Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Stephanie Murg, Managing Editor, smurg@ioma.com

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CONTENTS

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Roche Prepares to Enter U.S. Market for HPV Testing

Roche (Basel, Switzerland) is on track to enter the rapidly growing U.S. market for human papilloma virus (HPV) testing later this year. "We set out to change the game in clinical HPV testing," said Daniel O'Day, chief operating officer of Roche Diagnostics, at Roche's investor conference on March 18 in New York City. He was referring to ATHENA (Addressing THE Need for Advanced HPV Diagnostics), the company's 47,000-patient U.S. registration trial designed to demonstrate the effectiveness of HPV genotyping in cervical cancer screening. Preliminary results from the trial reported earlier this year support genotyping for high-risk HPV 16 and 18 as actionable information for intervention. Additional data will be released in July and throughout the three-year follow-up study.

"There's a very important message here, which is the value of genotyping," said O'Day. "We've demonstrated that even in the presence of a negative Pap smear, if someone is 16/18 genotype positive, they are much more at risk [for developing cervical cancer]." Roche has received CE Mark certification for HPV genotyping tests, including the test launched last year in the European Union for use on its new Cobas 4800 system. O'Day says that Roche will submit the test to the U.S. Food and Drug Administration in mid-2010. The Roche test would compete for market share with Qiagen's market-leading Digene HPV test, but O'Day highlighted the ATHENA data as a key differentiator for Roche. "This isn't something you can just ride on the back of," he said of the major trial. "Every company is going to have to demonstrate how their assay works in this segment." For more on Roche Diagnostics, see *Inside the Diagnostics Industry,* pp. 5-6.

Updated Plavix Label Highlights Dosing Risks, Vaue of Genetic Testing

On March 12, the U.S. Food and Drug Administration (FDA) announced the addition of a black-box warning to the anti-blood clotting drug Plavix (clopidogrel) that highlights the utility of genetic testing for cytochrome P450 2C19 (CYP2C19), which is responsible for the metabolism of an array of drugs. The updated label is intended to alert patients and health care professionals that the drug can be less effective in people who cannot metabolize the drug to convert it to its active form.

Continued on p. 2

▲ **Updating Plavix Label Highlights Dosing Risks,** *from page 1*

Manufactured under a partnership of Bristol-Myers Squibb and Sanofi Pharmaceuticals, Plavix reduces the risk of heart attack, unstable angina, stroke, and cardiovascular death in patients with cardiovascular disease by making platelets less likely to form blood clots. The drug gains its anti-platelet effects when it is metabolized into its active form by the liver enzyme, CYP2C19.

The estimated 2 percent to 14 percent of the U.S. population who have reduced functioning of CYP2C19 cannot effectively convert Plavix to its active form. As a result, Plavix may be less effective in altering platelet activity in those people. These "poor metabolizers" may not receive the full benefit of Plavix treatment and may remain at risk for heart attack, stroke, and cardiovascular death, according to the FDA.

The new boxed warning notes that tests are available to identify genetic differences in CYP2C19 function, but it does not mention specific tests. The updated label also advises health care professionals to consider use of other anti-platelet medications or alternative dosing strategies for Plavix in patients identified as poor metabolizers.

The FDA added this information to the drug's label in May 2009. Further data led the agency to call attention to the risks associated with Plavix dosing in a boxed warning. "We want to highlight this warning to make sure health care professionals use the best information possible to treat their patients," said Mary Ross Southworth, Pharm.D., a clinical analyst in the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research.

The label change may lead to an uptick in requests for CYP2C19 genotyping, a molecular diagnostic test that is performed by approximately a dozen U.S. laboratories. In December 2004, the FDA cleared Roche Diagnostics' AmpliChip CYP450, a microarray-based test that detects variations in the CYP2C19 and CYP2D6 genes.

Medicare Will Cover Vermillion's Ovarian Tumor Triage Test

Medicare has established reimbursement coverage for OVA1, the ovarian tumor triage test manufactured by Vermillion (Fremont, Calif.). The U.S. Food and Drug Administration (FDA) cleared the in vitro diagnostic multivariate index assay (IVDMIA) in September 2009 as an adjunctive test to complement, not replace, other diagnostic and clinical procedures.

Highmark Medical Services (Camp Hill, Pa.) will cover OVA1 in keeping with the test's FDA-cleared indication "until such time that a local coverage determination is developed and implemented." The Centers for Medicare and Medicaid Services (CMS) contractor noted in a coverage bulletin issued March 11 that until a specific current procedural terminology (CPT) code is issued, the OVA1 test will be billed to Medicare utilizing the "not otherwise classified" (NOC) CPT code, 84999.

OVA1 is a qualitative, serum-based test that combines the results of immunoassays for five biomarkers: transthyretin, apolipoprotein A-1, beta2-Microglobulin, transferrin, and cancer antigen 125. The test uses a proprietary algorithm to calculate a single numerical score between 0 and 10 to indicate the likelihood that a pelvic mass is benign or malignant.

OVA1 is intended only for women, 18 years and older, who have already been selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening

or for a definitive diagnosis of ovarian cancer.

Quest Diagnostics (Madison, N.J.) has a three-year exclusive agreement to offer the test to the clinical reference laboratory market in the United States. The laboratory services provider launched the test nationwide on March 9.

"The test is unusual because it's really a triage test," Jon R. Cohen, M.D., Quest's chief medical officer and senior vice president, told DTTR. "In gynecology, there's a pretty clear divide between OB/GYNs who are trained to do most gynecological procedures and gynecological oncologists who are specifically trained to deal with cancer," he explained. "What happens with gynecological malignancies is that if they are malignant at the time of exploration, they can frequently become very large procedures that the gynecologist is not trained to do. The real positive around the OVA1 test is the ability to triage appropriately."

The test would be requested by OB/GYNs once they have a patient worked up for a pelvic mass. "We would hope that gynecological oncologists would also request it on the referral," added Cohen.

Publicly traded Vermillion, which emerged from Chapter 11 bankruptcy protection in January, plans to resume development of novel diagnostics in the wake of its reorganization. The company is working with researchers at Stanford University to develop a blood test to stratify an individual's risk of developing peripheral artery disease. Vermillion was formerly known as Ciphergen Biosystems.

FDA Grants EUA for Diagnostic Hybrids H1N1 Test

Diagnostic Hybrids, which was acquired in February by Quidel (San Diego) has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its D3 Ultra 2009 H1N1 Influenza A Virus ID kit, a monoclonal antibody fluorescent staining kit for the specific identification of 2009 H1N1 influenza A in direct patient specimens or incubated tissue cultures.

The D3 Ultra 2009 H1N1 Influenza A Virus ID Kit is to be used for individuals with signs and symptoms of influenza and who previously tested positive for the presence of influenza A virus-infected cells by a currently available FDA-cleared direct immunofluorescence influenza A antibody device.

"Currently available tests are all based on the detection of 2009 H1N1 nucleic acid," noted Steve Ewers, senior product manager at Diagnostic Hybrids. "This technology is not available in all laboratories due to its equipment expense and complexity. The D3 Ultra 2009 H1N1 ID Kit gives these laboratories the opportunity to identify 2009 H1N1 influenza A virus using the immunofluorescent methodologies without any added equipment or training."

Other H1N1 tests that the FDA has authorized for emergency use include molecular diagnostic tests manufactured by Roche (Basel, Switzerland), DxNA (St. George, Utah), and TessArae (Potomac Falls, Va.), which offers a microarray-based targeted sequencing assay. Diagnostic Hybrids' D3 Ultra HN1 ID kit is the first indirect fluorescent assay available on the market that specifically identifies the 2009 H1N1 influenza A virus from nasopharyngeal swabs, aspirates, and washes.

Cystoscopy Trumps Urinary Markers for Bladder Cancer Screening

Even amidst a range of novel diagnostic tools, cystoscopy remains a cost-effective method of detecting early-stage bladder cancer, according to a study presented on March 6 at the American Society of Clinical Oncology (ASCO) Genitourinary Cancer Symposium in San Francisco. Adding other tests to cystoscopy increases the cost, as well as the number of false positives, according to the researchers.

Early-stage bladder cancer, or non-muscle invasive bladder cancer (NMIBC), has a high rate of recurrence. Patients are tested every three to six months, often for the rest of their lives, with the goal of catching the cancer early if it returns. Cystoscopy, an outpatient procedure in which a tube with a small camera attached is inserted into the bladder, allows physicians to visually examine the inside of the bladder for tumors. Other tests are often added to the procedure.

"The tests frequently added to cystoscopy have many more false positives than commonly believed, and they can lead to unnecessary workups," said Jose Karam, M.D., a fellow in genitourinary oncology at the University of Texas M. D. Anderson Cancer Center and the study's senior author. "Our findings also may help reduce the cost of caring for bladder cancer patients, which currently is in the range of $4 billion annually."

A new study questions the cost- effectiveness of adding tests such as NMP22 Bladder-Chek and UroVysion to cystoscopy.

The researchers set out to identify which bladder surveillance method provides acceptable tumor detection rate while minimizing costs. In a prospective evaluation of 200 M. D. Anderson patients with NMIBC, they compared the accuracy and cost of cystoscopy alone and cystoscopy combined with cytology, testing for NMP22 (a tumor marker for bladder cancer), fluorescent in situ hybridization (FISH)-based testing for chromosomal aberrations in bladder cells, and NMP22 testing confirmed by FISH.

By looking at the number of tumors detected and the cost of the tests (based on 2009 Medicare reimbursement data) plus the cost of workup for a false positive result, researchers arrived at a cost per tumor detected for each method. Cystoscopy alone was the least expensive at $7,692, while cystoscopy plus FISH was the priciest at $19,111.

Despite their added costs, additional tests did not give better results. Cystoscopy was most cost-effective in finding tumors. Cystoscopy had two false positives, the fewest of any test, while cystoscopy plus FISH had the most false positives at 30.

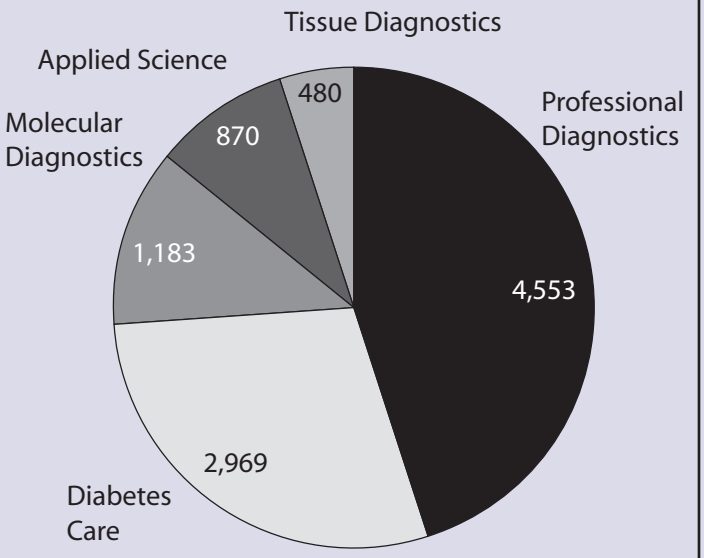
"There are some who believe that the ancillary tests have the property to predict recurrences early," said Ashish Kamat, M.D., associate professor of urology at M. D. Anderson. "In order to account for this, we took into account tumors detected later—at the first follow-up—to assess whether the tests added to detection rates. Our results suggest that while the ancillary tests did turn positive prior to actual tumor recurrence in a handful of patients, the vast majority were still falsely positive."

Roche Posts 9% Growth in Diagnostics in 2009, Seeks to 'Revalue Diagnostics' in Health Care

In a difficult year, Roche (Basel, Switzerland) posted growth in all segments of its diagnostics division, which accounted for 10.1 billion Swiss francs (approximately $9.5 billion) of the group's total 2009 revenue of 49.1 billion Swiss francs ($46.4 billion). Total revenue at Roche was up 10 percent in local currencies (8 percent in Swiss francs, 7 percent in U.S. dollars) compared to 2008. Sales in the diagnostics division grew by 9 percent (4 percent in both Swiss francs and U.S. dollars).

Roche's professional diagnostics segment, which accounts for almost half of the division's sales, grew by 9 percent in local currencies compared to 2008. The division was fueled by strong sales of immunoassays and the third-quarter launch of the Cobas 8000 clinical chemistry analyzer. Designed for use in high-volume laboratories, the instrument will be introduced in the United States later this year.

Roche Diagnostics 2009 Revenue by Segment *(millions CHF)*



Source: Roche

Diabetes care, the segment most exposed to the challenging consumer economy of 2009, grew by 6 percent in local currencies in 2009. Steady sales of single-strip blood glucose monitoring systems were bolstered by the launch of several new products.

The molecular diagnostics segment grew by 5 percent in local currencies. Strong sales in core blood screening and virology products were helped toward the end of the year by the European Union launch of the Cobas 4800 analyzer with CE-marked tests for human papilloma virus (HPV), chylmydia, and gonorrhea.

A milestone in molecular diagnostics for 2009 was completing enrollment for ATHENA (Addressing THE Need for Advanced HPV Diagnostics), the company's 47,000-patient U.S. registration trial designed to demonstrate the effectiveness of HPV genotyping in cervical cancer screening. Roche plans to submit its HPV genotyping test to the U.S. Food and Drug Administration (FDA) in mid-2010.

In the applied science segment, Roche reported strong demand for its MagNA Pure and LightCycler product lines. Sales were also lifted by the FDA's November 2009 emergency use authorization of Roche's RealTime ready Influenza A/H1N1 Detection Set for use in CLIA high-complexity laboratories.

Roche also used 2009 to expand its presence in tissue diagnostics. In February 2008, the company acquired Ventana Medical Systems for $3.4 billion and has since invested millions in automation and sales force expansion. Roche saw 29 percent growth in tissue diagnostics in 2009, with significant growth coming from outside of the United States.

"This is a very important strategic business for us, as tissue is the sample of choice in oncology, and we're are very focused in [pharmaceuticals] on oncology," said Daniel O'Day, chief operating officer of Roche Diagnostics, at the company's annual meeting in Basel on Feb. 3. "And this gives us a technology that allows us to have the broadest base of technologies across our therapeutic areas."

Although the clinical implementation of the widely heralded advances of "personalized medicine" remains slow, Roche remains committed to its unique combination of therapeutics and diagnostics. In a presentation at Roche's investor conference on March 18 in New York City, CEO Severin Schwan pointed to "the enormous advances we see in molecular biology" as a key driver of the growth at the company, which attributes more than 60 percent of sales to biotechnology products. Schwan highlighted close collaboration between Roche's pharmaceuticals and diagnostics divisions as critical to both understanding differences among populations and targeting those populations.

"I believe we're at an inflection point in terms of diagnostics' contribution to health care," said Roche Diagnostics COO Daniel O'Day.

"The real competitive advantage is in early research and development, because typically in this phase, you would hesitate to work together with an external partner. . . . [I]t can become complicated in terms of [intellectual property] issues." Across the company, Roche has more than 40 companion diagnostics programs at various stages of development.

O'Day sees this as a pivotal time for diagnostics in health care. "I believe we're at an inflection point in terms of diagnostics' contribution to health care," he told the crowd of investors and analysts. "Roche Diagnostics is uniquely positioned to help revalue the diagnostics market going forward."

A value shift will depend largely on data that demonstrate how the use of diagnostic tests can affect clinical decisionmaking and health care costs. "Although diagnostics are used in at least 60 percent to70 percent of clinic decisions, today it commands only 2 percent of the overall health care budget," noted O'Day. "That share of the pie will continue to increase in terms of the reward for diagnostics that can make a difference" by, for example, helping to select patients who can benefit from certain drugs, predicting treatment response, or monitoring their response to therapy.

Beyond the codevelopment of companion diagnostics and novel drugs, Roche is now looking to leverage its infrastructure to demonstrate the clinical utility of a variety of diagnostics. Early results from the large-scale ATHENA study are promising. O'Day called HPV "one of the most exciting areas of diagnostics today" and singled out the market opportunity as an area of high unmet medical need with significant room for improved screening and medical outcomes data. O'Day also highlighted Roche's work on diagnostic tests for preeclampsia and gene rearranagements in aggressive prostate cancer.

CMS Releases Revised Guidance on EHR Rules

As promised at the most recent meeting of Clinical Laboratory Improvement Advisory Committee (CLIAC), the Centers for Medicare and Medicaid Services (CMS) has released revised interpretive guidance relating to the electronic exchange of laboratory information and further identifying authorized individuals who may receive laboratory test results information.

The guidance was issued by CMS's Center for Medicaid and the State Operations/ Survey and Certification Group.

The revision on electronic exchange of laboratory information offers interpretive guidance on surveying laboratories that use Health Information Technology (HIT) for the electronic exchange of laboratory information. The revisions focus on data to be included under existing retention requirements, additional considerations laboratories need to take into account with using HIT for the electronic exchange of laboratory information, and an explanation on how to manage corrected laboratory reports for an electronic health record.

The revision on authorized individuals offers interpretive guidance for the exchange of laboratory information by allowing laboratory results to be sent to the authorized individual and others designated by the authorized individual to receive the information.

The entire set of revisions went into effect on March 1, 2010.

Epigenomics Moving Forward With Septin 9 Test

Emerging molecular diagnostics company Epigenomics (Berlin) is moving forward with its commercialization of a test for Septin9, a methylation-based early detection biomarker for colorectal cancer. The company recently reported updated data from PRESEPT, a prospective multicenter clinical research study, showing that Septin9 in this study detected colorectal cancer cases with a sensitivity of approximately 63 percent. The finding is based on 32 colorectal cancer cases correctly identified out of 51 cancer cases with measurements of Septin9 in blood plasma samples.

With these results, the PRESEPT study meets its objective of detecting the majority of prevalent and incident cancers in a screening cohort, a requirement for noninvasive screening tests set forth in joint guidelines by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. With a specificity of approximately 89 percent, the Septin9 testing result meets the targeted specificity range of 85 percent to 90 percent, which based on an initial health economic analysis should support public and private payer coverage and reimbursement.

The announcement of the updated results follows a preliminary data analysis that indicated that one of the three laboratories involved in the study had reported a cancer detection rate that was significantly lower than those of the other testing labo-

ratories and of previous studies. An investigation into these results led to retesting potentially affected samples by the other two labs, according to Epigenomics.

Histopathological review and further statistical analysis are under way, but the study's steering committee believes that the data indicate that Septin9 testing may be a useful tool to detect the presence of occult colorectal cancer in a standard plasma specimen obtained from average-risk individuals eligible for colorectal cancer screening. The study results are expected to be submitted for publication later this year.

Epigenomics launched its Septin9 test, Epi proColon, in October 2009. The CE-marked test is now offered by several molecular diagnostic laboratories in Europe. Epigenomics is marketing the test through direct sales in its home market of Germany, Austria, and Switzerland and working with distributors to commercialize the test in other European markets.

The company also licensed the Septin9 biomarker to several laboratories and in vitro diagnostic companies. In January, Quest Diagnostics (Madison, N.J.) introduced ColoVantage, a laboratory-developed test that assesses the methylation status of the Septin9 gene. Meanwhile, Abbott Molecular (Des Plaines, Ill.) has received CE Mark certification for RealTime mS9, an automated assay for detecting the Septin9 gene in plasma using Abbott's m2000 real-time PCR platform. Epigenomics is also partnering with ARUP Laboratories (Salt Lake City) and Sysmex (Kobe, Japan) on Septin9 tests.

Abbott Inks Deal to Develop Companion Diagnostic for Skin Cancer

Abbott Molecular (Des Plaines, Ill.) has made a deal with GlaxoSmithKline (GSK; Clifton, N.J.) to develop a molecular diagnostic test to help select patients who may benefit from a skin cancer treatment that is being developed by GSK.

GSK's MAGE-A3 antigen-specific cancer immunotherapeutic candidate is currently being evaluated as an adjuvant treatment in melanoma biopsy specimens in a Phase III clinical study. To be eligible to receive the drug candidate, patients must have melanoma tumors that express MAGE-A3, a tumor-specific antigen that is expressed in skin cancer and a variety of other cancers.

According to the agreement, Abbott and GSK will develop and commercialize a polymerase chain reaction (PCR)-based test for use on Abbott's m2000 automated platform. The test will be designed to detect MAGE-A3. The companies announced a similar collaboration in July 2009 for a Phase III study of the MAGE-A3 marker in non-small-cell lung cancer.

Abbott and GSK plan to seek regulatory approval for the test in several markets, including the United States and Europe. Currently, there are no molecular tests approved by the U.S. Food and Drug Administration for use in identifying patients

who may respond to certain skin cancer drugs.

According to the Skin Cancer Foundation, melanoma is the most deadly form of skin cancer. However, if it is recognized and treated early, it is nearly 100 percent curable. The American Cancer Society estimates that in 2008, there were 8,420 fatalities in the United States alone. The number of new cases is estimated at more than 62,000.

In *NEJM* Study, HbA1c Outperforms Fasting Glucose for Risk Prediction

Measurements of hemoglobin A1c (HbA1c) more accurately identify persons at risk for clinical outcomes than those of fasting glucose do, according to a study that appears in the March 4 issue of the *New England Journal of Medicine.* Researchers found that HbA1c levels accurately predict not only future diabetes but also stroke, heart disease, and all-cause mortality.

"HbA1c has significant advantages over fasting glucose," said Elizabeth Selvin, Ph.D., MPH, the study's lead author. The A1c test has low variability from day to day, levels are not as affected by stress and illness, it has greater stability, and the patient is not required to fast before the test is performed.

This study comes on the heels of a major change in the way physicians diagnose diabetes. In January, the American Diabetes Association (ADA) published revised recommendations for the screening and diagnosis of diabetes. The revised recommendations include, for the first time, recommendations to use HbA1c to diagnose diabetes and also to identify people at risk of developing diabetes in the future, also known as "prediabetes."

The new findings can help doctors and patients interpret HbA1c test results. In the study, people with HbA1c levels between 5 percent to 5.5 percent were identified as being within "normal" range. The majority of the U.S. adult population is within this range.

With each incremental HbA1c increase, the study found, the incidence of diabetes increased as well; those at a level of 6.5 percent or greater are considered diabetic, and those between 6 percent and 6.5 percent are considered at a "very high risk" (nine times greater than those at the "normal" range) for developing diabetes.

The revised ADA guidelines classify people with HbA1c levels in the range of 5.7 percent to 6.4 percent as "at very high risk" for developing diabetes over five years. The range of 5.5 percent to 6 percent, according to the ADA guidelines, is the appropriate level to initiate preventive measures.

The *NEJM* study measured HbA1c in blood samples from more than 11,000 people, black and white adults, who had no history of diabetes. The samples were obtained between 1990 and 1992 as part of the Atherosclerosis Risk in Communities (ARIC) Study at four ARIC field centers.

Currently there are 9 million Americans who are diabetic but undiagnosed. "These data," said Selvin, "can help us interpret A1c values in clinical practice and help identify people who need treatment the most."

MedPAC Considers Excluding Some Lab Tests From In-Office Ancillary Services Exception

The Medicare Payment Advisory Commission (MedPAC) is considering three options for addressing problems resulting from in the in-office ancillary services exception to the Stark law, including excluding certain services from the exception (such as diagnostic tests that are not usually provided at the same time as the office visit).

In-office ancillary services are growing at a rapid pace, and the increased utilization may require narrowing the exception for such services under the physician self-referral law, as well as altering the payment system, the head of MedPAC said at a recent public meeting.

"Over the last several years, there's been an increase in imaging, lab tests, and physical therapy provided in physician offices," Ariel Winter, a senior analyst with MedPAC, said at the meeting. Winter provided three options for controlling the escalation of in-office ancillary services: excluding certain services from the in-office exception, creating new payment tools to reduce the incentive for using such services, and establishing a prior-authorization system for physicians who are self-referring for advanced imaging.

Merck to Use Roche Microarray Test for Cancer Drug Trials

A recently announced agreement between Roche Molecular Systems (Pleasanton, Calif.) and a subsidiary of Merck (Whitehouse Station, N.J.) will provide the pharmaceutical company with access to the microarray-based p53 test that Roche is developing. The test is designed to detect mutations in the tumor suppressor gene p53. Identifying cancers that harbor a dysfunctional p53 gene could help physicians determine which patients are most likely to respond to certain investigational drugs.

"Roche designed its investigational AmpliChip p53 Test to rapidly provide clinically important information that can be used early in pharmaceutical development to help predict cancer patient responses to certain therapeutic candidates," said Paul Brown, president and CEO, Roche Molecular Diagnostics. The AmpliChip p53 test, currently available only for investigational use, is designed to detect damage to p53 DNA in tumor cells in order to identify which cells carry dysfunctional p53 proteins that can lead to treatment resistance.

"The goal of our research is to discover and develop innovative cancer therapeutics and deliver them to the right patients at the right time," said Eric Rubin, M.D., vice president of oncology at Merck Research Laboratories. "By applying the AmpliChip p53 test in selected clinical trials we hope to identify those patients most likely to respond to specific therapeutic regimens in development."

IVD Stocks Climb 10%; Sequenom Soars 81%

The G-2 Diagnostic Stock Index gained an average of 10 percent in the four weeks ended March 5, with 16 stocks up in price and two down. The G-2 index has gained 6 percent so far this year, while the Nasdaq is up less than 1 percent and the S&P has slipped 1 percent.

Sequenom (San Diego) jumped 81 percent to close at $8.20 per share with a market capitalization of $478 million. Shares in the molecular diagnostics company saw a surge of buying activity after analysts upgraded the stock in early March. Pamela Bassett of Cantor Fitzgerald noted her "renewed confidence that Sequenom is back on track toward building its molecular diagnostics portfolio on the foundation of its genome analysis platform" and boosted her price target to $16 per share.

Bassett and others have big hopes for Sequenom's planned prenatal test for Down syndrome. In 2009, the company indefinitely delayed the launch of its SEQureDx Down syndrome test due to employee mishandling of research and development test data and results. In recent months, Sequenom has retooled its senior management and embarked on a number of new clinical studies as the company evaluates multiple RNA and DNA technologies for use in developing its Down syndrome test.

Another molecular diagnostics company was one of the few stocks to lose ground. **Nanosphere** (Northbrook, Ill.) dropped 23 percent to finish the period with a share price of $3.38 and a market capitalization of $121 million. The company's Verigene platform is aimed at hospital laboratories and currently supports a range of genetic and pharmacogenetic tests.

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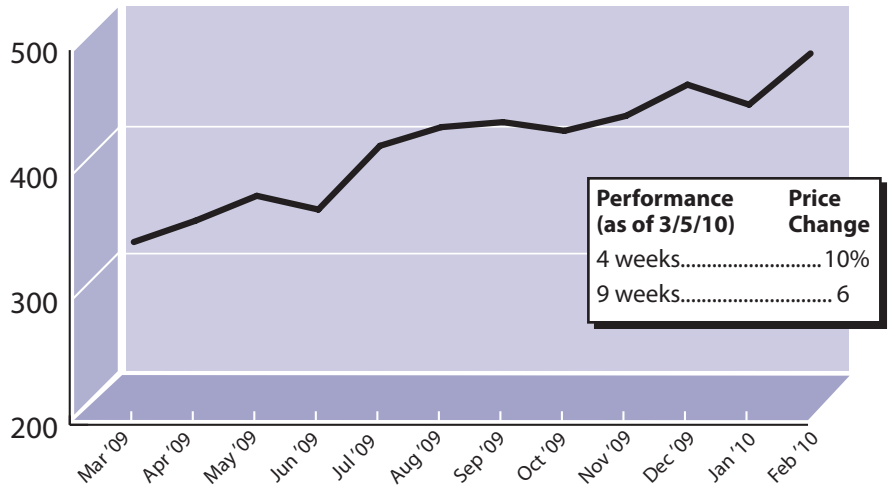
Nanosphere recently announced results for the 2009 fiscal year. Although revenue was up to $2.2 million compared to $1.4 million for 2008, the boost didn't come from product sales, which inched up to $1.1 million compared to $1 million in 2008. Another $1 million was service revenue related to Nanosphere's assay development contracts with Elli Lilly and Co.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 18 IVD companies.

Up	Price	% Chg
Abaxis	$26.13	3%
Abbott Labs	54.32	1
Affymetrix	7.94	8
Beckman Coulter	69.90	7
Becton Dickinson	78.23	4
Bio-Rad	100.56	7
Cepheid	17.56	13
Clinical Data	20.57	22
Gen-Probe	46.99	9
Immucor	21.06	12
Johnson & Johnson	64.04	3
Luminex	16.23	8
Meridian	23.10	11
OraSure	5.43	10
Quidel	13.78	5
Sequenom	8.20	81
Down		
Inverness Medical	$39.94	-3
Nanosphere	3.38	-23

G-2 Insider

Venture capital flows to IVD companies... The thawing economy is yielding fertile ground for investment in diagnostics companies. Among the companies that have recently completed funding rounds are Saladax Biomedical (Bethlehem, Pa.), Gold Standard Diagnostics (Davis, Calif.), and Eureka Genomics (Houston).

On March 5, Saladax announced that it had raised $8.4 million in a third funding round led by Excel Venture Management. Saladax, which previously raised $11.4 million, develops novel diagnostic tests that can help physicians tailor treatment. The company began with a focus in oncology and plans to use the new funding to accelerate product development and expand clinical support of its tests that measure blood levels of cancer drugs and drugs for central nervous system disorders.

Meanwhile, Gold Standard Diagnostics has completed its first funding round, although the company did not disclose the amount. Founded in 2007 by in vitro diagnostics industry veteran John Griffiths, Gold Standard serves both laboratories and manufacturers with a broad menu of tests, instruments, and services. Clients include Quest Diagnostics and LabCorp. Revenue reportedly climbed 300 percent in 2009, and the company plans to reach 20 employees by the end of 2010.

Finally, startup Eureka Genomics raised $3.7 million from individuals and angel investors. The company is focused on applying advanced bioinformatics analysis to next-generation gene sequencing data and plans to use the funding for further research aimed at identifying novel microorganisms associated with colorectal cancer, lymphoma, and cardiovascular disease.

Company References

Abbott 847-937-6100

CMS 410-786-3000

FDA OIVD 240-276-0450

Epigenomics 206-883-2900

Eureka Genomics 510-964-0461

Genomic Health 650-556-9300

Gold Standard Diagnostics 530-759-8000

GlaxoSmithKline 973-778-9000

Highmark Medical Services 877-235-8073

Merck 908-423-1000

Nanosphere 888-837-4436

Quest Diagnostics 973-520-2700

Quidel 800-874-1517

Roche 41-61-688-1111

Saladax Biomedical 610-419-6731

Sequenom 858-202-9000

Vermillion 510-226-2800

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