



Diagnostic Testing and Healthcare Industry News Update

March 25, 2009

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Contact Us

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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.

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Continued...

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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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March 24, 2009

Kaiser Permanente Data Provides Strong Evidence for Continued Value of Combined Pap and HPV Testing

Physicians from Kaiser Permanente and the National Cancer Institute report in the March issue of *Obstetrics & Gynecology* that results from an evaluation of more than 800,000 Pap and HPV tests conducted at Northern California Kaiser Permanente dispel the notion that excessive numbers of women would require increased surveillance and follow-up when HPV testing is implemented. Cervical cancer is a preventable cancer with a primary known cause - the human papillomavirus (HPV). QIAGEN developed and markets the *digene*[®] HPV Test, a cervical cancer screening test that detects the high-risk types of HPV that cause cervical cancer and identify women most at risk for developing the disease.

In the study "Five-Year Experience of Human Papillomavirus DNA and Papanicolaou Test Cotesting," Dr. Philip E. Castle of the National Cancer Institute, together with Dr. Walter Kinney of Kaiser Permanente and a team of other contributors, focused on the early results of combining HPV and Pap testing for routine cervical cancer screening. Kaiser exclusively used QIAGEN's Hybrid Capture[®] 2 High-Risk HPV DNA Test for its HPV detection in the study (also called the *digene* HPV Test) and conventional cytology for its Pap testing.

The physicians reported that 90.8% of the 580,000 women aged 30 and older had "double-negative" results, meaning their Paps were normal and they did not have high-risk types of HPV so were at low risk for developing cervical cancer. Overall, 6.27% of co-tests were carcinogenic HPV positive, and 2.28% showed carcinogenic HPV infection together with Pap results showing pre-cancerous cell changes or inconclusive results. Only 3.99% were found HPV-positive with a normal Pap result. Under Kaiser's previously published protocol, this group of women would be scheduled for re-testing in 12 months to monitor the persistence of HPV infection. The study authors concluded, "In a general screening population, concerns about excessive HPV test positives among women aged 30 years and older are not borne out."

Investigators also revealed that among those women who tested positive for high-risk HPV infection with the *digene* HPV test, patients in the age segments of 30-34 years (10.82%) and 35-39 years (8.03%) had the highest infection rates and also were the groups with the highest prevalence of CIN2/3, thus reinforcing the clinical benefit of reserving routine HPV testing for women age 30 and higher.

"These study results illustrate the benefits to large health systems of combined screening with the *digene* HPV Test and a Pap for all women age 30 and older, and dispels the notion that excessive numbers of women would require increased surveillance and follow-up when HPV testing is implemented," said Dr. Jim Godsey, Sr. VP for QIAGEN. "Some doctors have exercised caution using HPV testing out of now-disproven concern that they would have a lot of patients with Pap normal/HPV positive test results who would require counseling and follow-up. This study demonstrates that this is not the case, and importantly shows cotest outcome rates within the very large and diverse patient population that Kaiser serves. This is good news to the clinical community who may have been overly anxious about the management of a large number of HPV positive, Pap normal test results. In fact, by identifying the women who test positive for infection with one of the cancer causing types of HPV -- and who are hence at greater risk of developing cervical disease -- clinicians can more effectively direct treatment and follow-up, potentially detecting more early stage disease."

Kaiser Permanente Northern California performs HPV testing with the *digene* HPV Test and provides Pap and HPV cotesting to its female patients age 30 and older to better identify those at risk of developing cervical cancer. The *digene* HPV Test detects the presence of high-risk types of HPV, the primary cause of cervical cancer. The test is recommended for use along with the Pap to screen women age 30 and older, the group most at risk of developing cervical cancer, as well as for follow-up evaluation in women whose Pap results are inconclusive.

"We recognize that women who test positive for carcinogenic HPV and negative by cytology are at an elevated risk for cervical pre-cancer and cancer compared with women who test negative on both," the study authors write, suggesting that future clinical research will need to focus on identifying "the best strategies for managing women who test positive for carcinogenic HPV and negative by cytology."

While the Pap test relies on a lab technician to manually look for cell changes that may signal cervical disease, QIAGEN's *digene* HPV Test, which uses the company's proprietary Hybrid Capture 2 technology, uses advanced molecular technology to identify the presence of the genetic code of 13 high-risk, cancer-causing types of HPV.

More than 40 million tests for carcinogenic HPV have been performed with the *digene* HPV Test. FDA-approved since 1999, the *digene* HPV Test has been published in more than 300 peer-reviewed journal articles and studied in clinical trials involving more than 825,000 women worldwide. Its well-validated clinical value has helped HPV testing develop as the new standard-of-care for cervical cancer screening. QIAGEN's *digene* HPV Test is recognized as the "gold-standard" in HPV testing.

March 23, 2009

Gen-Probe Board of Directors Elects Carl Hull Chief Executive Officer

Gen-Probe Incorporated announced today that its board of directors has elected Carl W. Hull the Company's new chief executive officer (CEO), effective May 18, 2009. He also is expected to join the Company's board of directors at that time.

Mr. Hull, currently Gen-Probe's president and chief operating officer, will become president and CEO following the retirement of Henry L. Nordhoff as the Company's CEO on May 17, 2009. Mr. Nordhoff, who has served as Gen-Probe's chief executive officer since 1994, will become non-executive chairman upon his re-election to the board by stockholders at the Company's 2009 annual meeting.

"I'm delighted to announce the board's unanimous election of Carl as Gen-Probe's next CEO," Nordhoff said. "He brings unparalleled experience in our field and a deep understanding of molecular diagnostics. His keen intellect and unflagging energy will prove invaluable as he takes the helm of the Company."

"In nearly 15 years as CEO of Gen-Probe, Hank has presided over tremendous business growth, product innovation and shareholder value creation," said Armin Kessler, Gen-Probe's lead independent director and former chief operating officer of Hoffman-La Roche. "The Company has grown from a subsidiary of Chugai, with \$61 million in annual revenues, to a public company with a market capitalization exceeding \$2 billion and revenues of \$473 million last year. Gen-Probe's customers, employees and shareholders owe him a debt of gratitude, and the board is fortunate to be able to continue benefiting from his guidance and leadership."

March 24, 2009

Study Shows Jump In Pediatric MRSA; Rate of Cepheid Announces New Diagnostic Technology For Mycobacterium Tuberculosis (TB)

Cepheid today announced details of technology expected to revolutionize the speed of diagnosis of Mycobacterium tuberculosis (TB) and the resistance to common drug treatment for the disease.

The new test technology, developed in partnership with Foundation for Innovative New Diagnostics (FIND) and the University of Medicine and Dentistry of New Jersey (UMDNJ), and funded by the National Institute of Allergy & Infectious Diseases (NIAID), will leverage the power of Cepheid's GeneXpert 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 infected with Mycobacterium tuberculosis. Each year approximately nine million people develop active TB and two million people lose their lives to the illness. This equates to one life every 20 seconds.

"One of FIND's main goals is to help to save the millions of lives that are needlessly lost to TB every year," says Giorgio Roscigno, Chief Executive Officer of FIND.

"Cepheid's commitment to researching and bringing this test to market has been outstanding, as is their intention to sell Xpert MTB/RIF on a cost for product basis in the developing world, where it is most needed. We are proud to be working with them on this project."

Rapid diagnosis of TB is vital in areas such as sub-Saharan Africa and Southeast Asia due to the close connection between HIV and TB. 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 need for accurate and rapid detection of tuberculosis is becoming increasingly acute with the development of drug resistant strains and the growing at-risk populations in the developing world," 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 the Xpert MTB/RIF test.

Clinicians will now be able to obtain dependable test results for not only detection of TB but simultaneous determination of whether or not it is a drug resistant strain in virtually any clinical setting.

Appropriate therapeutic management has been a significant factor in the development of drug resistant strains of tuberculosis and the availability of the Xpert MTB/RIF test should be a breakthrough technological leap forward in helping to ensure proper therapeutic management and in helping to halt transmission. We are expecting to make this test available as a CE IVD Mark product next month."

Xpert MTB/RIF not only detects the presence of TB, but also identifies whether it is resistant to Rifampicin, a common first-line drug for treatment of the disease and a reliable surrogate marker of strains that are multidrug-resistant (MDR-TB). The test is expected to enable physicians to dramatically improve patient outcomes -- possible only with on-demand, actionable results to guide therapy decisions within the timeframe of an initial patient visit.

"Multidrug-resistant TB is becoming increasingly prevalent throughout the world, making TB harder to treat with the usual treatment 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 in all corners of the world, including resource-limited settings where it is most needed."

Currently, the most common testing method for TB is the sputum microscopy, or 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.

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. For patients in the developing world, lengthy turnaround times of current test methods can lead to catastrophic consequences as the chain of transmission grows.

"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."

March 19, 2009

Study Shows Jump In Pediatric MRSA; Rate of Increase More Than Doubles

The nationwide rate of head and neck infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in children has more than doubled recently. This is based on a study of hospitalized children from January 2001 to December 2006. In January 2001, the rate of MRSA infections in the head and neck area was almost 12%. That figure jumped to 28% by the end of 2006, according to researchers from Emory University and Eggleston Hospital in Atlanta, Georgia.

Their evaluation of pediatric MRSA infections of the head and neck region is based on data from more than 300 hospitals nationwide and appears in the January 2009 issue of *Archives of Otolaryngology – Head and Neck Surgery*.

The study also suggests that the majority of children become infected in the community rather than in hospitals. The researchers noted that almost 60% of all MRSA pediatric head and neck infections in their study were from outpatient sources.

“There is a nationwide increase in the prevalence of MRSA in children with head and neck infections that is alarming,” said lead researcher Steven E. Sobol, MD, MSc, primary investigator of the study and director of Pediatric Otolaryngology in the Department of Otolaryngology - Head and Neck Surgery at Emory. Citing concern about antimicrobial drug resistance, he called upon doctors to prescribe antibiotics more carefully.

Public health departments across the nation have advised primary care doctors to suspect MRSA when examining *S. aureus* skin or soft tissue infections, but to hold off treating them until they get results from a culture of the sample taken from the infected area. Laboratory professionals take the sample and place it onto a thin layer of nutrient gel or into a nutrient broth and examine the sample for growth of characteristic *S. aureus* colonies. If present, the lab professional does another test to determine whether the staphylococci are MRSA. Usually the process takes at least one to two days.

Infections caused by MRSA do not respond to usual treatment for *S. aureus* and are notoriously difficult and expensive to treat. Many studies have shown that rates of MRSA infection have been rising for several years, but research has mostly focused on skin infections.

The study by the Atlanta researchers is the first to show skyrocketing national rates of infection in deeper head and neck tissues. These include certain ear and sinus infections and abscesses in the tonsils and throat.

Many hospitals are now taking more aggressive action to combat MRSA. In addition to testing patients with suspected MRSA infections, these institutions routinely test all patients entering departments with higher infection rates, like the intensive care unit. A very few hospitals are now using much faster molecular tests that screen for genes present in MRSA, but these tests are far more expensive than culture.

Several states have passed or are considering legislation that would mandate reporting rates of MRSA and other hospital-acquired infections.

Meanwhile, the federal government's Medicare program has stopped reimbursing institutions for treatment related to MRSA and other infections that are acquired while the patient is in the hospital.

March 19, 2009

Roche Acquires Innovatis To Complement Its Product Portfolio In The Growing Area Of Cellular Analytics

Roche recently announced that it has signed a definite agreement under which Roche will acquire 100% of innovatis, a privately held company based in Bielefeld, Germany.

Innovatis is a leading provider of automated cell analysis solutions, especially focusing on cell counting, viability testing, and cell function analysis in research, as well as bioproduction. The purchase price for this transaction is 15 million Euros.

"This acquisition is a further step in our strategy to strengthen our position as a complete solution provider in the cell analysis research market," said Dr. Jürgen Schwiezer, CEO Division Roche Diagnostics. "Innovatis' technology will complement the existing Roche cell analysis portfolio and is synergistic to the xCELLigence technology launched in 2008."

Michael Grohmann, Managing Director of the innovatis AG stated: "Roche has been one of our key customers for many years, in particular since the successful development of our cell analysis technology over 10 years ago. The innovatis technology is very well placed for future growth as part of Roche Applied Science."

Innovatis will become a fully-integrated part of Roche Applied Science, a global business area of the Diagnostic Division of Roche. The company will continue to develop and market products for cell analysis through Roche Applied Science's extensive worldwide network. The transaction is expected to be completed within the next few weeks, subject to shareholder approval and regulatory clearance.

March 18, 2009

Prostate Cancer Screening Found to Save Few, if Any, Lives

The PSA blood test — the screening test for prostate cancer — saves few if any lives and exposes large numbers of men to risky and unnecessary treatment, two large and rigorous studies have found.

The findings raise new questions about the rapid and widespread adoption of the test, which measures a protein released by prostate cells. It was introduced in 1987 and quickly became a routine part of preventive health care. Experts debated its value, basing their views on data that often involved statistical modeling and inferences. Now, with the new data, cancer experts said men should carefully consider the test's risks and benefits before deciding to be screened. Some may decide not to be screened at all.

The studies, said Dr. Otis Brawley, the chief medical officer at the American Cancer Society, are “some of the most important studies in the history of men's health.” For years, the cancer society has urged men to be informed before deciding to have a PSA test. “Now we actually have something to inform them with,” he said. “We've got numbers.” Dr. H. Gilbert Welch, a professor of medicine at Dartmouth who studies cancer screening, also welcomed the new data. “We've been waiting years for this,” he said. “It's a shame we didn't have it 20 years ago.”

Both reports were published online on Wednesday by The New England Journal of Medicine. One involved 182,000 men in seven European countries; the other, by the National Cancer Institute, involved nearly 77,000 men at 10 medical centers in the United States. In both, participants were randomly assigned to be screened — or not — with the PSA test, whose initials stand for prostate-specific antigen. In each study, the two groups were followed for more than a decade while researchers counted deaths from prostate cancer, asking whether screening made a difference.

The European data involved a consortium of studies with different designs. Taken together, the studies found that screening was associated with a 20 percent relative reduction in the prostate cancer death rate. But the number of lives saved was small — seven fewer prostate cancer deaths for every 10,000 men screened and followed for nine years.

The American study, which had a single design, found no reduction in deaths from prostate cancer after most of the men had been followed for 10 years. Every man has been followed for at least seven years, said Dr. Barnett Kramer, a study co-author at the National Institutes of Health. By seven years, the death rate was 13 percent lower for the unscreened group.

The European study saw no benefit of screening in the first seven years of follow-up. The reason screening saved so few lives, cancer experts say, is that prostate cancers often grow very slowly, if at all, and most never endanger a man if left alone. But when doctors find an early-stage prostate tumor, they cannot tell with confidence whether it will be dangerous so they usually treat all early cancers as if they were life-threatening.

As a result, the majority of men, whose early-stage cancers would not harm them, suffer serious effects of cancer therapy but get no benefit. Others, with very aggressive tumors, may not be helped by screening because their cancer has spread by the time it is detected.

Prostate cancer is not the only one that is hard to stop with screening. If the European study is correct, mammography has about the same benefit as the PSA test, said Dr. Michael B. Barry, a prostate cancer researcher at Massachusetts General Hospital who wrote an editorial accompanying the papers. But prostate cancers often are less dangerous than breast cancers, so screening and subsequent therapy can result in more harm.

In the European study, 48 men were told they had prostate cancer, and needlessly treated for it, for every man whose death was prevented. With mammography, about 10 women receive a diagnosis and needless treatment for breast cancer to prevent one death.

Dr. Peter B. Bach, a physician and epidemiologist at Memorial Sloan-Kettering Cancer Center, says one way to think of the data is to suppose he has a PSA test today. It leads to a biopsy that reveals he has prostate cancer, and he is treated for it. There is a one in 50 chance that, in 2019 or later, he will be spared death from a cancer that would otherwise have killed him. And there is a 49 in 50 chance that he will have been treated unnecessarily for a cancer that was never a threat to his life or health.

Prostate cancer treatment can result in impotence and incontinence when surgery is used to destroy the prostate, and painful defecation or chronic diarrhea when the treatment is radiation.

When the American and European studies began, in the early 1990s, PSA testing was well under way in the United States, and many expected that the screening test would make the prostate cancer death rate plummet by 50 percent or more. Dr. Brawley was at the cancer institute then, though not directly involved with its prostate cancer screening study. But he saw the reactions.

Some urologists said the study was unethical, because some people would not be screened, and demanded it be shut down, he said. One group of black urologists encouraged black men not to participate because blacks have a greater risk of prostate cancer and it seemed obvious they should be screened.

Some thought that they would see fewer cancer deaths among the screened men as quickly as five years. But as the studies continued, it became clear that screening would not have a large, immediate effect — if it did, the studies would have been stopped and victory declared. Cancer researchers began turning to less rigorous sources of data, with some arguing that screening was preventing prostate cancer deaths and others arguing it was not.

In the US, many men and their doctors have made up their minds — most men over age 50 have already been screened, and each year more than 180,000 receive a diagnosis of prostate cancer. In Europe, said Dr. Fritz H. Schröder of Erasmus University, the lead author of the European study, most men are not screened. “The mentality of Europeans is different,” he said, and screening is not so highly promoted.

The publication, of data from the two studies should change the discussion, said Dr. David Ransohoff, an internist and cancer epidemiologist at the University of North Carolina. “This is not relying on modeling anymore,” Dr. Ransohoff said. “This is not some abstract, pointy-headed exercise. This is the real world and this is real data.”

Both studies will continue to follow the men. It remains possible that the United States study will eventually find that screening can reduce the prostate cancer death rate, researchers say, or that both studies will conclude that there is no real reduction.

In the meantime, Dr. Brawley said, “I certainly think there’s information here that’s food for thought.” The benefits of prostate cancer screening, he said, are “modest at best and with a greater downside than any other cancer we screen for.”

March 23, 2009

To Screen or Not To Screen? What Those Prostate Studies Mean

Last week, two major studies from the United States and Europe found that P.S.A. testing — the annual blood test used to screen men for prostate cancer — saves few if any lives, while exposing patients to aggressive and unnecessary treatments that can leave them impotent and incontinent.

The news was unsettling and confusing to many middle-age men, particularly those who already have diagnoses of prostate cancer as a result of P.S.A. testing. Doctors say some men are reconsidering surgery or radiation treatment they have planned. Others, convinced that their lives were saved by P.S.A. screening, wonder how anyone could question the value of early detection of prostate cancer.

In the face of all this confusion, what's a man to think? Here are answers to some frequently asked questions. The bottom line of both studies is that P.S.A. screening does find more prostate cancers — but finding those cancers early doesn't do much to reduce the risk of dying from the disease.

The American study showed no statistical difference in prostate cancer death rates between a group of men who had the screening and a control group who did not. The European researchers found that P.S.A. screening does reduce the risk of dying from prostate cancer by about 20 percent.

But in terms of individual risk, even that is not a huge benefit. It means that a man who isn't screened has about a 3 percent average risk of dying from prostate cancer. If that man undergoes annual P.S.A. screenings, his risk drops to about 2.4 percent.

And there is an important tradeoff. P.S.A. testing increases a man's risk of being treated for a cancer that would never have harmed him in the first place. The European study found that for every man who was helped by P.S.A. screening, at least 48 received unnecessary treatment that increased risk for impotency and incontinence. Dr. Otis Brawley, chief medical officer of the ACS, summed up the European data this way: "The test is about 50 times more likely to ruin your life than it is to save your life."

So do these studies settle the debate about the value of p.s.a. screening? Not necessarily. Both have problems that make it difficult to interpret the data. The American study found no benefit in P.S.A. screening over a period of 7 to 10 years. But so far, only about 170 men out of 77,000 studied have died of prostate cancer.

Prostate cancer is slow-growing, so it's possible that in the next few years, meaningful differences in mortality rates between the two groups will emerge. A larger concern is what statisticians call "contamination" in the unscreened control group. Because it would have been unethical to tell men in the control group that they could not be screened, many either sought the test or were offered it by their doctors. Investigators initially estimated that 20 percent of the control group would fit in this category, but the numbers ended up being far higher — 38 to 52 percent. As a result, the study doesn't really compare the risks and benefits of screening and no screening. It compares aggressive screening and some screening.

The fact that so many men in the nonscreening group "dropped in" to the screening category "is a serious concern," said Dr. Eric A. Klein, chairman of the Glickman Urological and Kidney Institute at the Cleveland Clinic, who added: "The argument for screening today is no different than before. These studies do not settle the issue definitively one way or another."

The American investigators said that while contamination did complicate the interpretation of the data, they were still confident in the finding that there is little or no benefit to P.S.A. screening.

“Our statisticians still felt the power of the study to detect a medically meaningful benefit was retained,” said Dr. Barnett S. Kramer, co-author of the study and associate director for disease prevention at the National Institutes of Health.

The European research has its own set of problems. Although the finding that P.S.A. screening reduces cancer deaths by 20 percent is statistically significant, experts say it’s on the borderline, and a few more years of data could weaken the result. Finally, parts of the study were not “blinded,” meaning that biases could have crept into the interpretation of the data.

Does this mean men should not receive prostate cancer screening? No. Before the studies were released, most major medical groups said P.S.A. testing was a personal decision that a man should discuss with his doctor. The two new studies are unlikely to change that advice, experts say; instead, they give men and their doctors more information with which to make the decision.

For older men, the screening decision should be easier. P.S.A. screening is already not advised for those 75 and older. And the American research confirms that P.S.A. testing is not helpful for men with 10 years or less of life expectancy. In the European study, among men 70 or older, there were more deaths in the P.S.A. screening group, although the trend could be caused by chance.

The advice is murkier for middle-age men. In the European study, 50- to 54-year-olds didn’t benefit from screening. But men ages 55 to 69 were 20 percent less likely to die from prostate cancer than those who weren’t screened. (Still, men in that age group must decide whether the high risks of unnecessary treatment are worth it.)

March 18, 2009

Diagnostic Errors: The New Focus of Patient Safety Experts

Johns Hopkins patient safety experts say it's high time for diagnostic errors to get the same attention from medical institutions and caregivers as drug-prescribing errors, wrong-site surgeries and hospital-acquired infections.

Diagnostic misadventures represent a potentially much larger source of preventable health problems and deaths than many of the more popular targets of safety reform, they say in a commentary in the March 11 issue of the *Journal of the American Medical Association*.

In the article, David Newman-Toker, M.D., Ph.D., and Peter Pronovost, M.D., Ph.D., report that misdiagnosis accounts for an estimated 40,000 to 80,000 hospital deaths per year and that tort claims for diagnostic errors — defined as diagnoses that are missed, wrong or delayed — are nearly twice as common as claims for medication errors.

Typically, they note, diagnostic errors were thought to originate with individual doctors lacking the training or skill they should have, but blaming physicians hasn't produced many solutions. As with successful approaches to reducing treatment errors, they point out that reducing diagnostic errors will likely require a focus on larger "system" failures that affect medical practice overall.

"Moving away from a model that chastises individual physicians to one that focuses on improving the medical system as a whole could offer big payoffs for improving diagnostic accuracy as well as the cost effectiveness of care," says Newman-Toker, assistant professor of neurology with joint appointments in otolaryngology, health sciences informatics, epidemiology, and health policy and management at the Johns Hopkins University School of Medicine and the Johns Hopkins Bloomberg School of Public Health. "Right now," he adds, "there is often a mismatch between who gets advanced diagnostic testing and who needs it, leading to worse outcomes and higher costs. Realigning resources with needs could improve outcomes at lower cost."

Much as bloodstream infections in intensive care units have decreased through systematic solutions adopted by hospitals, such as requiring physicians to follow a procedural checklist that emphasizes sterile techniques when inserting medical catheters, Newman-Toker and Pronovost suggest that system-wide solutions could be the key for decreasing diagnostic errors.

For example, Newman-Toker notes, triage protocols in emergency departments often categorize patients with typically benign symptoms, such as isolated headache, as being at "low-risk" of having a bigger problem, even though such symptoms are sometimes indicative of dangerous conditions, such as a bleeding brain aneurysm. A systems fix that could decrease diagnostic errors might be to change the overall rules for the triage protocol so that it considers specific symptom details that help distinguish between "low-risk" and "high-risk" types of headache.

The Johns Hopkins team suggests that diagnostic errors might be reduced by systematically adopting tools such as checklists that help physicians remember critical diagnoses or by making available computer programs known as "diagnostic decision-support systems" that assist physicians in calculating the level of risk of a given patient's having certain diseases.

Health systems could further decrease diagnostic errors, they say, with time-tested, low-tech tools such as independent second looks at X-rays and CT scans or rapidly directing patients with unusual symptoms to diagnostic experts.

Because diagnostic errors can be tricky to track to their roots, Pronovost, an expert on breaking down complex medical problems, says more research is needed to understand and find patterns in the origins of such errors. Pronovost, a professor of anesthesiology, critical care medicine and surgery, is medical director of Johns Hopkins' Center for Innovation in Quality Patient Care.

"The first step in addressing the diagnostic error problem is to shine a light on them so they are clearly visible," Pronovost says. "Then with wise investments, clinicians, researchers and patients can discover how to prevent them."

March 18, 2009

Quest Diagnostics Postnatal Molecular Test Receives Clinical Laboratory Approval from New York State

Quest Diagnostics Incorporated, the world's leading provider of diagnostic testing, information and services, today announced that its ClariSure[®] microarray-based comparative genomic hybridization (aCGH) postnatal test is now available for testing on patients in the state of New York. With licensure by the State Department of Health Clinical Laboratory Evaluation Program, Quest Diagnostics operates one of only three laboratories in the U.S. approved to perform aCGH testing on postnatal samples collected on patients in New York.

The state has approved the use of the ClariSure aCGH postnatal test as an aid in detecting copy-number chromosomal abnormalities implicated in dozens of medical conditions, including mental retardation, birth defects, and autism spectrum and developmental disorders, which conventional laboratory tests may fail to detect.

"With approval by New York State, our advanced ClariSure test has demonstrated that it fulfills test validation requirements widely regarded as among the most rigorous in the lab industry," said Charles (Buck) Strom, M.D., Ph.D., medical director of the genetic testing center of Quest Diagnostics Nichols Institute, the esoteric testing laboratory and research and development center of Quest Diagnostics.

"Since its launch in mid-2007, physicians outside of New York have used our ClariSure test to identify the genetic etiology of congenital anomalies, autism and other disorders for dozens of patients whose conditions had eluded prior diagnostic efforts. We look forward to providing broader access to our ClariSure test, so that more parents have the diagnostic insights they need to provide appropriate schooling and social support to their infants and children."

Scientists at Nichols Institute have validated the ClariSure test's ability to use a single blood specimen to identify chromosomal abnormalities associated with dozens of disorders, including Down, cri du chat, DiGeorge and Williams syndromes. A positive result may be confirmed using a fluorescence in situ hybridization (FISH) methodology.

aCGH technologies compare and contrast a specimen's DNA to the DNA of a healthy individual to identify, at a high resolution, extra or missing genetic material in the specimen. These technologies can detect a proportion of additional abnormalities even in patients who have already had extensive cytogenetic and/or FISH testing.

aCGH tests are also more efficient, as multiple tests are required to generate the same amount of information produced from one microarray-based test. Chromosome abnormalities, such as extra copies of chromosomes and other copy number changes, have been implicated in some types of mental retardation, developmental disorder and congenital anomalies, as well as in autism and autism spectrum disorders.

In the U.S., the clinical laboratory testing services are regulated under the federal Clinical Laboratory Clinical Laboratory Improvement Amendments (CLIA). Laboratory-developed tests must fulfill CLIA requirements, including validation studies, before they can be introduced to their markets.

New York has the only state licensure program, which requires pre-approval of a laboratory's validation procedure prior to testing of patient samples. Under the state program, laboratory-developed tests must be able to demonstrate they perform as intended, according to clinical and analytical validation studies, before they can be used to conduct testing on specimens collected in the state.

March 16, 2009

Quidel Says POC Rapid Influenza Test Sales Slower Than Expected

Quidel Corporation, a leader in point-of-care rapid diagnostic tests, announced today that the company has not seen the typical seasonal spike in demand for its influenza tests. Although it is not possible for the company to predict the ultimate outcome of the domestic 2008/2009 influenza season, as of today, the influenza season appears to be marked by both a late start as well as weakness in overall flu incidence.

“In light of both the late start and weakness of this influenza season, we have seen few re-orders of our influenza products from our distribution partners in this first quarter of 2009,” said Douglas Bryant, President and Chief Executive Officer of Quidel.

“The number of doctor visits for influenza like illness is significantly lower than the prior year. We believe this has had a negative impact on the sales of our influenza as well as our Group A Strep products. Although there are two weeks remaining in this quarter, we anticipate that the company will incur a loss for the first quarter of 2009 primarily as a result of a significant reduction in sales of our influenza products.”

“In response to the absence of flu sales in the quarter, we will implement additional cost control measures and appropriately focus the use of resources,” said Mr. Bryant. “For 2009 and beyond, we will implement new inventory management programs and guidelines in a continuing effort to better balance distributor inventories with anticipated market demand. We remain confident in our market share strength and believe that we are well positioned for future growth.”

March 11, 2009

Roche To Fully Acquire Genentech

Roche and Genentech announced today that they signed a merger agreement under which Roche will acquire the outstanding publicly held interest in Genentech for US\$95.00 per share in cash, or a total payment of approximately US\$46.8 billion to equity holders of Genentech other than Roche. The special committee of Genentech’s Board of Directors has approved the agreement and recommends that Genentech shareholders tender their shares in Roche’s tender offer.

Dr. Charles Sanders, Chairman of the Special Committee of Genentech’s Board of Directors, said: “We believe this is a fair offer for Genentech shareholders, and the Committee is pleased to come to a successful conclusion of this process. We look forward to working with Roche to complete the transaction as expeditiously as possible”.

Franz B. Humer, Chairman of the Roche Group, said: “We are very pleased that we have reached an agreement with Genentech and secured a positive recommendation from the special committee. As stated previously, an agreed transaction offers clear and important advantages for the shareholders of both companies.

I am delighted that the intensive negotiations have led to a successful conclusion. Working together, we aim to close the transaction quickly, thus removing uncertainty for employees and allowing us to focus even more intently on innovation and long-term projects. We have tremendous respect for our colleagues at Genentech and look forward to working with them to further accelerate our search for solutions to unmet medical needs”.

Arthur D. Levinson, Ph.D., chairman and chief executive of Genentech, said: “We have had a highly successful partnership with Roche for more than 18 years, and we intend to pursue our shared goal of discovering medications for serious and life-threatening conditions. We look forward to working with our partners at Roche to ensure a smooth transition once the transaction is complete and to continue our mission of serving patients”.

Severin Schwan, CEO of the Roche Group, said: “Roche and Genentech saw the potential of a pharma-biotechnology partnership early on and we are now in an enviable position to expand on the success of our longstanding relationship, which has been a source of immense value for patients, employees and shareholders of both companies. We are excited about working with our colleagues at Genentech and look forward to partnering with them to develop a plan for the successful combination of the two companies”.

Roche will amend its existing tender offer to reflect the increased price and eliminate the financing and certain other conditions to the offer. The tender offer remains subject to the condition that a majority of the public shareholders tender their shares. If the tender offer is completed, Roche will promptly consummate a second-step merger in which all remaining public shareholders will, without the need for further action by any public shareholder, receive \$95.00 per share for their shares. Roche and Genentech have also amended their affiliation agreement to permit all shareholders to receive the same increased price in the tender offer and the merger. The expiration date for the offer is March 25, 2009. As of the close of business on March 11, 2009, approximately 2.9 million shares have been tendered pursuant to the offer.

The combined company will be the seventh largest U.S. pharmaceuticals company in terms of market share. It will generate approximately US\$17 billion in annual revenues and will employ around 17,500 employees in the U.S. pharmaceuticals business alone, including a combined sales force of approximately 3,000 people.

Research and early development will operate as an independent center within Roche from its existing campus in South San Francisco, retaining its talent and approach to discovering and progressing new molecules. Roche’s Pharma commercial operations in the U.S. will be moved from Nutley, New Jersey to Genentech’s site in South San Francisco. The combined company’s U.S. commercial operations in pharmaceuticals will operate under the Genentech name, leveraging the strong brand value of Genentech in the U.S. market. The existing U.S. sales organizations of both companies will be maintained, resulting in a very strong presence in several specialty areas.

The transaction will provide the opportunity to simplify the structure of the combined organization and maximize the benefits of enhanced scale. Roche has already begun to wind down operations at its Palo Alto facility and will relocate the site’s Virology research and development activities to South San Francisco. Roche’s Palo Alto

Inflammation group is in the process of becoming part of Roche's Nutley research and development organization. Genentech's Late Stage Development and Manufacturing operations will be combined with the global operations of Roche, achieving substantial scale benefits, operational synergies and cost avoidance. Roche's manufacturing operations in Nutley will be closed and support functions, such as informatics and finance, will be consolidated with those of Genentech.

March 9, 2009

American Cancer Society: More Evidence Prostate Tests Overdiagnose Cancer

As many as two of every five men whose prostate cancer was caught through a PSA screening test have tumors too slow-growing to ever be a threat, says a new study that raises more questions about the controversial tests. The work "reinforces the message that we are overdiagnosing prostate cancer," said Dr. Len Lichtenfeld of the American Cancer Society, who was not involved in the new study.

More than 186,000 U.S. men will be diagnosed with prostate cancer this year, and nearly 29,000 will die, according to cancer society estimates. Most men over 50 have had a blood test that measures prostate specific antigen, or PSA, mostly for routine screening.

There begins the list of problems: Most men who undergo a biopsy for an abnormal PSA test don't turn out to have prostate cancer; high PSAs often signal a benign enlarged prostate. Of those who do have cancer, there's no proof yet that early detection saves lives -- as most prostate tumors grow so slowly that had they not been screened, those men would have died of something else without the anxiety. How many? Estimates vary widely. Enter the new study, which tracked prostate cancer diagnosed in U.S. men ages 54 to 80 between 1985 and 2000, and used three different models developed by cancer centers to more accurately estimate overdiagnosis.

Depending on how it's calculated, anywhere from 23 percent to 42 percent of PSA-detected cancers would otherwise never have been detected in the man's lifetime, concluded the team led by researchers at Erasmus University Medical Center in the Netherlands. The study was published online Tuesday by the Journal of the National Cancer Institute.

Why is overdiagnosis such a concern? Because finding an early tumor forces men to choose among contested treatments -- "watchful waiting," surgery, hormone therapy, radiation. And because some treatments can cause incontinence and impotence, men whose tumors wouldn't have been a threat can suffer serious side effects for no gain.

In fact, national health guidelines issued last year said men over age 75 shouldn't undergo PSA screening, while younger men should make an individual choice after hearing the pros and cons and weighing their own cancer risk.

The new study's estimate of U.S. overdiagnosis probably is too low -- because since 2000, doctors have begun performing biopsies for lower PSA levels than once were the trigger, wrote Dr. Michael Barry of Massachusetts General Hospital in an accompanying editorial.

It's a confusing issue, acknowledged the cancer society's Lichtenfeld. It boils down to: "If we diagnose this disease, are we making your life better? We know that for other cancers," such as breast, cervical and colorectal, which have strong evidence showing early detection hugely improves survival, he said.

Major studies are under way that in a few years should offer better guidance for prostate cancer screening, and scientists are furiously hunting new tests that might help pinpoint who has a worrisome tumor and who can relax.

March 9, 2009

More Rigorous Screening Effective In Detecting Early Ovarian Cancer

Only about one-quarter of invasive ovarian cancers are detected in the early stages, when the disease is most treatable. Now, preliminary results from a large, continuing trial indicate that postmenopausal women who are screened for ovarian cancer either by transvaginal ultrasound scan or by a blood test followed by a scan are more likely to have their cancers detected at early stages, with almost half the cancers picked up before they had spread beyond the pelvis.

While the results suggest that widespread screening for ovarian cancer may be feasible, long a point of scientific controversy, the researchers warned that the benefits were still far from clear. Many of the women in the trial had false positive results on screening tests that led to unnecessary surgeries and complications, especially among those who had ultrasound scans alone. And there is still no evidence that screening reduces the death rate from ovarian cancer, the researchers said.

Interim results from the initial screening tests of some 100,000 British women were published online Tuesday in *The Lancet Oncology*. The trial uses a sophisticated research algorithm to interpret the results of a controversial blood test for the CA125 tumor marker, repeating the tests at specified intervals and following up with scans when indicated. The study is expected to continue through at least 2014.

“We have now demonstrated we can pick up the vast majority of women with ovarian cancer earlier than they would have otherwise been detected and before they have symptoms,” said Dr. Ian Jacobs, director of the Institute for Women’s Health at University College London, and director of the trial, “and that a good proportion of those women have earlier stage disease than we would normally expect them to have.”

But, Dr. Jacobs cautioned that “women thinking of having this must understand and realize that there’s a possibility it will do more harm than good. We have reason to think it will save lives,” he added, “and then the question is, will it save enough lives to balance out the harm it does?”

The clinical trial includes some 202,638 British women ages 50 to 74 that were recruited from 2001 to 2005. About half were randomly assigned to a group that received no screening for ovarian cancer, while the rest were randomly assigned to receive annual screenings via transvaginal ultrasound scans or blood tests for the CA125 tumor marker followed by an ultrasound when indicated.

Some 58 invasive cancers were detected at first screening, and 28 of them, or 48 percent, were in the early stages, the study reported. There were no significant differences between the two screening methods, though the rate of unnecessary surgery was much higher among women screened by ultrasound alone.

Robert Smith, director of cancer screening for the American Cancer Society, said that while it was important to run large clinical trials, the preliminary results must be interpreted with caution. “We’re not even remotely close to knowing how to screen women of average risk with these tests, or even if we should,” he said.

Medical groups have long cautioned against using the results of a single blood test as a basis for further intervention. Ovarian cancer, which is usually asymptomatic in its early stages, strikes 21,650 women annually in the United States, killing 15,520 a year.

March 3, 2009

BG Medicine Appoints Doug White as Executive Vice President & General Manager, Diagnostics

BG Medicine today announced that Doug White has joined the organization as Executive Vice President & General Manager, Diagnostics. In this newly created role, Mr. White will be responsible for the strategic direction and overall management of the company’s commercial operations as it advances a broad portfolio of high-value diagnostic tests toward commercial launch.

Mr. White brings more than 24 years of successful experience in the *in vitro* diagnostic marketplace to BG Medicine, including roles at innovative leading companies such as QIAGEN, Digene, Bayer, Chiron Diagnostics, and Abbott Diagnostics. Prior to joining BGM, Mr. White served as QIAGEN's Sr. Vice President of Sales and Marketing for the Americas, and Chair of the Americas Management Council, where among other responsibilities he played a critical role in the successful integration of Digene Corporation following its acquisition.

Mr. White also served as Senior Vice President of Commercial Operations, leading commercial activities in the Americas and Asia Pacific and heading the company's global product management organization at Digene.

"Doug's vast experience with leading diagnostics innovators will be a tremendous asset to BG Medicine as we prepare to commercialize important new diagnostics in cardiology and other therapeutic areas," said BG Medicine President and CEO Pieter Muntendam. "The success that Doug achieved in a variety of commercial leadership roles has prepared him well to help BG Medicine effectively develop and penetrate these large, important markets."

"I am very excited to join BG Medicine at such a critical juncture, as we turn our biomarker discovery abilities into groundbreaking new diagnostic tests," Mr. White said. "BG Medicine is poised to have a major impact on the improvement in patient care and management of a wide array of diseases, beginning with cardiology."

BG Medicine is a life sciences company focused on the discovery, development and commercialization of novel molecular diagnostics based on biomarkers to improve patient outcomes and contain healthcare costs. BG Medicine discovers biomarkers and is developing its diagnostic product candidates using its proprietary, versatile, and scalable technology platform, which integrates and automates the precise measurement, analysis, characterization and interpretation of proteins, and metabolites collected from bodily fluids.

March 3, 2009

Mass General Hospital To Use Gene Testing To Personalize Cancer Care

Cancer doctors at Massachusetts General Hospital plan within a year to read the genetic fingerprints of nearly all new patients' tumors, a novel strategy designed to customize treatment.

The hope is to spare patients from the traditional hit-or-miss approach to cancer care, when expensive drugs with harmful side effects are often given without knowing whether they will work.

Doctors will hunt for 110 abnormalities, carried on 13 major cancer genes that can predict whether drugs already on the shelf or in development might thwart a patient's tumor. They will use robots - and lab machines nicknamed John, Paul, George, and Ringo - that are capable of swiftly identifying genetic quirks in 5,000 to 6,000 patients a year, replacing labor-intensive techniques that had been used only selectively for a handful of cancers.

Mass. General's decision to make gene testing standard in cancer treatment - it's believed to be the first hospital in the nation to do so - represents a major step in delivering personalized medicine to the masses. But doctors acknowledge that it is unclear whether screening patients for an expanded library of tumor defects will actually save money on drugs, or whether it will translate into longer lives.

"Right now, as an oncologist, much of what we do is really barely educated guesswork in terms of what therapy is going to be the best for a particular patient," said Dr. Leif Ellisen, a Mass. General breast cancer specialist. "We needed a new way to think about cancer diagnosis and cancer therapy."

Routine tumor screening, which began with lung cancer patients this week, opens a window onto the frontier of cancer medicine, where doctors focus more on the genetic profile of a tumor and less on whether it's in the lung, breast, or prostate. The genes that reside inside the malignancy may prove vastly more important than its address.

The testing could be especially helpful to patients with rare tumors, cancers that stoke little interest among researchers or drug companies. That is because they may share genetic signatures with more common tumors already being successfully treated.

"What we've been trying to do is set the stage for this kind of personalized medicine," said Anna Barker, deputy director of the National Cancer Institute. "We'll be able to say, 'That drug will work well for you, that drug will not work well for you.' "

Still, cancer specialists from across the country - including at Mass. General - caution against vesting too much hope in any single approach to defeating a disease notorious for resisting medical advances. Sometimes, they said, a tumor can harbor so many genetic abnormalities that no single test and no single drug proves sufficient.

"I'm one of the most enthusiastic people for molecular personalized medicine that you will find," said Dr. George Demetri, director of the Ludwig Center for Cancer Research at Dana-Farber Cancer Institute. "But the cancer field has sometimes been plagued by people saying, 'We're going to cure cancer next month.' "

Linnea Duff illustrates the promise of genetic fingerprinting. The 49-year-old mother was diagnosed with lung cancer in 2005 - "It felt like I was on a plane that was going down," she recalled.

One lung was partially removed, followed by chemotherapy. But by last summer, her lungs were speckled with small nodules. "I began to see a psychiatrist and a social worker at MGH to prepare for my death," said Duff, who lives in Meredith, N.H.

When Duff was initially diagnosed, doctors performed genetic screening, knowing that as a nonsmoker she might have a form of cancer susceptible to a particular drug. She didn't.

With the cancer spreading, testing was performed again - and, this time, it revealed that her tumors carried an abnormality called EML4-ALK, which had only recently been identified. And a drug company was testing a pill targeting this defect.

Duff began taking it in October. Within days, she began feeling better.

Mass. General expects to charge about \$2,000 a test and will ask insurers to pay as part of basic care. But representatives of the state's three major health plans said they pay for gene testing only when it has proven medical benefits, meaning insurers may balk at paying for some of the new testing. In such cases, a top Mass. General cancer doctor said, the hospital might absorb the cost or, in some cases, seek payment from patients.

Other centers, including Dana-Farber, perform gene testing on select patients. For example, Dana-Farber patients with certain melanomas - under fingernails or inside the mouth - are genetically screened because doctors know those malignancies can carry abnormalities that are susceptible to certain drugs. And at Memorial Sloan-Kettering Cancer Center in New York, most patients with lung cancer, the most lethal malignancy in the United States, will have their tumors genetically analyzed starting within weeks.

Eventually, said Dr. Marc Ladanyi, chief of Sloan-Kettering's Molecular Diagnostics Service, such screening during a visit to the oncologist will be as commonplace as tests performed during an annual physical.

"You can think of it a little bit like when you get your blood drawn," he said.

Some of the earliest clues about tumor genetics were yielded by breast cancer.

Puzzled doctors noticed that despite giving patients the best treatments available, a substantial segment derived little benefit.

Research showed that about 1 in 4 breast cancer patients carry high levels of a protein called HER2, the result of a genetic abnormality in their tumors. When given the drug Herceptin, which blocks the protein, their survival prospects soared, but the drug does nothing for patients who didn't have HER2.

Similar findings were made regarding lung tumors. Then researchers discovered something that roiled the field even more: The same abnormal genes found in certain breast and lung tumors can also exist in other tumor types. Those findings electrified Mass. General specialists, setting them on a course a year-and-a-half ago toward universal screening.

"If you don't go the extra mile to find those rare mutations, there are going to be some patients who don't get the right drug," said Dr. John Iafrate, a Mass. General pathologist who, with Ellisen, oversees the gene testing lab.

Scientists tinkered with robots and developed processes so that in seven hours, samples from 96 patients can undergo the laboratory equivalent of a car wash, reducing the cancer tissue to its most important constituent parts so genes can be easily read.

For Linnea Duff, there is now no evidence of cancer. How long the experimental drug will work, no one can say for sure. But she didn't expect to get this much time. "The thing with cancer is," she said, "if you can hold on, there is always the chance there will be a new discovery right around the corner."

March 1, 2009

10 Questions For QIAGEN's Senior Global Marketing Director Regarding The Company's Success.

Pharmaceutical Technology Europe interview with Marie-Claude Marchand, Senior Global Marketing Director at QIAGEN, about the company's success. QIAGEN was first established in 1984 as a spin-off from the University of Dusseldorf (Germany).

Q1: Although QIAGEN is a relatively young company, it boasts of being the world's leading provider for innovative sample and assay technologies for research in molecular diagnostics, applied testing, pharma and academic research. What do you think is the recipe for achieving success in such a short period of time?

The company's success is built around a solid strategy and mission to create sample and assay technologies that enable access to content from any biological sample. Initially, our founder, Metin Colpan, revolutionized the process for stabilizing, purifying and processing a sample. His discovery reduced the time for the preparation of plasmid DNA from 3 days to 2 hours. The introduction of the first standardized kit became the foundation for QIAGEN's success.

In more than 40 countries, we support our customers from academic research, diagnostic laboratories, and pharmaceutical and biotech companies. Our innovation and growth are based on internal R&D work, acquisitions, key partnerships and licensing. Today, more than 2600 employees worldwide work with our customers to help drive breakthroughs in healthcare and science. Our technologies have been developed in synergy with the direction and demands of life science researchers, moving from enzymes that accelerate generation of high-quality data to innovative areas such as microRNA and epigenetic analysis. Ultimately, our goal is to standardize the steps to take researchers and molecular diagnostic laboratories from sample to result, enabling the highest quality answers in the shortest period of time.

Q2: In its early days, QIAGEN was known as a provider of sample technologies for the academic research market. How has your range of products altered since then?

Our product development is defined by the needs of the customers that we serve. Initially, this was primarily academia. Since the launch of our plasmid spin column technologies in 1986, we have developed technologies for the purification of DNA, RNA and protein from all biological material. Listening to the needs of pharma, we quickly broadened our portfolio of high-throughput solutions; for example, our Allprep technology enables multiple analyte purification from single samples ideal for precious clinical material.

More recently, the applied markets of veterinary diagnostics and forensics have brought about solutions for analyzing very complex samples. Additionally, since 2001 we have created a leading portfolio of molecular diagnostic solutions in a highly regulated environment. Through internal developments and a focused M&A strategy, we have developed the company into a market leader in molecular diagnostics — with a focus on oncology, infectious diseases and pharmacogenomics.

Q3: Many companies are suffering because of the current economical climate. How does QIAGEN plan to deal with the situation?

Currently, we are not experiencing any significant impact from the financial crisis. We are in a somewhat better position than many companies because the customer segments we serve are more resistant to declines in demand; for example, hospitals will not stop performing necessary tests on patients, nor will crime laboratories cease DNA profiling just because the economy is struggling.

Additionally, our products are integral to many laboratory workflows and they cannot simply be replaced or omitted. If a laboratory has validated a process with our technologies, they can't quickly swap it out for another or 'skip' the step in the workflow. We realize that our pharma partners are feeling the impact much more directly, but we continue to work with these companies to provide solutions that will help them remain innovative, even in these very difficult times.

Q4: QIAGEN is planning to launch many new products in the area of epigenetics and miRNA. How will these products benefit molecular biologists?

We have already launched epigenetic and miRNA products that add significant capabilities to biomedical research directed towards the identification of new molecular disease targets. Our existing broad portfolio of technologies for gene regulation has contributed to several scientific publications.

In 2006, we launched our EpiTect product line of pre-analytical solutions for DNA methylation research. We now offer standardized solutions covering all steps of epigenetic analysis. With the recent acquisition of the Biosystems business from Biotage (Sweden), we have added proprietary pyrosequencing technology and products for high-resolution sequence detection and quantification to our molecular testing solution portfolio. On 10 November 2008, we launched the CE-marked molecular assay for the cancer biomarker, K-RAS. We intend to launch this in the US in 2009 for *in vitro* diagnostic use.

In 2006, we also launched our miRNA purification products followed by the miScript System in 2007. This is a three-component system that covers all the conversion steps of miRNA and mRNA into cDNA, and detection of miRNAs in SYBR Green based, real-time PCR. The modular system enables the detection of individual miRNAs of interest using miScript Primer Assays or screening of multiple human, mouse or rat miRNAs using miScript Primer Assay Sets. Alternatively, researcher-designed assays can be used for newly discovered miRNAs.

With cancer a focus of gene regulation and expression profiling studies, we have developed a very flexible web portal, GeneGlobe.com, which offers the largest database of matching siRNA and RT-PCR assays. Through this site, customers can access on-line sequence data for every gene and view predesigned primers, miRNA, siRNA species and optimized constructs for protein expression and purification.

These technologies and tools help molecular biologists to better understand gene expression patterns and make discoveries that can potentially impact biotherapeutics and clinical studies.

Q5: You have recently launched QIASymphony, the first of a series of modular instruments that can be integrated to automate entire workflows. How much of a breakthrough is this and how many years has it been in development?

We are very proud of the QIASymphony. More than 100 scientists spent more than 4 years developing this instrument. During that time, they were able to blend cutting edge technology, innovative kit design and easy-to-operate software into the foundation of a complete system series. The system is the first to enable automation of the complete workflow from sample preparation to assay setup in a range of markets including pharmaceutical research laboratories.

Q6: The media is continuously reporting a draught of innovative products. How is QIAGEN's pipeline looking?

One of our goals is to be known as an innovator, standard-setter and industry leader. To garner those accolades, we must constantly work to develop new technologies to enable our customers' success. We have more than 460 scientists devoted to R&D. In 2007, we developed 72 new products. At this time, we have 226 R&D projects on-going. We are well poised to continue to bring novel technologies to the market.

Q7: Why do you think many companies in today's pharmaceutical and biopharmaceutical industries struggle with innovation?

"First be best, but best be first" is a quote I heard at a recent conference. We find our pharma customers all want to be the most well-renowned innovators in the industry, but at the same time, they need to be the first ones to get there. This becomes a larger challenge for a multitude of reasons.

Starting with the obvious, diseases that are not yet effectively treated are those that are more complex, which makes successful targeted therapies harder to develop. The complexity of disease and our mechanistic understanding is what drives technology innovation.

From a business perspective, our technologies are developed to simplify the complexity of disease pathogenesis, and to address decision making in clinical development and, ultimately, in patient prescription. Through elucidation and clinical application of biomarkers, I believe this innovation gap can be filled by utilizing a combination of stratified medicine and the new breed of biologics and small molecules. Where necessary, these can be combined to develop the right therapy for the patient. Ultimately, the industry will develop the right drug, for the right patient, given at the right time and at the right dosage. This will enable pharma to increase their compliance levels while reducing the time required for clinical trials and increasing success rates. Equally important are the benefits for the patients in terms of reducing unnecessary treatments and side effects, which results in increased efficacy, thus improving the patient outcome.

With stratified medicine, there also comes a need to redefine and align financial and regulatory models that will support this new paradigm, but this takes time. Some companies are already taking this approach to understand, on a country-by-country basis, how to favor an incremental cost-effectiveness ratio that helps prioritize healthcare dollars and win approval. A final question that comes to mind is, are we utilizing our collective knowledge effectively? There is a great deal of pipeline collaboration in the industry. However it is only recently that we see technology platform developers uniting with pharma to build the discovery and development catalysts in the form of workflow/application solutions. This is an area where our company adds value to pharma with not just tools, but experience, knowledge and infrastructure to accelerate the market delivery of our partners' products.

Q8: QIAGEN's technologies and automated solutions are used in pharmaceutical research. How big a part do your products play in the drug discovery process and have they enabled any scientific breakthroughs?

Across the globe, we work in close partnership with our customers to provide high-value, innovative solutions that span drug discovery, pre-clinical and clinical development. Our technologies are most prominently utilized in the early stages of target identification and validation for a variety of applications in discovery genetics and functional genomics.

We have been a partner in more than 100 clinical trials. Our automation enables our customers to standardize their work with proven technologies, within one site and across multiple geographical locations. This standardization has a positive impact on the speed of drug discovery.

Q9: When developing a new pharmaceutical product, how important is it to choose the correct technology?

With regard to analyzing the PK/PD, safety and efficacy, it very important to standardize the process of data collection using robust, sensitive and reproducible technologies. These technologies need to be scalable to accommodate varying assay throughput, and flexible to deal with a variety of patient sample material.

Today, more and more drugs are being developed for specific patient populations. In the process, regulatory bodies are pushing for pharma to collect and store samples from each individual enlisted in clinical development programmes. Here, the extraction, stabilization and storage technology selection is critical because researchers want to ensure the stored material is going to be usable many years later.

Ideally, the best technologies are automated and scalable. Choosing the right partner, chemistry and technology are key to progress along the drug discovery continuum.

Q10: In such a competitive sector as biotechnology, how does your company differentiate itself?

Our combination of scientific expertise, commercial success and extremely high quality. We have repeatedly succeeded in quickly transferring proven technologies to new requirements.

This has resulted in a wide range of approximately 500 products and more than 1000 patents. Because we are often the first to tackle certain issues, we often set the standards in the industry.

February 27, 2009

Beckman Coulter to Acquire Lab-Based Diagnostics Business From Olympus Corporation

Beckman Coulter, a leading developer, manufacturer, and marketer of products that simplify, automate, and innovate complex biomedical tests, and Olympus Corporation, a Tokyo-headquartered precision technology leader, creating innovative opto-digital solutions in healthcare, life science and consumer electronics products, announced today that they have entered into a definitive agreement under which Beckman Coulter will acquire the diagnostic systems portion of Olympus' Life Sciences business for 77.45 billion yen, or approximately USD \$800 million.

This acquisition will broaden Beckman Coulter's Chemistry offering, establishing a leadership position with particular strength in larger hospital laboratories. In addition, the transaction will extend our broad chemistry customer base representing a valuable new customer set for Beckman Coulter's Immunoassay products.

In 2010, the Olympus Diagnostics business is anticipated to increase Beckman Coulter's revenue by approximately \$500 million on a full year basis and generate approximately \$40 to \$50 million in operating income (excluding FAS141R associated amortization). Beckman Coulter believes that 2010 pre-tax savings of between \$50 and \$60 million can be achieved from the combination of Olympus operating expenses of about \$200 million and Beckman Coulter operating expenses of more than \$1 billion. Savings are expected to be realized from leveraging existing global infrastructure and integrating sales, service, administrative and R&D activities. Excluding amortization costs related to FAS141R, a new standard guiding accounting for acquired businesses; the company believes that the acquisition will be substantially accretive to earnings in 2010.

As part of the agreement, Beckman Coulter has the right to deliver up to 37.5% of the purchase price in the form of Beckman Coulter stock. Correspondingly, Beckman Coulter expects to finance the acquisition with a combination of newly issued Beckman Coulter common stock (approximately \$300 million) and newly issued debt (approximately \$500 million). Under the intended conservative financing structure, the company does not anticipate a change in its current investment grade ratings.

Scott Garrett, Beckman Coulter's Chairman, President and Chief Executive Officer, said, "This compelling transaction combines the chemistry product lines of our two companies into a complete chemistry systems offering. It enhances Beckman Coulter as a leading provider of chemistry products with additional opportunities to expand our immunoassay reach into their chemistry installed base. Customers will benefit from the expanded range of products, particularly those large hospital and university laboratories where higher throughput systems are preferred. In addition, Beckman

Coulter's strength in total lab automation will be complemented by Olympus' strong pre-analytical automation position in Europe and Asia.

"We remain focused on creating shareholder value through growth, quality and operating excellence. The combination of Beckman Coulter and Olympus demonstrates our commitment to further expand chemistry and sustain our above-market growth in immunoassay. A foundation of stable markets, a defensive business model, well-recognized competencies in optimizing lab processes and an unyielding commitment to quality positions us for continued leadership in biomedical testing," Garrett concluded.

February 25, 2009

Epigenomics Licenses Biomarker for Development of Prostate Cancer Test to Quest Diagnostics

Epigenomics AG, a cancer molecular diagnostics company, today announced that it has entered into a non-exclusive licensing agreement for its proprietary biomarker mGSTP1 with U.S.-based Quest Diagnostics Incorporated, the world's leading provider of diagnostic testing, information and services.

Under the agreement, Quest Diagnostics has obtained rights to uses of the GSTP1 DNA methylation biomarker (mGSTP1) to establish and commercialize a molecular-based laboratory-developed test that can help pathologists better diagnose prostate cancer based on testing of a patient's tissue specimen.

Prostate cancer is the leading cause of cancer death in men in the U.S., with more than 230,000 cases diagnosed annually. Epigenomics and others have demonstrated that methylated DNA of the GSTP1 gene in tissue may indicate the presence of prostate cancer. A test that detects the DNA methylation of the gene GSTP1 in tissue biopsies in combination with conventional histopathology may augment the accuracy of prostate cancer diagnosis in particular in cases with suspicious but inconclusive histology findings or patients with elevated PSA but repeatedly negative biopsies.

Quest Diagnostics' experience in DNA methylation diagnostics includes offering tests for Prader-Willi and Angelman Syndromes, two neurologic epigenetic disorders that may be caused by faulty DNA methylation. In 2008, Quest Diagnostics licensed rights to use Epigenomics' proprietary colorectal cancer biomarker mSEPT9 to develop and validate a blood-based laboratory-developed test as an aid in the detection of colorectal cancer.

"We are pleased that Quest Diagnostics is expanding its menu of DNA methylation tests using our technologies and biomarkers. Quest Diagnostics has a strong record of innovation in diagnostics, including development of other DNA methylation diagnostic tests. They also share our goal to develop technologies that will help physicians achieve improved health outcomes for their patients through better diagnosis of prostate cancer and early detection of colorectal cancer", said Geert Nygaard, Chief Executive Officer of Epigenomics.

February 26, 2009

BioMérieux Receives AOAC Certification For High Performance Salmonella Test

The AOAC Research Institute (RI), a subsidiary of AOAC INTERNATIONAL, granted Performance Tested MethodsSM certification to bioMérieux, a world leader in the field of in vitro diagnostics, for VIDAS[®] Easy SLM (Salmonella). The test is a rapid, automated solution that requires fewer steps than traditional methods for Salmonella testing. bioMérieux also submitted the VIDAS Easy SLM (Salmonella) to the recently launched AOAC RI Emergency Response Validation (ERV) program for Salmonella contamination in peanut butter.

"In hectic times of product contamination and recalls, we formed the ERV Program to rapidly evaluate and certify investigative methods," said Scott G. Coates, managing director of AOAC Research Institute. "We are very pleased that bioMérieux has taken the next step in commitment to total quality by participating in the ERV program for Salmonella contamination in peanut butter."

VIDAS Easy SLM (Salmonella) provides a simple solution for detection of Salmonella species in a variety of foods. VIDAS Easy SLM (Salmonella) is an assay test that reduces hands-on technician time, materials and provides a faster turn-around-time versus conventional methods. When selected and utilized as the preferred method, the VIDAS technology has been proven to detect the targeted pathogen.

"We are deeply saddened by the illnesses and deaths that have been associated with the recent Salmonella outbreaks," said Herb Steward, executive vice president and general manager, bioMérieux North America. "bioMérieux has been pro-actively working with Food Industry experts, including the AOAC, to reinforce emergency response programs and to drive quality control and food safety initiatives."

The ERV program is based on the Performance Tested Methods program operated by the AOAC Research Institute. The ERV program takes advantage of the existing pool of

PTMs and AOAC Official Methods of AnalysisSM. The ERV program is designed to evaluate these previously AOAC-approved methods for the specific contaminant and food type causing the crisis, in this case Salmonella species in peanut butter products.

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:

Edward Weiner
Tel: 508-358-2221
E-Mail: ed_weiner@emmesgroup.com

Emmes 2008 Molecular Testing Database

Lab: <input type="text" value="XXX Hospital"/> Address: <input type="text" value="123 Any Street"/> City: <input type="text" value="Anywhere"/> State: <input type="text" value="MI"/> Zip: <input type="text" value="48073"/> Telephone: <input type="text" value="248-111-1111"/> Name: <input type="text" value="John Q. Manager"/> Title: <input type="text" value="Molecular Supervisor"/>	Type of Institution: <input type="text" value="Teaching Hospital"/> Type of Lab: <input type="text" value="Molecular Lab"/> * Interview Number: <input type="text" value="265"/> Number of Beds: <input type="text" value="1058"/>	Month of Interview: <input type="text" value="Dec"/> Year of Interview: <input type="text" value="2008"/>
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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	50%	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 <input type="text" value="YES"/> Reason: tests are not currently offered <input type="text" value="Not enough time to bring them in"/>	If Yes Which tests: <input type="text" value="BK Virus & PCAS"/> Outsource or Perform <input type="text" value="Outsource"/>	If limitations did not exist what tests your lab would most like to add <input type="text" value="Adenovirus"/> <input type="text" value="Influenza A/B"/> <input type="text" value="Respiratory Virus"/>	Real world limitations/barriers: 3 molecular tests that your lab would most like to add <input type="text" value="Adenovirus"/> <input type="text" value="Influenza A/B"/> <input type="text" value="Respiratory Virus"/>
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