvenience doctors or their patients for the information we need to conduct tests and bill for them. Having timely access to accurate information helps us eliminate potential delays while also helping us to ensure health plans will reimburse us for tests."

“When health plans and care providers understand the impact of their choices on the quality and cost of care, the patient benefits,” said Matthew Zubiller, business leader for McKesson’s new solution. Zubiller added, “McKesson is at the forefront of this important and emerging market. Having the right criteria to select the right test and a clear understanding of insurance coverage before that test is performed are fundamental to improving the economics and quality of healthcare.”

The Advanced Diagnostics Management solution offered through McKesson centralizes clinical and financial rules to automate authorizations and help ensure reimbursable lab orders.

April 2, 2009

Osmetech and Fisher HealthCare Sign Distribution Agreement For U.S.

Osmetech the international molecular diagnostics business, announces that it has signed a five-year distribution agreement with Fisher HealthCare, a part of Thermo Fisher Scientific, whereby Fisher HealthCare will distribute Osmetech’s eSensor XT-8 instrument platform and molecular diagnostic tests and consumables in the U.S.

James White, Chief Executive, Osmetech plc, said: “We are delighted that Fisher HealthCare has partnered with Osmetech, highlighting the attraction of our eSensor XT-8 platform. Fisher HealthCare has a strong presence in the U.S. diagnostics market with a dedicated team of molecular sales specialists and over 150 leading edge healthcare sales representatives. We will work closely with Fisher HealthCare in order to capitalize on the significant market interest for our products and the growing number of customer leads.

“As we roll out our eSensor XT-8 platform, Fisher HealthCare’s considerable sales and marketing strength and established relationship with key customer accounts will play an important role in accelerating our market penetration.”

Mark Smits, Fisher HealthCare, said: “We are excited by the opportunity to offer our customers Osmetech’s eSensor XT-8 system. It provides next-generation multiplex testing with industry leading standards in terms of speed and ease of use and is ideally suited for the needs of the rapidly growing and decentralizing molecular diagnostics market. The value proposition of the XT-8 for diagnostic laboratories and hospitals is compelling, enabling them to meet their objectives of improving patient care and enhancing the profitability of their operations. The planned expansion of the test menu will be very attractive to our customer base.”

Osmetech plc is an AIM-listed public company on the London Stock Exchange. The Company is a fast developing, international diagnostics business with operations in Boston and Pasadena in the US, serving the high growth molecular diagnostic market targeting hospitals and reference laboratories. Osmetech has a strong portfolio of over 200 issued and pending patents and has launched its first generation eSensor 4800 platform, an electrochemistry-based array system, together with an FDA cleared *in vitro* diagnostic test for Cystic Fibrosis carrier detection.

Osmetech's second generation platform, the eSensor XT-8 received FDA 510(k) clearance in July 2008 together with our eSensor Warfarin Sensitivity Test. These products are now being marketed in the U.S. together with a 2C9 Genotyping Test for drug metabolism and a Cystic Fibrosis carrier detection test which are both available for research use purposes only.

The eSensor XT-8 System is designed to support a broad menu of tests and Osmetech has scheduled for commercial launch a number of further tests including: extended warfarin panel with the proprietary 4F2 marker, venous thrombosis (Factor II, Factor V Leiden and MTHFR) and the RESPLEX II respiratory pathogen assay recently in-licensed from Qiagen. The System provides accurate results while minimizing technician involvement and its features compare favorably to those of other molecular detection systems. Its ease of use, readily interpretable results, speed and low maintenance are particularly suited to the needs of the decentralizing market.

April 1, 2009

Cancer Molecular Diagnostics Evolving In Use

In the field of cancer diagnostics, early detection through screening programs with highly sensitive and extremely specific cancer diagnostic protocols has supported accurate and appropriate therapy selection. While the incidence of cancer and the deaths due to cancer still remain high, novel cancer molecular diagnostics (CMD) are allowing physicians and pathologists to more accurately diagnose cancers, identify predisposition, and select targeted and individualized therapeutic regimens.

Technological advancement has paved the way for personalized medicine as applied to CMD and therapeutics. The thrust toward biomarker discovery and diagnostic-drug codevelopment has been possible given our ability to mine the changes at the genetic, epigenetic, and proteomic levels. Accordingly, the application of genomic and proteomic technologies has significantly furthered the CMD field. While the traditional pathological examination of cancer remains an essential clinical objective, newer technologies such as microarrays, RT-PCR, mass spectrometric proteomic analyses, and protein chips are taking center stage.

The life cycle for the development of a CMD assay through the different stages of biomarker discovery or identification, assay development and validation, and biomarker qualification typically takes four to five years. This is approximately half the time required to bring a new drug to market.

Given that the process is twice as fast, and is only a fraction of the drug development costs, there is a great incentive for molecular diagnostics companies to innovate and bring new tests to market. This creates a big opportunity for diagnostics companies to reap the benefits of time and cost savings, as well as for investment firms and venture capitalists to generate a quicker return on their investment.

The high value of molecular diagnostics tests on the market make new test development an attractive proposition. The time to market can be further reduced by more than two years with the introduction of subsequent tests based on similar platforms, albeit for different cancer types and sub types. The learning and standardization that occurs during the development of the first test cuts down development time by approximately 40% for the subsequent tests. The biggest value proposition, however, lies in the development of companion diagnostics, or the Dx-Rx model.

Despite the market opportunity for new CMD tests, there are concerns about gaining the support of reimbursement agencies for novel molecular diagnostic tests for cancer. The FDA has issued draft guidelines for the molecular diagnostics industry with regard to tests that fall under the category of in vitro diagnostic multivariate integrating assay (IVDMIA). The compliance issue will certainly force companies to rethink their strategies about bringing tests to market. For existing players, this means adapting to the challenge of going through the FDA for an IVDMIA approval.

The effect of regulation will be less drastic if the FDA allows for some buffer time for companies to establish compliance with the new FDA rules when they are finalized. At the current time, the FDA is expected to publish another set of guidelines, which will then be followed by discussions, finally culminating in drafting of the rules. Pressure from the FDA may significantly alter the dynamics of the CMD industry.

With more than 98% of CMD testing currently occurring through CLIA-certified laboratories, the share of revenue from FDA-approved tests is minimal. The balance is likely to shift in the near future as many tests transition to the FDA-approved segment. Some tests may still remain in the domain of CLIA laboratories depending on the degree of complexity and risks involved.

March 26, 2009

NEJM Study: Substantial Doubts Regarding Digital Health Data

Now that the federal government plans to spend \$19 billion to spur the use of computerized patient records, the challenge of adopting the technology widely and wisely is becoming increasingly apparent.

Two articles, to be published on Thursday in the New England Journal of Medicine, point to the formidable obstacles to achieving the policy goal of not only installing electronic health records, but also using them to improve care and curb costs.

One article reports that only 9 percent of the nation's hospitals have electronic health records, based on a survey of nearly 3,000 hospitals. The study, financed by the federal government and the Robert Wood Johnson Foundation, is the most definitive measure to date of the use of computerized patient records by hospitals. The government-backed study found a far lower level of use than some earlier, less rigorous surveys.

The study, the authors said, measured only the adoption of digital patient records. The survey did not ask whether the electronic records were used to advance the health policy goals of the federal plan, like tracking the quality of care and communicating effectively with outside specialists and clinics to coordinate a patient's care.

"We have a long way to go," said Dr. Ashish K. Jha, an assistant professor at the Harvard School of Public Health who was the article's lead author. "And we did not measure effective use. Even if a hospital does have electronic health records, it does not mean it is sharing information with other hospitals and doctors down the road." In a second article in the journal, two experts in health information technology at Children's Hospital Boston assert that spending billions of dollars of federal funds to stimulate the adoption of existing forms of health record software would be a costly policy mistake.

In the article, identified as a "perspective," Dr. Kenneth D. Mandl and Dr. Isaac S. Kohane portray the current health record suppliers as offering pre-Internet era software — costly and wedded to proprietary technology standards that make it difficult for customers to switch vendors and for outside programmers to make upgrades and improvements.

Instead of stimulating use of such software, they say, the government should be a rule-setting referee to encourage the development of an open software platform on which innovators could write electronic health record applications. As analogies, they point to other such software platforms — whether the Web or Apple's iPhone software, which the company has opened to outside developers.

In the Mandl-Kohane model, a software developer with a new idea for health record features like drug allergy alerts or care guidelines could write an application, and those could be added or substituted for a similar feature.

Such an approach, they say, would open the door to competition, flexibility and lower costs — and thus, better health care in the long run. “If the government’s money goes to cement the current technology in place,” Dr. Mandl said in an interview, “we will have a very hard time innovating in health care reform.” To justify spending taxpayers’ money, the government program must expand digital records beyond routine tasks like billing to focus on “how the technology will be used to improve clinical performance,” said Herbert S. Lin, a senior scientist the National Academy of Sciences, an advisory group to the government.

The Obama administration’s health technology plan, which is part of the economic recovery package, includes incentive payments for adopting electronic health records — more than \$40,000 per physician and up to several million dollars for hospitals. The payments are spread over a few years and are based on “meaningful use” of “certified” records, although Congress left defining those terms to the Department of Health and Human Services.

The incentive payments, industry experts say, are enough to greatly accelerate the adoption of electronic health records. In the new survey of hospitals, the cost of digital record systems was cited as the single largest obstacle to adoption.

Dr. David Blumenthal, a professor at the Harvard Medical School, oversaw the hospital study. Last week he was named the national coordinator for health information technology in the Obama administration. In a conference call to discuss the study, Dr. Blumenthal declined to talk about his plans in detail.

But clearly, he sees electronic health records as a tool to reform health care, and the Obama administration intends to shift Medicare and Medicaid reimbursement toward paying for better health outcomes, which will be measured and monitored using technology.

“The goals are quality and efficiency, instead of just putting machinery in offices,” Dr. Blumenthal said. “If we encourage better performance, then physicians are going to find ways to improve performance. And health information technology is one crucial way to do that.”

April 22, 2009

Mapping a Human Genome, via an eBay Auction

How much would you bid to have your personal genome mapped? In a sign that genome-mapping is becoming increasingly common, a company called Knome plans to offer its personal gene-sequencing service to the highest bidder in an eBay auction set to begin on Friday and continue for 10 days. The company plans to opening the bidding at \$68,000.

Any winning bid below \$99,000 would be a relative bargain, since that is the price Knome now charges to sequence a person's complete DNA. And it would be a deep discount from the \$350,000 that Knome (pronounced like gnome) was charging for a personal genome as recently as last year.

Scientists envision that in a few years it will cost only \$1,000 to determine the sequence of virtually all 6 billion chemical units of DNA in a person's 46 chromosomes. Someday, such personal genetic blueprints could be used to predict people's risk of disease and what drugs might work best for them.

But at present the information has little value — even for a low-ball bid of \$68,000. Just last week, experts writing in *The New England Journal of Medicine* acknowledged that scientists still know very little about which genetic variations contribute to the risk of common diseases.

Knome's chief executive, Jorge Conde, declined to say how many customers the company currently has, although he said there was an uptick in business in December. "People ordered genomes for Christmas," he said. "I wouldn't have anticipated that." The auction is essentially a publicity stunt. Proceeds will go to the X Prize Foundation, which is offering a \$10 million prize to the first group that can sequence 100 human genomes in 10 days at less than \$10,000 per genome. There are 17 entrants in the X Prize contest.

Knome's auction will be run by Kompolt Cause Media, which has conducted other charity auctions on eBay, liked selling lunch with Warren E. Buffett for \$2.1 million last year to benefit the Glide Foundation in San Francisco.

Mimicking that idea, Knome is throwing in a bonus to help attract bidders — a private dinner with George Church, a prominent Harvard scientist who co-founded Knome.

April 22, 2009

Advances Elusive in the Long Drive to Cure Cancer

In 1971, flush with the nation's success in putting a man on the Moon, President Richard M. Nixon announced a new goal. Cancer would be cured by 1976, the bicentennial. When 1976 came and went, the date for a cure, or at least substantial progress, kept being put off. It was going to happen by 2000, then by 2015.

Now, President Barack Obama, discussing his plans for health care, has vowed to find "a cure" for cancer in our time and said that, as part of the economic stimulus package, he would increase federal money for cancer research by a third for the next two years. Cancer has always been an expensive priority. Since the war on cancer began, the National Cancer Institute, the federal government's main cancer research entity, with 4,000 employees, has alone spent \$105 billion. And other government agencies, universities, drug companies and philanthropies have chipped in uncounted billions more.

Yet the death rate for cancer, adjusted for the size and age of the population, dropped only 5 percent from 1950 to 2005. In contrast, the death rate for heart disease dropped 64 percent in that time, and for flu and pneumonia, it fell 58 percent.

Still, the perception, fed by the medical profession and its marketers, and by popular sentiment, is that cancer can almost always be prevented. If that fails, it can usually be treated, even beaten.

The good news is that many whose cancer has not spread do well, as they have in the past. In some cases, like early breast cancer, drugs introduced in the past decade have made an already good prognosis even better. And a few rare cancers, like chronic myeloid leukemia, can be controlled for years with new drugs. Cancer treatments today tend to be less harsh. Surgery is less disfiguring, chemotherapy less disabling.

But difficulties arise when cancer spreads, and, often, it has by the time of diagnosis. That is true for the most common cancers as well as rarer ones. With breast cancer, for example, only 20 percent with metastatic disease — cancer that has spread outside the breast, like to bones, brain, lungs or liver — live five years or more, barely changed since the war on cancer began.

With colorectal cancer, only 10 percent with metastatic disease survive five years. That number, too, has hardly changed over the past four decades. The number has long been about 30 percent for metastatic prostate cancer, and in the single digits for lung cancer.

As for prevention, progress has been agonizingly slow. Only a very few things — stopping smoking, for example — make a difference. And despite marketing claims to

the contrary, rigorous studies of prevention methods like high-fiber or low-fat diets, or vitamins or selenium, have failed to find an effect.

What has happened? Is cancer just an impossibly hard problem? Or is the United States, the only country to invest so much in cancer research, making fundamental mistakes in the way it fights the cancer war?

Researchers say the answer is yes on both counts. Cancer is hard — it is not one disease or, if it is, no one has figured out the weak link in cancer cells that would lead to a cure. Instead, cancer investigators say, the more they study cancer, the more complex it seems. Many are buoyed by recent progress in cancer molecular biology, but confess they have a long way to go.

There also are unnecessary roadblocks. Research lurches from fad to fad — cancer viruses, immunology, genomics. Advocacy groups have lobbied and directed research in ways that have not always advanced science.

And for all the money poured into cancer research, there has never been enough for innovative studies, the kind that can fundamentally change the way scientists understand cancer or doctors treat it. Such studies are risky, less likely to work than ones that are more incremental. The result is that, with limited money, innovative projects often lose out to more reliably successful projects that aim to tweak treatments, perhaps extending life by only weeks.

“Actually, that is the biggest threat,” said Dr. Robert C. Young, chancellor of the Fox Chase Cancer Center in Philadelphia. “Every organization says, ‘Oh, we want to fund high-risk research.’ And I think they mean it. But as a matter of fact, they don’t do it.” A recent New York Times/CBS News poll found the public divided about progress. Older people, more likely to have friends or relatives who had died of cancer, were more dubious — just 26 percent said a lot of progress had been made. The figure was 40 percent for middle-aged people, who may be more likely to know people who, with increased screening, had received a cancer diagnosis and seemed fine.

Yet the grim facts about cancer can be lost among the positive messages from the news media, advocacy groups and medical centers, and even labels on foods and supplements, hinting that they can fight or prevent cancer. The words tend to be carefully couched, but their impression is unmistakable and welcomed: cancer is preventable if you just eat right and exercise. If you are screened regularly, cancers can be caught early and almost certainly will be cured. If by some awful luck, your cancer is potentially deadly, miraculous new treatments and more in the pipeline could cure you or turn your cancer into a manageable disease.

Unfortunately, as many with cancer have learned, the picture is not always so glowing.

Phyllis Kutt, 61, a retired teacher in Cambridge, Mass., believed the advertisements and public service announcements. She thought she would never get cancer — she is

a vegetarian, she exercises, she is not overweight, she does not smoke. And only two people in her extended family ever had cancer.

Then, in May 2006, Ms. Kutt's mammogram showed a foggy spot. The radiologist decided it was insignificant, but six months later, her internist found a walnut-sized lump in her right breast close to her armpit. It was the area that had been foggy on the mammogram.

"I was in real shock," Ms. Kutt said. "How could this be happening to me?" Still, it looked as if she would be fine. There was no sign of cancer in her lymph nodes, and her surgeon removed the tumor.

Ms. Kutt, her husband and her oncologist were worried, though, and decided on aggressive treatment — four months of chemotherapy followed by 33 rounds of radiation. When it ended, she thought she was finished with cancer.

"My doctors never used the word 'cure' and I bless them for that," Ms. Kutt said. "But they do celebrate the end of chemo and they celebrate the end of radiation."

Last May the cancer came back, as a string of tiny lumps under her arm and a lump on her bicep. CT scans revealed she also had tumors in her lungs.

But cancer is curable, she thought. There are amazing new treatments. She found out otherwise.

It turns out that, with few exceptions, mostly childhood cancers and testicular cancer, there is no cure once a cancer has spread. The best that can be done is to keep it at bay for a while.

Last June, Ms. Kutt started a new regimen — three weeks of chemotherapy, followed by a week off. She is also taking a new drug, Avastin.

"I am still on that and will be forever until the cancer progresses and I change to other drugs or some new drugs are developed, or I die," she said.

The hardest part is explaining to friends and family.

"People will say to me, 'So when is your treatment going to be over?' " Ms. Kutt said. "That's the perception. You get treated. You're done. You're cured."

"I think some of my family members still believe that," she added. "Even though I told them, they forget. I get cards from my nieces, 'How are you doing? You'll be done soon, right?' "

Dr. Leonard Saltz, a colon cancer specialist at Memorial Sloan-Kettering Cancer Center, deals with misperceptions all the time. "People too often come to us expecting that the newest drugs can cure widespread metastatic cancer," Dr. Saltz said. "They are often shocked to find that the latest technology is not a cure."

One reason for the misunderstanding, he said, is the words that cancer researchers and drug companies often use. “Sometimes by accident, sometimes deliberately, sometimes with the best intentions, sometimes not, we may paint a picture that is overly rosy,” he said.

For example, a study may state that a treatment offers a “significant survival advantage” or a “highly significant survival advantage.” Too often, Dr. Saltz says, the word “significant” is mistaken to mean “substantial,” and “improved survival” is often interpreted as “cure.”

Yet in this context, “significant” means “statistically significant,” a technical way of saying there is a difference between two groups of patients that is unlikely to have occurred by chance. But the difference could mean simply surviving for a few more weeks or days.

Then there is “progression-free survival,” which doctors, researchers and companies use to mean the amount of time from the start of treatment until the tumor starts growing again. It does not mean that a patient lives longer, only that the cancer is controlled longer, perhaps for weeks or, at best, months. A better term would be “progression-free interval,” Dr. Saltz said. “You don’t need the word ‘survival’ in there.”

As a doctor who tries to be honest with patients, Dr. Saltz says he sees the allure of illusions.

“It would be very hard and insensitive to say, ‘All I’ve got is a drug that will cost \$10,000 a month and give you an average survival benefit of a month or two,’ ” he said. “The details are very, very tough to deal with.”

That does not help Ms. Kutt, who chafes at the way breast cancer is presented — the pink ribbons, the celebration of survivors, the emphasis on early detection, as though that will insure you will never get an incurable cancer.

She knows she frightens people with her bald head, so obviously a cancer patient. When someone is on crutches with a broken ankle, strangers offer condolences and ask about the injury. But people avert their eyes when they see Ms. Kutt. Only once, she said, did a stranger approach, and that was a woman who also had breast cancer.

And in her online discussion group of women with metastatic disease, some said they had been asked to leave breast cancer support groups. Members whose cancer had not spread considered themselves survivors, and those whose cancer had spread were too grim a reminder of what could happen.

“It’s fear,” Ms. Kutt said. “You’re part of the death group.”

March 25, 2009

MD-OnCall: Access To Physicians In Any Specialty -- Complete Answers To Your Proprietary Questions -- Quickly and Unambiguously

Capturing and analyzing the 'voice of the customer' is integral to driving growth and can be a critical competitive advantage. When the customer voice you are seeking to hear is that of a physician this process can be particularly challenging. However, with MD-OnCall, a new and dynamic research and analysis service from the Emmes Group, you can attain the physician feedback you seek rapidly and easily – often gleaning revealing, in-depth responses from 100 or more MD's in less than a week.

Here's how it works:

- The Emmes Group has established a series of physician panels (MD's on call) consisting of well-experienced clinicians in virtually every medical specialty (*ranging from infectious disease to oncology; from cardiology to gynecology; from surgery to anesthesiology, to radiology to endocrinology, to pediatrics, to internists*) ready to answer your questions candidly and thoroughly.
- Our research staff works closely with you to establish and implement appropriate screening criteria to ensure we reach the specific physician audience your investigation requires. Next we collaborate with you in creating a survey that will provide the particular knowledge you seek.
- Each survey is unique, customized to your specifications, and programmed by our technical staff for maximum flexibility. Beyond just questions, your survey can include: pictures, diagrams, pop-up graphics or video, and a wide range of qualitative and quantitative response types including: multiple choice, verbatim text box, drop down, skip patterns or fill in the blank.
- The results: a comprehensive written report and analysis, focused on bottom line objectives, provided to you rapidly -- often within a few days, with appropriate graphs, tables, charts and other useful presentation-friendly data summaries.

MD-OnCall takes the heavy lifting out of your hands and delivers in-depth results, quickly and efficiently. It is ideal for managers who want to understand the likely rate of adoption of a new product, test or service; the impact of proposed new features, designs or capabilities; physicians' attitudes toward a messaging or marketing campaign, or any other important business issue that would benefit from difficult to access customer input.

For more information regarding how you can obtain comprehensive, verbatim answers from experienced physicians complemented by an objective meta-analysis, please contact:

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February 25, 2009

Powerful Database Containing Deep Wells Of Essential Molecular Diagnostics Information For Over 30 Assays Performed In 1,000 Labs -- Now Available

Subscribers Can Easily Access Desired Information - By Assay, By Vendor, By Test Volume, By Test Type (FDA-Cleared, ASR or Homebrew) By Sales Region, and By Customer Satisfaction -- Individually or in Combination With Virtually Any Set of Designated Criteria -- Directly or Online.

The Emmes Group, a leading provider of essential IVD market information and insights for over 25 years is now accepting subscriptions to its acclaimed 2009 Molecular Testing Database as well as access to its recently completed 2008 Molecular Testing Database.

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 Molecular Testing 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.

An authentic (low-resolution) profile of 1 of the 1,000 laboratories that comprise the 2008 Emmes Molecular Testing Database (with genuine data but with the hospital name and address concealed) is shown on the next page.

For further FREE profiles, or an [online demonstration](#), or for any additional information regarding access to the 2008 Database, or a subscription to the 2009 Database, please contact:

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Emmes 2008 Molecular Testing Database										
Lab: XXX Hospital		Address: 123 Any Street			City: Anywhere State: MI Zip: 48073			Telephone: 248-111-1111		Name: John Q. Manager Title: Molecular Supervisor
Type of Institution: Teaching Hospital		Type of Lab: Molecular Lab		Interview Number: 265		Number of Beds: 1058		Month of Interview: Dec		Year of Interview: 2008
Test	Perform	Annual Volume	Samples Per Run	Test Freq.	Trend +/- %	Commercial ASR, Homebrew	Manufacturer/Platform	Will Change	Reason Why Considering Change	
Adenovirus	no									
Bordetella	no									
Chlamydia Gonorrhea	YES	50000	200	5	15%	Commercial	Roche - Cobas	no	N/A	
CMV	YES	500	5	2	20%	Commercial	Roche - Cobas	no	N/A	
EBV	no									
Group A Strep	no									
Group B Strep	no									
Enterovirus	YES	350	1	7	Same	Homebrew	Roche - RT PCR	no	N/A	
Influenza A/B	no									
Herpes (HSV)	YES	2450	7	7	40%	Commercial	Roche - LightCycler	no	N/A	
HbV Viral Load	YES	500	10	1	50%	Commercial	Roche - Cobas	no	N/A	
HCV Viral Load	YES	1250	25	1	10%	Commercial	Siemens - bDNA	no	N/A	
HCV Genotyping	YES	250	5	1	Same	Commercial	Siemens - Auto-LIPA	no	N/A	
HIV Viral Load	YES	1250	25	1	10%	Commercial	Roche - Cobas	YES	TaqMan - Broader dynamics	
HIV Genotyping	YES	100	1	2	Same	Commercial	Siemens - Trugene	no	N/A	
HPV	YES	1500	30	5	30%	Commercial	Digene - Hybrid Capture	no	N/A	
Lab: XXX Hospital		Emmes 2008 Molecular Testing Database					Type: Teaching Hospital			
City/State: Anywhere, MI		Page: 2					Interview Number: 265			
Test	Perform	Annual Volume	Samples Per Run	Test Freq.	Trend +/- %	Commercial ASR, Homebrew	Manufacturer/Platform	Will Change	Reason Why Considering Change	
HPV Genotyping	no									
MRSA	no									
MSSA	no									
MTD (Tuberculosis)	YES	700	2	7	10%	ASR	Gen-Probe - TMA	no	N/A	
VRE	no									
Respiratory Virus	no									
BCR/ABL	YES	300	6	1	5%	Homebrew	PCR Electrophoresis	no	N/A	
Bladder Cancer	no									
CF	YES	1000	20	2	10%	ASR	Luminex - CFTR	no	N/A	
Factor II	YES	1200	12	2	Same	ASR	Third Wave - Invader	no	N/A	
Factor V Leiden	YES	2000	20	2	Same	ASR	Third Wave - Invader	no	N/A	
Fragile X	no									
Her2Neu	no									
HLA Typing	YES	350	7	7	10%	ASR	Biotest - SSP	no	N/A	
MTHFR	YES	500	10	2	Same	ASR	Third Wave - Invader	no	N/A	
Prothrombin	YES	1200	12	2	Same	ASR	Third Wave - Invader	no	N/A	
Requested tests not currently offered		If Yes Which tests		If limitations did not exist what tests your lab would most like to add				Real world limitations/barriers. 3 molecular tests that your lab would most like to add		
<input type="checkbox"/> YES		<input type="checkbox"/> BK Virus & PCA3		<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Adenovirus Influenza A/B Respiratory Virus </div>				<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Adenovirus Influenza A/B Respiratory Virus </div>		
Reason: tests are not currently offered		Outsource or Perform								
<input type="checkbox"/> Not enough time to bring them in		<input type="checkbox"/> Outsource								