G2 INTELLIGENCE

Diagnostic Testing &Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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LabCorp Extends Agreement With UnitedHealthcare: Could Signal Increased MCO Interest in Lab Pricing

Laboratory Corporation of America (Burlington, N.C.) recently announced a two-year extension of a previous 10-year agreement to serve as UnitedHealthcare's (Minnetonka, Minn.) "exclusive national laboratory." The arrangement will continue through 2018.

As cost pressures mount and consumers are increasingly sharing costs of testing services, this extension serves as a sign that payers, particularly managed care organizations, are seeking to engage in contractual relationships with lower-cost laboratory providers and could possibly signal a looming volume shift away from traditionally higher-priced hospital outreach laboratories.

"Through our partnership, we have delivered high quality laboratory services to UnitedHealthcare's customers and lowered their laboratory spend," said David King, CEO of LabCorp, in a statement. "This extension is an important mutual recognition of the benefits that our strategic partnership has brought to both companies and demonstrates our renewed commitment to work together to provide the highest quality care at the most reasonable cost."

In the terms of the deal, LabCorp will be the national laboratory for UnitedHealthcare and Oxford Health Plans and the exclusive laboratory provider for the health maintenance organization benefit plans of PacifiCare of Colorado and Arizona, Neighborhood Health Partnership in Florida, and Mid-Atlantic Medical Services (Maryland and Virginia).

Analysts speculate the two companies will develop pilot programs aimed at driving patients to LabCorp facilities. For more on pricing pressures facing laboratories, please see *Inside the Diagnostic Industry* starting on page 5.

Two Companion Dx Approvals Give Signals as Industry Awaits Final FDA Rule

In late August the U.S. Food and Drug Administration (FDA) approved two targeted oncology drugs with companion diagnostic tests. In addition to garnering attention for their expedited reviews, these approvals are being closely examined in the search for clues on what the FDA is looking for in submissions while the industry awaits the FDA's final guidance on companion products.

Among the approvals was Pfizer's (New York) Xalkori (crizotinib) therapy for late-stage non-small cell lung cancers (NSCLCs) which was approved with the

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▲ Industry Awaits Final FDA Rule, *from page 1*

Vysis ALK Break Apart FISH Probe test kit marketed by Abbott (Des Plaines, Ill.) to identify patients who express the abnormal anaplastic lymphoma kinase (ALK) gene. Xalkori works by blocking kinase proteins, including those produced by the abnormal ALK gene. About 1 percent to 7 percent of patients with NSCLC have the ALK gene abnormality.

According to a report in *Forbes*, Xalkori costs about $9,600 per patient per month or a total of $80,000 for the average patient. An ALK test kit costs approximately $250 but lists for $1,500 including the laboratory's pathology service.

> ***"From the 50,000 feet perspective these approvals are manifestations of a sea change taking place because of molecular medicine. Pharmaceutical companies may not have advocated for them, but molecular diagnostics are part of the process."***
>
> ***—Keith Batchelder, M.D.***

The FDA also approved Roche's (Basel, Switzerland) Zelboraf (vemurafenib) to treat late-stage melanoma in patients with a BRAF gene mutation. Zelboraf, a BRAF inhibitor that blocks the mutated BRAF protein, was approved with the 4800 BRAF V600 Mutation Test, also by Roche.

"From the 50,000 feet perspective these approvals are manifestations of a sea change taking place because of molecular medicine," says Keith Batchelder, M.D., CEO of consulting firm Genomic Healthcare Strategies (Boston). "Pharmaceutical companies may not have advocated for them, but molecular diagnostics are part of the process. They think of diagnostics as part of the product."

Batchelder says that the trend to look for in the future is the approval of a companion diagnostic outside of the field of oncology with a test in cardiology or autoimmune disorders likely leading the way. While companion diagnostics may be an accepted necessity in drug development, the industry is still looking for clarification from the FDA on the approval process. The FDA's summer release of its draft guidance on in vitro companion diagnostic devices unveiled few surprises and might have ameliorated some uncertainty, but experts say the draft still lacks clarity, particularly in the assignment of risk.

"It is a big topic with huge implications. I think people in the meantime, before the final guidance, look at the individual clearances for insight into what is expected and what the FDA is looking for," says Jeffrey Gibbs, an attorney and director at the law firm Hyman, Phelps & McNamara (Washington, D.C.). "The FDA is trying to signal what it is receptive to and desirous of in companion diagnostics."

The draft guidance, which is currently available for public comment until Oct. 12, defines a companion test as a device that provides information that "is essential for the safe and effective use of a therapeutic product" and believes the two products should be developed and approved or cleared "contemporaneously," with clinical performance and clinical significance of the IVD companion diagnostic device established using data from the clinical development program of the corresponding therapeutic product.

Because the FDA believes that use of an IVD companion diagnostic device raises important safety and effectiveness concerns as inadequate performance characteristics could expose a patient to preventable treatment risks, the FDA will apply a risk-based approach to

determine the regulatory pathway for IVD companion diagnostic devices. A companion diagnostic device will "generally be considered a significant risk device" requiring a pre-market approval, although there may be cases when 510(k) would be allowed.

FDA is also developing appropriate internal policies and procedures to ensure effective communication among its centers to foster consistent and efficient reviews.

LabCorp Launches HCV GenoSure NS3/4A Drug Resistance Assay

Laboratory Corporation of America (Burlington, N.C.) has launched a nucleic acid sequencing assay that identifies mutations related to the resistance of protease inhibitor drugs approved for the treatment against the hepatitis C virus (HCV). The pharmacogenomic test adds to LabCorp's portfolio of HCV assays and could change clinical management of HCV infection.

"HCV GenoSure NS3/4A represents the first in a series of HCV drug resistance assays that have been developed at Monogram Biosciences (San Francisco; a LabCorp company) to support the clinical evaluation of HCV direct-acting antiviral (DAA) agents and their use in the management of HCV infection," said Chris Petropoulos, Ph.D., chief scientific officer, Monogram Biosciences, in a statement. "We look forward to expanding our broad HCV assay portfolio to support the development and clinical application of additional DAA agents that target other distinct steps in the HCV replication cycle."

In May 2011 the U.S. Food and Drug Administration approved the first two HCV direct anti-viral agents, Victrelis (boceprevir; Merck & Co.) and Incivek (telaprevir; Vertex Pharmaceuticals). During clinical trials conducted to support regulatory approval, HCV variants were discovered that contained mutations that confer reduced susceptibility to the drugs and created a suboptimal treatment response.

The HCV GenoSure 3/4A assay detects these mutations in HCV genotypes 1a and 1b and identifies those patients resistant to boceprevir and telaprevir. HCV Drug Resistance Advisory Group's recent recommendations emphasize the value of resistance testing at baseline and with treatment failure.

Low DHA Levels Linked to Suicide Risk in Military Personnel

A study of 1,600 active-duty service members showed that all had low omega-3 levels and that the lowest levels of docosahexaenoic acid (DHA), an omega-3 fatty acid that is required for optimal neural functioning, was a significant risk factor for suicide death.

The study, published online in the *Journal of Clinical Psychiatry*, comes as the rise in U.S. military suicides has led to an accelerated search for modifiable risk and protective factors. The authors believe these findings, as well as existing evidence for the cardiovascular benefits of omega-3s, will lead to increased utilization of omega-3 blood spot testing.

The researchers analyzed 800 confirmed suicide cases and 800 matched controls. Among men, risk of suicide death was 62 percent higher with low serum DHA status. Each standard deviation of lower DHA levels was associated with a 14 percent greater risk of suicide.

Low sera levels of highly unsaturated omega-3 essential fatty acids likely result from nutritional deficiencies, particularly insufficient seafood consumption, and may increase vulnerability to combat deployment stress and may manifest in psychiatric

symptoms. Aside from the nutritional implications of the findings, the authors say, these findings contribute to growing evidence of the future importance of omega-3 testing both for military and civilian populations.

"Right now there are sufficient other reasons, regardless of suicide, why it is prudent for the military to utilize fatty acid testing," says CAPT Joseph Hibbeln, M.D., acting chief of the Section of Nutritional Neurosciences at the National Institute of Alcohol Abuse and Alcoholism, National Institutes of Health. "To implement [these findings] in a clinically useful way you must deliver the substance and then measure and verify. . . . Our field is rapidly moving towards simple verifying and validating blood tests with a finger prick, much like measuring glucose, two or three spots of blood on a filter paper."

Hibbeln says the chemistry is there, the mechanism is readily available, and testing can be "very rapidly" developed. A handful of companies currently offer omega-3 testing services, including Metametrix (Duluth, Ga.), OmegQuant (Sioux Falls, S.D.), IdealOmega (United Kingdom), for about $100 to $150. Hibbeln believes there is potential to reduce testing costs to as low as $50 per test.

Low-Level, Chronic Hematuria in Young Is Risk for Later ESRD, Leads to Calls for Urine Screening in Teens and Young Adults

A study found that persistent, trace amounts of blood in the urine of teens and young adults may be an indicator of significantly increased risk of future end-stage renal disease (ESRD). The findings published in the *Journal of the American Medical Association* (*JAMA*) are leading some physicians to advocate for the reintroduction of urine dipstick screening in all young adults.

In analyzing more than 1.2 million young people aged 16 to 25 over 22 years, the researchers found that the presence of persistent asymptomatic isolated microscopic hematuria (PAIMH) is an early marker for primary glomerular injury and particularly put males at significantly increased risk of treated ESRD. Roughly 3,700 or 0.3 percent had PAIMH. For those individuals the overall incidence rate of treated ESRD was 34 per 100,000 person-years, while the incidence rate for those without the condition was two per 100,000 person-years. While the incidence and absolute risk remain quite low in this Israeli population, early detection of predialysis chronic kidney disease is important.

"In the United States, because the prevalence of chronic kidney disease (CKD) is estimated to be from 70- to 200-fold greater than the prevalence of treated ESRD, perhaps an argument could be made for the inclusion of [urine] dipstick testing for hematuria as part of routine screening of young adults," writes Robert S. Brown, M.D., a nephrologist at Beth Israel Deaconess Medical Center (Boston), in an accompanying editorial in *JAMA*. "However, a stronger case can be advanced by adding the advantage of simultaneously detecting unsuspected proteinuria with screening dipstick testing. Mild proteinuria . . . has been associated with an increased risk for cardiovascular and all-cause mortality, in addition to the increased risk for developing CKD."

The most recent American Academy of Pediatrics guidelines rescinded the recommendation for urine screening during the second decade of life, but the authors say that future studies are warranted to evaluate the utility of population screening in catching and treating kidney disease early.

G2 INTELLIGENCE
Inside the Diagnostics Industry

Economic Pressures Increase Sensitivity to Price Differentials in the Lab Industry

In an attempt to control unsustainable health care spending, insurers are requiring that patients pay a growing proportion of out-of-pocket medical expenses, including for some laboratory services, in the form of higher deductibles, copayments, or coinsurance. The cost-sharing schemes are meant to keep down employer premiums and improve utilization choices through informed consumer choices. Unfortunately, laboratory pricing is notoriously nontransparent, and when faced with footing a portion of the bill, even educated consumers are shocked to learn of steep price differentials between independent and hospital outreach laboratories.

"We expect independent labs to take share from hospitals over time as greater attention is put on costs. We acknowledge this has been an investment case for years, and one that has not materialized. However, given the significant upcoming changes brought on by reform and focus on cost effective healthcare, we believe this shift will occur, and view both Quest and LabCorp as well positioned to capitalize."

—Ralph Giacobbe, Credit Suisse

In a report titled "My Wife's Trip to the Lab; A Need for Managed Care Buy-In and Employer/Patient Education," Credit Suisse (New York) analyst Ralph Giacobbe makes the case based in part on his wife's laboratory experience that as consumers become more educated, a substantive shift may occur with test volumes being redirected to the "largest, most efficient, and lowest cost lab providers."

In Mrs. Giacobbe's case, a series of four routine lab tests she periodically receives cost 23 times more when performed at an in-network hospital laboratory rather than at a LabCorp facility ($384 vs. $16.25). This example "is not meant to imply that the magnitude of cost differential for every test across all hospitals is as large," Giacobbe warns, but it does raise the question why payers would reimburse at such different rates. Converging factors are currently creating an environment where price differentials are being exposed and hospitals face losing outpatient testing volume if they are not price-competitive.

"We expect independent labs to take share from hospitals over time as greater attention is put on costs," Giacobbe predicts. "We acknowledge that this has been an investment case for years, and one that has not materialized. However, given the significant upcoming changes brought on by reform and focus on cost effective healthcare, we believe this shift will occur, and view both Quest and LabCorp as well positioned to capitalize."

Why the Price Differences?

Historically, hospital laboratories have been able to capitalize on their higher reimbursement rates by generally slipping under the radar of both patients and payers.

"Most hospitals have 'umbrella' facility contracts that include rack rate, per diem prices, and the price of surgery in them. Since labs account for less than 5 percent of medical spend, negotiations around lab fees are often either an afterthought or are left as a percent of charges (typically 80 percent) as a means to leverage price on higher-cost hospital services. This creates an issue of huge variability in hospital lab pricing—sometimes as much as 250 to 350 percent of the published

Medicare fee schedule," says Michael Snyder, president of laboratory services, MedSpend (Cherry Hill, N.J.), a consulting and management services company. "While these fees are less than the published fees for the commercial labs, they represent a higher cost to patients in terms of out-of-pocket expense. . . . In the past, hospitals with outreach lab services were able to capitalize on their above-market pricing in that employers and health plans kept out-of-pocket costs low. Today, the practice is not competitive."

"Since labs account for less than 5 percent of medical spend, negotions around lab fees are often either an afterthought or are left as a percent of charges (typically 80 percent) as a means to leverage price on higher-cost hospital services. . . . While these fees are less than the published fees for the commercial labs, they represent a higher cost to patients in terms of out-of-pocket expense."

—Michael Snyder, MedSpend

Now there is a definite trend toward hospital labs moving toward ancillary fee schedules, Snyder says.

"Historical legacy can no longer be an excuse," says Giacobbe. "It worked until health care reform. Managed care cannot be a pass through. Passing through does not mean managing costs. The cost trend has to come down. The system can't afford it."

Payers, while interested in cost savings, are frequently contractually obligated to both independent labs and hospital labs as in-network providers. The recently announced extension agreement between LabCorp (Burlington, N.C.) and UnitedHealthcare (Minnetonka, Minn.; see page 1) is evidence, experts say, that payers may be increasingly willing to take action to direct patients to lower-cost settings, a trend expected to take hold over the next 24 to 36 months. Patients' awareness of the importance of their role in making medical cost decisions is also anticipated to expand both through educational programs in human resource departments and through word of mouth.

"My wife had no idea. There needs to be transparency in the model driven by the acknowledgement that consumers and employers need to understand the cost rather than take a passive role and go wherever the doctor sends them," says Giacobbe.

Many expect patient choice of laboratory services to eventually resemble the tiered structure of drug formularies. Tiered networks or tiered copay percentages may evolve to steer patients to lower-cost laboratory providers. It is likely patients will retain choice, at a cost to themselves.

A Tug-of-War—Ultimate Winner Not Clear

If price-savvy consumers were the only factor, large, low-cost independent laboratories would be the clear victor of increasing share of the laboratory testing market. But other factors make the battle for market share more like a game of tug-of-war with several factors playing to hospital labs' advantage.

"Hospitals have some advantages and will work toward making the most of it. . . . I don't believe they will give up without a fight to keep what testing makes sense in-house," says Donna Beasley, national director, McKesson Revenue Management Solutions (Alpharetta, Ga.). "Hospitals will be looking for ways to grow their outreach to better align the physicians in the community to their hospital and to increase the incremental revenue from the outreach lab to their bottom-line profit margins."

Hospital laboratories account for the majority of laboratory testing revenue in the industry (estimated at about 55 percent) and have even managed to grow market

share despite a general reduction in utilization as a result of the sour economy. This has been done, in part, as a result of strengthening alliances with physicians who are beholden to refer to hospital labs.

"With hospitals acquiring physician practices, the physicians have no back-office role. There are certainly some benefits[;] however, the hospital will want physicians to refer all business internally," says Giacobbe of the increasing number of physicians who are salaried employees of hospitals. "That is fine [for the health care system] as long as the costs are equivalent and that is clearly not the case now."

Recent payer experiments with bundled reimbursement arrangements may also ultimately affect who remains a player in the industry and laboratory pricing.

"Accountable care organizations and bundled payment schemes shift some of the power back in the hospital," says Snyder. "This leaves a tighter market where hospital labs, large reference labs, and specialty labs with proprietary testing have a better opportunity to participate. If, and that is a valid question, these new network and payment models are successfully implemented, it will be a game changer for the lab industry."

As the laboratory industry faces continued consolidation pressures, hospitals may be inclined to fight for their market share and adapt to the new pricing norms.

"Hospitals must have the ability to have separate fee schedules for their outreach or non-inpatients," says Beasley, acknowledging cost must be a consideration for hospital labs. "This is in some part due to the technology limitation of their legacy information systems and billing system software, which are designed for hospital, not lab, billing and may not have the extensive capabilities that the national labs have to offer customize pricing and discounting."

Hospitals are moving to outsource their billing for enhanced technological opportunities including to better understand their lab revenues, says Beasley. "To price competitively, labs need to understand which tests are profitable based on the costs to perform compared to the revenue collected per test and to look at profitability by payer, by provider, and by client."

Sample Price Differential in Routine Laboratory Testing

CareFirst BlueCross BlueShield is the largest health care insurer in the Mid-Atlantic region, serving nearly 3.4 million members. Many routine laboratory tests can cost up to six times more when performed in an outpatient hospital lab, instead of a CareFirst participating national lab.

DIAGNOSTIC TEST	OUTPATIENT HOSPITAL	NATIONAL (FREESTANDING) LABORATORY	POTENTIAL SAVINGS
Comprehensive Metabolic Panel	$59	$10	83%
Assay Thyroid Stimulating Hormone	$63	$16	75%
Glycosylated Hemoglobin Test	$46	$ 9	80%
Urine Culture/Colony Count	$41	$ 8	81%

Source: CareFirst.com

ABA Passes Resolution With Recommended Standards for DTC Genetic Tests

Adding to calls by states, Congress, and the U.S. Food and Drug Administration for stricter regulation of direct-to-consumer (DTC) genetic testing, the American Bar Association's (ABA; Chicago) House of Delegates in August passed a resolution urging government authorities to enact and enforce specific minimum regulations regarding the quality, marketing, and privacy assurances of DTC genetic testing.

The recommendations apply to "predictive and diagnostic medical genetic testing provided on-line, via the telephone, or by any other direct-to-consumer means." The resolution urges government authorities to enact regulations and "take action" for compliance failures. The suggested requirements include that samples are received and tests are performed only in CLIA-certified labs, results are reviewed by and consumers are advised to discuss results with "qualified health personnel," appropriate privacy guarantees are in place, and claims and test results are "truthful, accurate, and not misleading."

"Based upon press and government reports, there appear to be troubling practices within some parts of the industry. While not reflective of the industry as a whole, clearly there are concerns about quality—apparent lack of safeguards," says David Johnson, a partner at the law firm Bannerman & Johnson (Albuquerque, N.M.) and chair of ABA's Health Law Section. "The first issue is accuracy. The second concern is privacy of confidential and personal information. Consumers are used to protections under HIPAA. Is information sold to a third party or otherwise passed down the pipeline? The last piece is the ability of consumers to make useful, relevant clinical decisions for themselves and their children, or unborn children, in the absence of suitable genetic counseling."

The resolution elaborates upon additional consumer protections including requirements that consumers are fully informed about the tests' clinical utility and the limits of genetic testing, an explanation of what probabilities mean "in plain English," and inclusion of required statements that genes are not the only determinants of illness and that genetic links to diseases are still the subject of ongoing research.

"Face-to-face medical interactions are in the province of state regulation," say Johnson. But given interstate commerce issues, he says DTC genetic testing "should be federal in same way CLIA is the lab standard. . . . We hope [any future regulation] is consistent with the resolution. If any elements are left out I would have concerns."

Calif. Takes Lead in Enacting Genetic Anti-Discrimination Protections

With the Sept. 7 signing of the Genetic Information Nondiscrimination Act (Senate Bill 559), California takes the lead in expanding protections of an individual's genetic information beyond the scope of the national Genetic Information Nondiscrimination Act (GINA) that the U.S. Congress passed in 2008.

"There is no national, comprehensive genetic privacy law. GINA is a strong law, an important law, but it is not comprehensive," says Jeremy Gruber, president and ex-

ecutive director of the Council for Responsible Genetics (Cambridge, Mass.), whose organization advocated for the California law. "California is really the first post-GINA state. We hope other states will follow. . . . Congress will have to act by necessity when enough states have followed California's very important first steps. "

Legislation is pending in Vermont and Massachusetts.

The California law, which goes into effect Jan. 1, 2012, amends two existing state anti-discrimination laws and extends them to cover genetic discrimination in the areas of health and life insurance coverage, housing, mortgage lending, employment, education, public accommodations, and elections. GINA affords genetic protection from discrimination in the realms of health insurance and employment, which remain "crucial areas" and the sources "by far of the most discrimination and breeches in privacy," says Gruber. But he adds with any commercial interest with access to predictive information, there is the potential threat for misuse of information.

Medicare Unveils Bundled Payment Initiative

The Centers for Medicare and Medicaid Services (CMS) recently released details of its latest cost savings pilot program, the Bundled Payments Initiative, and invited providers to test four different models. Such bundled payment arrangements may pose a threat to laboratories, particularly those that provide proprietary tests.

"Traditionally with bundling, hospitals become financially responsible for the price of testing. . . . Nobody is looking at that the $4,000 test can save $40,000; they are focusing on the cost of the test," says Rina Wolf, vice president commercialization strategies, consulting and industry affairs, XIFIN (San Diego). "Hospitals try to do as many tests as possible in-house and they outsource to labs with large menus at steep discounts. But proprietary tests may not be performed by the LabCorps or Quests or regional labs. Much of the innovation is being done by independent, entrepreneurial laboratory entities. That puts those labs [that do the proprietary tests] in a very difficult position."

Wolf cautions labs looking at developing proprietary tests to study the fully loaded cost of bringing the test to market. "What is really the return on investment when all is said and done? A lot of [cost-saving] initiatives are really disincentivizing," she notes.

Analogous to diagnosis-related groups (DRGs), the bundled payment models shifts away from fee-for-service payment and link payments for multiple services patients receive during an episode of care, and in some cases across care settings. CMS identified clinical laboratory testing among the proposed services to be bundled in Models 2 and 3, which both include post-hospital discharge as part of the episode of care. CMS's cost-saving program's final form remains uncertain and depends on pilot program results.

"I believe in the next five years we will see some combination of all these initiatives and basic fee for service, especially in Medicare populations, will be greatly reduced," says Wolf. "The private sector will wait to see if it is successful and then jump on board. It will take longer."

Mark Your Calendar!

Fall

Lab Institute 2011
Oct. 19-21, 2011,
Arlington, Va.
www.labinstitute.com

Winter

LabCompete: Lab Sales and Marketing 2011
Dec. 12-14, 2011,
Chandler, Ariz.
www.labcompete.com

Syphilis Screening Not Utilized Enough in Pregnant Women

Offering decentralized, same-day testing and treatment service increased the coverage and effect of screening programs for antenatal syphilis and could greatly reduce adverse pregnancy outcomes, according to a study published in the September issue of *Lancet Infectious Disease*. Employment of rapid point-of-care testing in a comprehensive screening program could reduce the syphilis-attributable incidence of stillbirth and perinatal death by 50 percent, the study concluded.

Despite existing recommendations for syphilis screening, the authors say that fewer than one in eight of all pregnant women are screened at any point during their pregnancy. Estimates suggest annually there are 2.1 million pregnant women with active syphilis, with most living in low- and middle-income countries. Without treatment nearly 70 percent of these women will have an adverse outcome of pregnancy including stillbirth, prematurity or low birth weight, or an infected baby.

"The perception among many public health experts, program managers, and policy makers that syphilis has disappeared has probably been the greatest barrier to prevent syphilis deaths in babies. If you don't test for it, you don't find it, which reinforces the impression that it is no longer an issue," writes David Mabey, D.M., F.R.C.P., a professor of communicable diseases at the London School of Hygiene & Tropical Medicine, in a related commentary in *Lancet Infectious Disease*. "Simple, affordable point-of-care tests for syphilis . . . give a reliable result in 15 minutes, greatly facilitating the provision of a same-day testing and treatment. . . . These tests can be done on the same drop of blood as an HIV rapid test, offering an opportunity to integrate prenatal screening for these two infections and hence to reduce costs and to avoid the tragedy of babies avoiding HIV infection only to die of syphilis." G2

Biocept and Clarient Partner on CTC Test Commercialization

Biocept Inc. (San Diego) and Clarient Inc. (Aliso Viejo, Calif.), a unit of GE Healthcare, said in September that they will collaborate on the commercialization of Biocept's proprietary OncoCEE-BR blood test for circulating tumor cells (CTCs) in breast cancer patients. The test, which also determines HER2 status, is reportedly the first commercially available CTC test to analyze a treatment-associated biomarker.

Under the terms of the deal, Clarient will market and sell the test to community hospitals, pathologists, and medical oncologists. Biocept will perform the test in its CLIA-certified laboratory and results will be interpreted by Clarient's pathology group.

The "liquid biopsy" can consistently and accurately capture extremely rare cells from blood, like CTCs, which may be present in only one of every 50 billion to 100 billion blood cells. Biocept intends to add ER/PR status determination to the test "in the future." The test is based on Biocept's OncoCEE (cell enrichment and extraction) platform but can evaluate diagnostic biomarkers using mutation analysis, immunocytochemistry, or fluorescence in situ hybridization (FISH) technology, as in the case of HER2.

OncoCEE-BR is expected to be applied in several clinical situations including at the time of recurrence to determine if HER2 status has changed, in cases where a biopsy may be difficult to obtain, or in cases of tumor heterogeneity when tumor tissue analysis was negative for HER2 amplification. G2

G2 Index Rebounds, Rises With Market 8%

In a turnaround from the previous month's dramatic losses, the G2 Diagnostic Stock Index gained 8 percent for the four weeks ending Sept. 16, with 15 stocks up in price and two remaining unchanged. The G2 index's gains matched the S&P but were less than the Nasdaq's 12 percent increase over the same period.

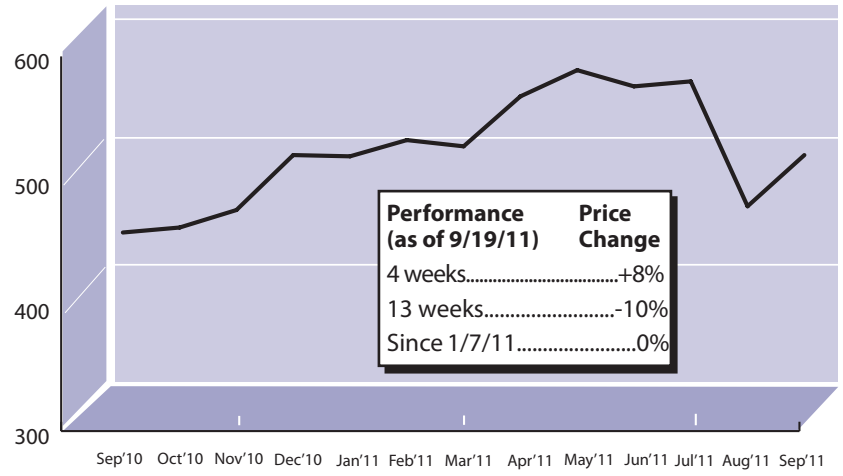
Following the Aug. 19 close of the previously announced $1.9 billion sale of **Immucor** (Norcross, Ga.) to private investment firm TPG Capital LP (Fort Worth, Texas), Immucor is no longer publicly traded or included in the G2 Diagnostic Stock Index.

Several companies including **Gen-Probe** (San Diego), whose stock rose 14 percent, made optimistic presentations at financial conferences in September. Gen-Probe is confident it can retain its dominant market position (47 percent, according to the company) in sexually transmitted disease testing and is awaiting Food and Drug Administration approval on its APTIMA HPV assay. GenProbe's next major growth opportunity is in virology testing with U.S. product introductions expected in 2014.

At a Morgan Stanley Conference **Luminex** (Riverside, Calif.), CEO Patrick Balthrop said that the company is "very optimistic" about continued annual revenue growth of 20 percent or more. Luminex, whose stock rose 12 percent this period, raised its annual guidance to $180 million from $170 million following a "robust" first half and from second-half revenue contributions from EraGen (Austin, Texas), which the company acquired this summer. Additionally, Balthrop said with more than 8,000 previously installed instruments the company is well-poised to fare well in down times when customers tend to hold on to equipment.

The market reacted favorably to **IRIS International's** (Chatsworth, Calif.) announcement that it is restructuring its personalized medicine division by consolidating Arista Molecular's operations, which were acquired by IRIS in July 2010. Additionally, IRIS will discontinue nonproprietary testing services. From the restructuring IRIS anticipates an annualized expense reduction of $4.5 million to $5 million, allowing a concentration of resources on new products and strategic initiatives.

G2 Diagnostic Stock Index



Source: The G2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 17 IVD companies.

Unchanged	Price	% Chg
Becton Dickinson	$77.25	0%
Qiagen	$14.49	0%
Up		
Abbott Labs	52.17	6
Abaxis	25.51	15
Affymetrix	5.43	20
Alere	23.84	3
Bio-Rad	98.22	1
Cepheid	36.84	20
Gen-Probe	62.08	14
Illumina	47.88	2
IRIS	8.72	10
Johnson & Johnson	64.59	2
Luminex	22.36	12
Meridian	17.91	5
OraSure	7.84	2
Quidel	15.38	15
Sequenom	6.00	14

G2 Insider

Misordering of genetic tests is costly and common . . . Genetic counselors (GCs) at ARUP Laboratories (Salt Lake City) generate an average cost savings of $36,500 per month by identifying inappropriately ordered genetic tests and working with ordering institutions to cancel or modify those orders. In a white paper, "The Value of Genetic Counselors in the Laboratory," ARUP says sharing results of their own "rigorous" review of genetic test orders can help other institutions reduce waste of health care dollars and underscores the role of GCs in improving appropriate test utilization.

In a review of all test modifications over an 11-month period for complex genetic tests (sequencing, large duplication/deletion analysis, or array-based technologies), ARUP found that GCs assisted in an average of 107 test modifications per month, approximately 30 percent of all complex genetic tests ordered. GC review of genetic tests saved nearly half a million dollars in inappropriate genetic test orders in 2010 and led to process improvements in test ordering at ARUP.

More than two-thirds of cancellations resulted from an incorrect test being ordered with an appropriate replacement test ordered in half of these cases. Duplicate test orders accounted for 9 percent of cancellations, and in 21 percent of cancellations gene sequencing was ordered but was replaced with a targeted panel or targeted test for familial mutation.

The most frequently misordered tests included alpha globin sequencing, rather than alpha globin deletion testing; NF1 deletion/duplication, when NF1 sequencing was desired but not offered at ARUP; Galactose-1-phosphate uridyltransferase, rather than galactomannan; Familial mutation targeted sequencing when there is a familial disease but no one in the family has previously had genetic testing and the familial mutation is unknown; and Cystic fibrosis panel with reflex to sequencing, rather than CF panel for a routine carrier screen.

ARUP added corrective measures to reduce these ordering errors including the addition of a statement to the test directory to contact a GC before ordering alpha globin sequencing and the removal of NF1 deletion/duplication testing from the directory until the lab can offer NF1 sequencing.

Company References

Abbott Laboratories 847-937-6100
American Bar Association 312-988-5000
ARUP Laboratories 800-522-2787
Biocept Inc. 888-332-7729
Clarient Inc. 949-425-5700
Council for Responsible Genetics 617-868-0870
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