Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT®

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

Issue 04-12/April 2012

HIGHLIGHTS

Supreme Court Voids Prometheus Patents on Test Methods

In a much-anticipated ruling, the Supreme Court March 20 invalidated two patents held by Prometheus Laboratories (San Diego). The case, *Prometheus v. Mayo*, has been closely watched by the biotech and diagnostics industries, which have worried that such a ruling could stifle diagnostic innovation.

At issue are patents on the method for determining the proper dosage of thiopurine, a stomach medicine, based on the rate at which particular patients metabolize the drugs. Prometheus, a unit of Switzerland-based Nestle S.A., was the exclusive licensee of two patents on the method. Prometheus sued Mayo Collaborative Services in 2004 after Mayo created its own test for determining thiopurine dosage, which Prometheus said infringed on its patents.

Continued on page 2

Lab-Developed Tests Would Be Exempt From User Fees Under Deal Reached With FDA

The Food and Drug Administration (FDA) has agreed to seek statutory authority that will allow it to waive user fees for laboratory-developed tests (LDTs) under the Medical Device User Fee Amendments (MDUFA).

FDA officials and industry groups have been negotiating for months over the next incarnation of the user fee program. In back-to-back meetings in early February, the FDA and groups representing labs and medical device manufacturers hashed out details of MDUFA III. The meetings followed a tentative accord reached in early February that would double the user fees paid over five years in exchange for the FDA meeting certain performance goals. User fees would double from $295 million to $595 million under the agreement.

User fees would only come into play for labs if the FDA issues guidance requiring LDTs to go through FDA clearance. The FDA says that it plans to regulate LDTs and believes it has the authority to do so. However, legislation pending in Congress would assign LDT oversight to the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare and Medicaid Services.

Continued on page 8

■ **Supreme Court Voids Prometheus Patents on Test Methods**, *from page 1*

In the unanimous decision, the high court ruled that the Prometheus patents were unpatentable because they merely describe the laws of nature and "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity."

"The question before us is whether the claims do significantly more than simply describe these natural relations," wrote Justice Stephen Breyer in the court's opinion. "To put the matter more precisely, do the patent claims add enough to their statements of correlations to allow the processes they describe to qualify as patent-eligible processes that apply to natural laws. We believe the answer to this question is no."

While test developers generally supported Prometheus, most groups representing health care providers supported Mayo, saying such patents threatened to limit care to patients. Myriad Genetics, which backed Prometheus, is fighting a challenge to its patents related to the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer. Myriad in January filed a brief with the Supreme Court in opposition to a petition seeking review in a case challenging its patents.

The Supreme Court on March 26 remanded the *Myriad* case back to the Court of Appeals for the Federal Circuit to reconsider in light of the court's ruling in *Prometheus*. Analysts view this decision as positive for Myriad. Equity research firm William Blair & Co. (Chicago) notes that the appeals court already upheld Myriad's isolated and cDNA patents in its decision on the case and denied the American Civil Liberties Union request for a rehearing. "Given the Prometheus decision was a fairly narrow ruling that was focused on the patent eligibility of diagnostic method claims, the case says nothing about composition of matter patents and the patenting of isolated and cDNA," writes Amanda Murphy, an analyst. "We see no reason to believe [the appeals court] would reach a different decision on the product claims than it did in 2011.

Spending on Genetic Testing Projected to Rise Sharply; Increase Bodes Well for Diagnostic Companies

Spending on genetic tests has reached $5 billion annually as of 2010 and they could become a $25 billion annual market within a decade, highlighting the need to identify which tests work the best, according to a new report by United-Health Group Inc. (UHG).

The increase in spending is also likely to intensify the debate over genetic testing as policymakers and employers struggle to contain spiraling health care costs. While genetic exams "hold great promise for better health and medical care . . . they also pose significant challenges to a system that is increasingly unaffordable," says the report.

The findings are consistent with estimates by G2 Intelligence that put the molecular testing market at about $5.5 billion in 2009, growing at a rate of more than 15 percent per year.

According to UHG, a majority of the 1,800 DNA tests developed to identify or manage medical conditions still haven't been studied enough to prove their effectiveness. The company estimates that three to five new genetic tests are being introduced each month.

The report echoed concerns from a study published in March in the *New England Journal of Medicine* that found cancer screening may be less useful than hoped because of the wide variety of mutations found in tumors. That may explain why some oncology drugs become less effective even when targeted at specific genes, scientists from the United Kingdom said.

UHG, which covers 36 million people in its medical plans, spent about $500 million for genetic exams and molecular diagnostics in 2010, with about 40 percent for infectious diseases, 16 percent for cancer, and the remainder for other inherited disorders. Test procedure usage per person was highest in UHG's Medicaid population, followed by the commercially insured population, and then the Medicare population. UHG estimates that spending per member on molecular and genetic tests increased by about 14 percent a year on average between 2008 and 2010.

Extrapolating from these data, the report suggests that national spending on these services may have reached about $5 billion and could potentially reach between $15 billion and $25 billion annually by 2021.

"While genetic exams "hold great promise for better health and medical care . . . they also pose significant challenges to a system that is increasingly unaffordable."
–United Health Group

UHG surveyed patients and physicians about their views on genetic testing and found that consumers are optimistic about the potential benefits from advances in this area. About three-quarters of survey respondents agree that genetic tests help doctors diagnose preventable conditions and offer more personalized treatment options.

The majority of U.S. doctors also say that genetic testing will improve care across a range of health problems in the future, allowing for more personalized medical decisions and more targeted choice of therapy. On average, physicians report having recommended genetic testing for 4 percent of their patients over the past year. Looking ahead five years, physicians on average feel that 14 percent of their patients will have had a genetic test; however, nearly three in five doctors say they are very concerned about the cost of genetic tests.

"The mapping of the human genome and use of genetic testing in diagnosing and treating diseases are landmark breakthroughs in modern medicine," said Reed Tuckson, M.D., chief of medical affairs at UHG and former chair of the U.S. Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society. "It is now up to all of us to foster an environment that encourages innovation in these tests and related treatments, as well as their responsible use, so as to bring about real-world improvements in care."

UHG makes recommendations in six areas where it believes action would ensure patients benefit the most from the new science, help advance patient care, and make sure that genetic tests are used effectively and that affordable care is preserved:

- ❑ Protecting, supporting, and informing patients through data confidentiality, nondiscrimination, and decision support;
- ❑ Benefiting patients by developing the clinical evidence base to determine which tests work;
- ❑ Stimulating future progress by encouraging the development of tests that are proven to work;

- ❑ Monitoring care through more transparent coding and reporting;
- ❑ Protecting patients by ensuring that lab tests are performed safety and accurately; and
- ❑ Making it easier for health professionals to stay up to date as genetic science evolves.

The report, "Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics," is available online at *www.unitedhealthgroup.com/hrm/UNH_WorkingPaper7.pdf.*

MDx Health Establishes California Lab, Boosts Revenue in Fourth Quarter 2011

MDxHealth (Liege, Belgium), which recently established a clinical laboratory in Irvine, Calif., reported that total revenues for the fourth quarter of 2011 increased by 48 percent to 9 million euros from 6 million euros during the same period in 2010. The revenue increase was attributable to the company's pharmaco-diagnostic business.

For the full year ended Dec. 31, 2011, revenues increased by 6 percent to 2.7 million euros.

In the fourth quarter, MDxHealth established a Clinical Laboratory Improvement Amendments (CLIA)-registered laboratory for the commercialization of its diagnostic assays. The company's California facility received its clinical laboratory license and CLIA certificate of registration in less than five months of leasing the lab facility.

In 2011, research and development activities and resources were directed to the clinical validation of the ConfirmMDx for Prostate Cancer test, accelerated development of additional cancer tests in the company's pipeline, and development of pharmaco-diagnostic tests.

The growth in revenues from their pharmaco-diagnostic business in Q4 2011 of nearly 50 percent versus Q4 2010 represents continued validation and acceptance of their epigenetic technology and tests within the pharmaceutical industry, said Jan Groen, Ph.D., chief executive officer of MDxHealth. "Additionally, we have made important strides in the development and validation of our ConfirmMDx for Prostate Cancer test and significantly advanced preparations for product launch in the coming months."

Outlook

The company is building the sales and marketing infrastructure necessary to support the expected launch of its ConfirmMDx Prostate Cancer test in the United States in early 2012. The company will also continue to focus on the development and validation of its PredictMDx for Brain Cancer (glioblastoma) test directed at the MGMT epigenetic biomarker, which is being used in Merck Serono's Phase III clinical trial for their drug candidate cilengitide. The test may be able to help identify glioblastoma cancer patients who could benefit from cilengitide treatment.

If You Can't Beat 'Em, Join 'Em; How to Cope With Insourcing of Pathology Services

As the growth of in-office histology labs continues to put financial pressures on independent pathology practices, many pathology groups are faced with a dilemma: Refuse to work with clients who decide to insource histology or find a way to continue to providing services to the clients while minimizing their impact on revenues.

KWB Pathology Associates (Tallahassee, Fla.), a practice with 14 pathologists, faced just such a conundrum. In 2009, one of its clients, a dermatology practice, hired a consultant to set up an in-house lab. This was soon followed by two more dermatology practices and an endoscopy center. Net revenue at risk from these four practices was almost $7.7 million.

Al Parker, administrator at KWB Pathology, said the group's initial reaction was anger, especially after one dermatology group "cut a deal with one of our pathologist partners who left in the middle of the night to set up their lab and provide the professional component." Parker shared the group's story during the inaugural Pathology Institute, held Feb. 9-10. The institute was cosponsored by G2 Intelligence and Laboratory Economics.

The Net Effect-KWB Pathology

	Net Revenue	
Clients With Insource Histology	**Before**	**After**
Dermatology Practice 1	$3,365,369	$1,721,155
Dermatology Practice 2	$1,985,762	$ 862,928
Dermatology Practice 3	$1,289,974	$1,246,669
Endoscopy Center	$1,026,764	$731,099
Total	$7,667,870	$4,561,851
Revenue Retained:	59 Percent	

Ultimately, KWB decided it was in the group's best interest to continue relationships with all four clients. For Dermatology Associates of Panama City, KWB still performs and bills for professional services. Three other groups—Dermatology Associates of Tallahassee, Gulf Coast Dermatology, and Digestive Disease Clinical, opened in-office labs in 2010 and either hired or contracted with other pathologists.

Not surprisingly, the practices that put in their own labs experienced increases in volume and utilization, and KWB helps to pick up the overflow work. As a result of maintaining the relationships with the four practices, KWB has been able to retain 59 percent of the net revenue that it was at risk of losing altogether. "You can maintain more revenue than you think," said Parker.

Good Neighbor Policy

CAP Lab, an independent pathology group in Lansing, Mich., also made the decision to work with clients who opened their own in-house labs. James Richard, M.D., D.O., a partner, said the group maintains good relationships with competing clients. "It's good business to be good neighbors," said Richard.

CAP Lab serves as medical director and provides professional services to three in-office histology labs, including a urology, gastroenterology, and dermatology group. The lab leases its histotechs at an hourly rate. The groups bill for the technical services and CAP Lab bills for the professional services.

In developing service agreements with clients, Richard advises putting yourself in the client's situation, tailoring your proposal to equally maximize benefits to both parties, and being as detailed and exact as possible with numbers and references to your positions and assumptions.

In general, clients would prefer to stay local if they can, want to make a reasonable profit for their risk and investment, respect expertise and experience, want a hassle-free operation, and will make an ethical choice if it's reasonable and if given the chance, he noted.

"It's Yours If You Want It"

Joe Plandowski, president of Lakewood Consulting Group and co-founder of In-Office Pathology LLC, a company that helps physician groups set up in-office labs, says insourcing represents a tremendous opportunity for pathologists who have an open mind. Plandowski's company has helped set up 50 histology labs at gastrointestinal (GI), urology, and dermatology groups over the past seven years.

Because many physician practices need local pathology services, pathologists looking for new opportunities probably won't be competing against larger national labs, according to Plandowski. And the opportunity is there, he says, noting that a

IOAS, Anti-Markup Rule Fuels Growth

The in-office ancillary services (IOAS) exception to the physician self-referral law, combined with the current anti-markup rule finalized in the 2009 physician fee schedule final rule, has fueled growth in ancillary services provided by physicians in their own offices.

Under the current anti-markup rule, a billing physician may mark up the technical component (TC) or the professional component of a diagnostic test if the performing physician or supplier "shares a practice" with the billing physician. To meet that requirement, the test has to be performed in the office of the billing physician. For the TC of anatomic pathology services, the Centers for Medicare and Medicaid Services (CMS) has taken the position that the anti-markup rule does not apply to the TC at all. Further, CMS in the 2009 rule removed all references to "purchased tests," thus eliminating a longstanding rule that prevented physicians from marking up tests they purchased from an outside supplier. As a result of these changes, anatomic pathology self-referral arrangements and in-office labs have exploded.

The Medicare Payment Advisory Commission (MedPAC) has examined the impact of the IOAS exception and concluded that it has led to inappropriate growth of ancillary services, including anatomic pathology, diagnostic imaging, physician therapy, and radiation therapy. MedPAC in its June 2011 report to Congress recommended narrowing the exception, but members of the Alliance for Integrity in Medicare, which includes the American Clinical Laboratory Association, the College of American Pathologists, and the American Society for Clinical Pathology, believe that MedPAC did not go far enough in its recommendations. They are continuing to push CMS to narrow the exception further.

Potential Market for Insourcing

The potential market for pathology insourcing is in the billions of dollars, according to Jondavid Klipp, publisher of *Laboratory Economics*. Reimbursement pressure is driving specialty physicians to expand their practices by adding ancillary services such as anatomic pathology labs. Between dermatologists, gastroenterologists, and urologists, the total market could be more than $4 billion.

Specialty	Number of Office-Based Docs	Annual Pathology Revenue Per Doc*	Total Market
Dermatologists	9,000	$200K	$1.8B
Gastroenterologists	10,000	$125K	$1.3B
Urologists	8,500	$150K	$1.3B

** Includes professional and technical revenue.*
Source: Laboratory Economics and AMA's Physician Characteristics and Distribution in the U.S. for 2011

four-person gastroenterology group can bill 5,000 CPT codes per year, while a four-person dermatology group can bill at least 8,000 codes.

"The business is yours if you want it and can handle it, can agree to the negotiated fees, and are acceptable to physician owners," he explained, adding that there are many advantages to working for a physician group: no need for an anatomic pathology (AP) lab, sophisticated computer systems, distribution services, sales and marketing capabilities, and a billing staff.

In addition, a pathologist working for a physician group can negotiate the payment they receive and typically will receive full payment within 30 days. Plandowski noted that in his experience pathologists typically receive about $26 per slide. "It beats TC/PC arrangements," he said.

So how does a pathologist capture this business? Plandowski advises identifying GI or urology groups with a least four doctors that are sending specimens to another path group or an outside reference lab and then asking them about their interest in having an in-office AP lab. Because in-office pathology labs operate under a distinct set of regulatory requirements, Plandowski recommends hiring an outside consultant to help set up the lab. He also warns that hospital-based pathologists should make sure their hospital contract allows them to work at an in-office lab and that their existing insurance covers it.

In addition, make certain that an American Society for Clinical Pathology-certified histotech has been hired by the specialty practice, proper Clinical Laboratory Improvement Amendments certification has been received, a compliant pathology services agreement has been signed, and a competent billing service is in place. G2

■ **Lab-Developed Tests Would Be Exempt From User Fees**, *from page 1*

In response to concerns raised by the American Clinical Laboratory Association (ACLA), the FDA said it would seek authority to waive or reduce fees on a case-by-case basis and said that if granted that authority, it would "ensure that no additional LDTs or laboratories would be subject to user fees during MDUFA III due to implementation of the regulation framework under consideration or due to other changes in policy on LDTs."

Groups representing medical device makers expressed concerns that such waivers might throw off the balance of resources to workload. Ultimately, the FDA and the groups—including ACLA—agreed to a deal that would place a $15 million cap on the total value of waivers and would exempt waived applications from the same performance goals as those applied to standard applications.

The agreement now heads to the Department of Health and Human Services and the Office of Management and Budget for approval before making its way to Congress.

Coapproval Said Necessary to Market Companion Diagnostic Test, Therapeutic

The coapproval requirement for companion diagnostic tests and therapeutic products outlined in Food and Drug Administration (FDA) draft guidelines has generated many comments and some expressions of concern, an agency official told a conference audience March 12.

Elizabeth Mansfield of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety said, however, that the requirement is important and likely to remain in place. The best advice for biopharma companies developing such companion products is to talk to FDA and plan ahead, she told CBI's Fourth Annual Forum for Payers on Personalized Medicine in Washington, D.C.

"Biopharmas should indicate [as soon as possible] to the FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research that there will be a companion diagnostic test to a therapeutic product that [they] will need to review at the same time," Mansfield said. "The watchword is to plan ahead."

FDA's regulatory concept as expressed in its draft guidance, she said, "is for premarket review, that at the time the drug is approved there is an assurance that the companion diagnostic has been appropriately validated for intended use. Contemporaneous approval will be required," she said, although there will be exceptions.

In the conclusion to her remarks, Mansfield expressed concern about the rapid development of next-generation DNA sequencing and the lack of tools to evaluate tests that are developed from the new technology. During the question-and-answer period, she also drew a sharp distinction between FDA-approved tests and laboratory-developed tests (LDTs) certified under the Clinical Laboratory Improvement Amendments (CLIA).

Regulatory Concept Is Coapproval

FDA in July 2011 issued the draft guidance to facilitate the development and review of companion diagnostics. Comments were due Oct. 12, 2011. "We received quite a number of comments," Mansfield said. "There were over 50, and we expect to publish the guidance as a final this year."

According to the guidance, an in vitro companion diagnostic device (IVD companion diagnostic) is an in vitro diagnostic device that provides essential information for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic with a particular therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, as well as in the labeling of any generic equivalents of the therapeutic product.

Mansfield said there are different types of companion diagnostic devices. Some are predictive, such as Roche's KRAS Mutation Test that identifies mutations in the KRAS gene of colorectal cancer tissue that are predictive of individual response to therapy with anti-epidermal growth factor receptor antibody therapies.

Others she characterized as "selection claims," such as Roche's 4800 BRAF V600 Mutation Test. "The selection claims tests are used when a pharmaceutical company believes it has a targeted agent, and the test is utilized as an integral part of a therapeutic clinical trial conducted to support the market approval of a therapeutic product."

Discussing the guidance's requirement for coapproval of the therapeutic product and the companion diagnostic test, Mansfield said that it was presenting "incredible timing issues" for FDA. "But coapproval is important. The companion diagnostic test and the therapeutic product depend on each other. The failure to obtain approval of the test means that there will be no therapeutic product approval, although there are exceptions for unmet medical needs."

Verinata, Stanford Challenge Sequenom on Validity of Prenatal DNA Test Patent

Verinata Health Inc. and Stanford University filed litigation Feb. 22 in federal district court that seeks a declaration that the company's prenatal test using cell-free DNA does not infringe Sequenom Inc.'s patent and that the patent is invalid (*Verinata Health Inc. v Sequenom Inc.*, N.D. Cal., No. 4:12-cv-00865-YGR).

The plaintiffs also allege that Sequenom's prenatal test has infringed a patent owned by Stanford and exclusively licensed by Verinata.

According to the complaint filed in the U.S. District Court for the Northern District of California, the Verinata test employs novel techniques to analyze cell-free DNA circulating in the blood of a pregnant woman by DNA sequencing to determine whether a fetus is at risk for having an abnormal number of chromosomes (aneuploidy).

Verinata states that it plans to start offering the Verinata test commercially in early 2012 and has been using it in Northern California to conduct clinical valida-

tion studies. The company says it has spent tens of millions of dollars to research, evaluate, and develop the test; moved its operations into larger facilities; designed a new clinical laboratory with an initial capacity of more than 150,000 tests annually; and acquired an exclusive license from Stanford for U.S. Patent Nos. 8,008,018 ("Determination of fetal aneuploidies by massively parallel DNA sequencing," issued Aug. 11, 2011) and 7,888,017 ("Non-invasive fetal genetic screening by digital analysis," issued Feb. 15, 2011).

According to the complaint filed in the U.S. District Court for the Northern District of California, the Verinata test employs novel techniques to analyze cell-free DNA circulating in the blood of a pregnant woman by DNA sequencing to determine whether a fetus is at risk for having an abnormal number of chromosomes (aneuploidy).

In their complaint, the plaintiffs report that San Diego-based Sequenom, which is the exclusive licensee of U.S. Patent No. 6,258,540 ("Non-invasive prenatal diagnosis," issued July 10, 2001), contacted Verinata in August 2010, claiming that the practice of noninvasive prenatal diagnostics, as described in a press release issued by Verinata's predecessor Artemis, infringes the '540 patent. Artemis's counsel responded that Sequenom's infringement position was not supported by its patent.

Since then, the plaintiffs write, Sequenom has repeatedly claimed that anyone who performs a noninvasive prenatal test using cell-free DNA circulating in the blood of a pregnant woman would infringe the '540 patent and has specifically stated at conferences, during earnings calls, in articles, and in interviews that Verinata has infringed the '540 patent. Each of these statements has been published on the Internet, the plaintiffs claim.

Other Sequenom Litigation Cited

The complaint notes that Sequenom has also filed litigation in the U.S. District Court for the Southern District of California against Aria Diagnostics, *Sequenom v. Aria Diagnostics*, S.D. Cal., No. 3:12-cv-00189, filed 1/24/12, and Natera Inc., *Sequenom Inc. v. Natera Inc*., S.D. Cal., No. 3:12-cv-00184, filed 1/24/12, which also seek to enter the market for noninvasive prenatal testing using cell-free DNA. Sequenom filed a motion for a preliminary injunction against Aria Feb. 22.

Verinata and Stanford allege in their complaint that Sequenom's '540 patent is invalid for failure to comply with 35 U.S.C. §§101 (patentability), 102 (novelty), 103 (obviousness), and 112 (written description and enablement).

They also allege that Sequenom's commercial noninvasive prenatal test for Down syndrome, which is marketed under the trade name MaterniT21 and uses analysis of circulating cell-free DNA extracted from maternal blood using massively parallel shotgun DNA sequencing, infringes the '018 and '017 patents.

Verinata asks the court for a declaratory judgment of noninfringement and invalidity of the '540 patent, and both Verinata and Stanford ask for a judgment that Sequenom has infringed the '018 and '017 patents and an award of damages, treble damages, attorneys' fees, and costs.

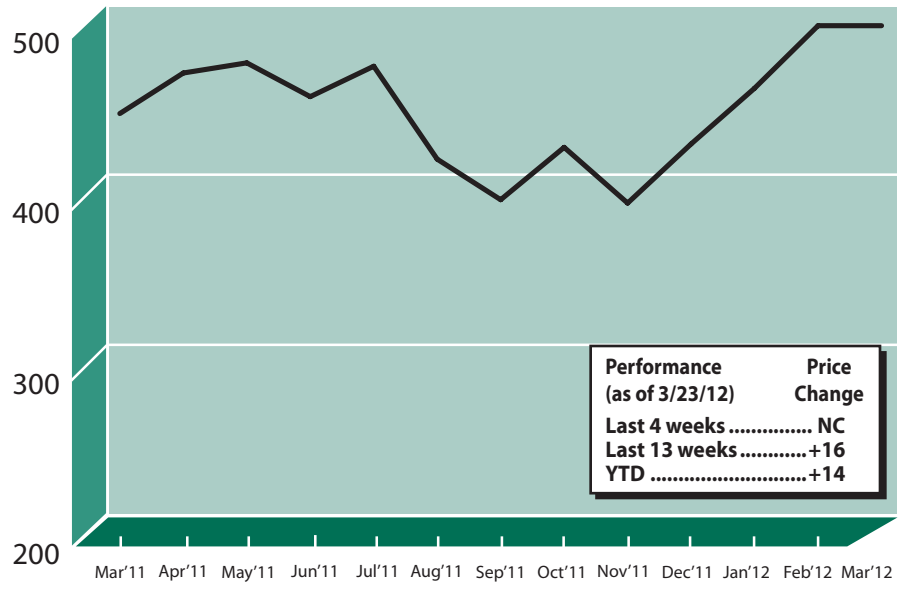
Lab Index Holds Steady in March

The G2 Intelligence Laboratory Stock Index held steady in the four weeks ended March 23, 2012, with four stocks rising in price, four falling, and one unchanged. Since the beginning of the year, the index has risen 14 percent. In comparison, the Nasdaq composite is up almost 18 percent, and the S&P 500 is up 11 percent.

Shares of **Bio-Reference** (Elmwood Park, N.J.) rose 12 percent to $22.76 after the company beat expectations on revenues and earnings per share (EPS) for the quarter ended Jan. 31, 2012. For the quarter, Bio-Reference notched revenues of $149.9 million, beating analyst expectations of $143.1 million. Revenues were 23 percent more than the $121.7 million reported for the first quarter of 2011. EPS came in at 26 cents, beating expectations of 21 cents per share. Net income before taxes for the quarter totaled $12.9 million, an increase of 54 percent compared with the same period the previous year. Revenue per patient for the quarter was $82, a slight increase over the $80.88 reported for the same period in 2011. The number of patients served increased 22 percent to 1,814 during the quarter. Esoteric business was 59 percent of revenues, and days sales outstanding was 91 days.

Enzo-Biochem (New York) shares fell 3 percent to $2.78 even though the company reported improved results for the fiscal quarter ended Jan. 31, 2012. Revenues for the second quarter were $25 million, compared with $23.7 million a year ago, an increase of 5 percent, as a result of both continued growth at Enzo Clinical Labs and an increase in royalty and licensing fee income. Gross profit improved to 46 percent, from 44 percent year over year. Operating expenses declined $0.5 million to $15.4 million, due to a reduction in legal and research and development expenses, partially offset by an increased provision for uncollectable accounts receivable due to higher service volume at Enzo Clinical Labs.

G2 Laboratory Stock Index



Source: The G2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 9 laboratory testing service stocks.*

Percent Price Change, As of 3/23/2012

	Price	Percent Change
UP		
Bio-Reference	$22.76	12%
Genomic Health	30.84	7
Medtox	17.20	2
Quest	59.17	3
NO CHANGE		
LabCorp	89.47	NC
DOWN		
Enzo Biochem	2.78	-3
Myriad Genetics	22.78	-5
Psychemedics	9.86	-1
Neogenomics	1.65	-1

INDUSTRY BUZZ

Putting MDx to Work in the Lab

What was once a rare form of testing, the field of molecular diagnostics is now growing so rapidly, it's more crucial than ever to have insight into both what's happening now—and what's next. G2 Intelligence invites you to join us in Boston April 17-19 for our seventh annual MDx conference.

To ensure that you receive the most innovative and successful business models and strategies, cutting-edge content, and invaluable networking opportunities, MDx NEXT: Gaining the MDx Edge, will bring you face to face with a world-class faculty of molecular and genetics experts and laboratory business leaders from some of the nation's top labs in the areas of molecular business strategy, reimbursement, billing, legal, regulation, and results reporting.

2012 Laboratory Reference Testing Survey

Interested in volume and cost trends for send-out tests at your peer laboratories?

Participate in G2's Lab Reference Testing Survey and receive a high-level executive white paper with our thanks.

www.G2Intelligence.com/RefTestSurvey

Stafford O'Kelly, president of Abbott Molecular and chair of the Personalized Medicine Coalition, will present the opening keynote address: Putting Molecular Diagnostics to Work: What's Now and What's Next. Kenneth Buetow, Ph.D., formerly associate director for bioinformatics and information technology at the National Cancer Institute, will present the keynote on day two of the conference: The Next Frontier: Personalized Medicine and Cancer.

For full program details or to register, visit *www.mdxconference.com.*

References

CAP Lab 877-372-5520

Enzo Biochem
800-522-5052

KWB Pathology
888-878-5143

Lakewood Consulting Group
847-840-3077

Mayo Collaborative Services
800-533-1710

MDx Health
866-259-5644

Prometheus Laboratories
858-332-3376

Roche +41 61 688 1111

Sequenom
858-202-9000

UnitedHealth Group
866-204-0911

Verinata Health
650-503-5200

LIR Subscription Order/Renewal Form

❑ **YES**, enter my one-year subscription to the ***Laboratory Industry Report (LIR)*** at the rate of $449/yr. Subscription includes the ***LIR*** newsletter and electronic access to the current and all back issues. Subscribers outside the U.S. add $100 postal.*

❑ AAB & NILA members qualify for special discount of $25 off — or $336.75. (Offer code LIRI1)

❑ I would like to save $269 with a 2-year subscription to ***LIR*** for $629.*

Please Choose One:

❑ Check enclosed (payable to Kennedy Information, LLC)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date_____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company _____

Address _____

City _____ St _____ ZIP _____

Phone _____ Fax _____

e-mail address_____

Mail to: G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Or call 800-401-5937 and order via credit card or fax order to 603-924-4034

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere. For multi-user and firm-wide distribution programs or for copyright permission to republish articles, please contact our licensing department at 973-718-4703 or by email at: jping@g2intelligence.com.

LIR 04/12

 Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Tel: 800-401-5937. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.