Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Breaking Down Barriers To Integrating Pharmacogenomics Into Clinical Practice

This was one of the key questions discussed and debated at the recent meeting of the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), where the committee's Pharmacogenomics Task Force provided an update on its progress and Steve Gutman, M.D., the director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, presented on the FDA's guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers.

Led by Chairperson Emily Winn-Deen, Ph.D., the SACGHS Pharmacogenomics Task Force is now working on a report that examines key issues related to pharmacogenomics, including the state of federal efforts in the area, research and development, oversight, education, and integration into clinical practice. For more on the work of the task force, see *Inside the Diagnostics Industry*, pp. 6-7.

HIV Testing: New CDC Recommendations And FDA-Approved Tests

Last month, the Centers for Disease Control (CDC) issued recommendations that all United States residents aged 13 to 64 years have HIV tests as part of routine medical exams in private practices, clinics, hospitals, and emergency departments. The agency will also likely recommend revisions to current guidelines that require patients to sign consent forms or undergo counseling before being tested for HIV. The revised guidelines would enable patients to perform HIV tests with oral consent and/or minimal pre-test consultation.

In 1993, the CDC outlined recommendations for routine HIV testing in certain acute care settings (hospitals where the prevalence of HIV infection was 1% or more), but since then, only three studies have been published assessing the utility of routine HIV testing. A study published in April by researchers at the Boston Medical Center found that without the routine testing recommended by the CDC, they would not have identified half of the individuals they diagnosed with HIV.

Although estimates vary, as many as 312,000 people in the United States are unaware that they're infected with HIV, and evidence suggests that many new infections are caused by those who are unaware of their HIV infection. ➥ *p. 2*

▲ **HIV Testing,** *from page 1*

"The time- and labor-intensive procedures to identify who may be offered an HIV test have failed, resulting in the U.S epidemic," said Amar V. Munsiff, M.D., interim chair for the HIV-AIDS department at North General Hospital in New York City. "The new [CDC] proposal will remove barriers, while allowing for a discussion of risk behaviors tailored to the patient's lifestyle." Munsiff added that with the availability of rapid HIV laboratory tests, the focus should be shifted from pre-test to post-test counseling.

The CDC estimates that approximately 40,000 persons become infected with HIV each year.

Meanwhile, Chembio Diagnostics (Medford, NY) has received FDA approval for its rapid Sure Check HIV and HIV 1/2 Stat-Pak test Pre-Market Applications (PMAs). The approval comes only weeks after Chembio's receipt of an "approvable" letter from the FDA (see *DTTR*, June 2006, p. 3). PMA approval, a process initiated by Chembio in February of 2005, was subject to final review by the FDA.

Sure Check HIV and HIV 1/2 Stat-Pak are rapid tests that detect HIV-1 and HIV-2 antibodies in fingerstick whole blood, venous whole blood, serum, and plasma. The specificity and sensitivity of the tests exceed 99.6%, and results are available within about 15 minutes.

In accordance with FDA export regulations, Chembio has been manufacturing and selling these tests to customers in countries including Brazil, Mexico, and India, since 2001. According to Chembio President and CEO Lawrence Siebert, the company expects the tests to have higher average selling prices in the U.S. than in the developing world due to the required investment and ongoing costs related to U.S. approval, marketing, and distribution. The company also plans to apply for a CLIA waiver to expand the tests' usage settings to include public health clinics, physicians' offices, and other venues in addition to hospitals and laboratories.

FDA-Approved Rapid HIV Antibody Tests For HIV-1 Detection

Rapid HIV Test	*Specimen Type*	*CLIA Waived?*
Chembio Sure Check	whole blood, serum, plasma	no
Chembio Stat-Pak	whole blood, serum, plasma	no
OraQuick Advance	oral fluid, whole blood	yes
	plasma	no
Reveal G-2	serum, plasma	no
Uni-Gold Recombigen	whole blood	yes
	serum and plasma	no
Multispot	serum	no

Source: *DTTR* and Greenwald et al., *Current Infectious Disease Reports* (2006), 8:125-131.

The price for other FDA-approved rapid HIV test kits ranges from about $14 to $25, with costs for multidose external control vials ranging from $20 to $26.25. Average Medicare reimbursement for a CLIA-waived rapid HIV-1 antibody test is $12.41 per test, and it is $19.17 for a CLIA-waived HIV 1/2 test. Internationally, Chembio offers its tests for $1.00 to $2.00 each.

ARUP Looks To Further Automate Molecular Testing

A little over a decade ago, ARUP Laboratories (Salt Lake City, UT) performed 1,000 molecular-based tests in a year. That was in 1995. Today, about 550,000 of the 7,000,000 specimens processed annually by the University of Utah-owned ref-

"I thought molecular genetics was starting to level off, but it really isn't," says ARUP's Edward R. Ashwood, M.D. "There are more tests on the horizon."

erence lab are for molecular-based diagnostic tests. And the growth continues. ARUP is now focusing on expanding its client base, growing volumes for more recently added molecular tests, pioneering niche areas such as sequencing, and gaining efficiency through automation.

ARUP has a menu of more than 2,000 tests and test combinations in the clinical laboratory testing and clinical pathology arena. Four different areas of the lab perform molecular tests, employing 70 FTEs out of a total workforce of 1,800. Their non-molecular laboratories may, on occasion, perform molecular-based tests as well. Molecular testing accounts for approximately 15% of ARUP's total revenues.

Edward R. Ashwood, M.D., senior vice president, director of laboratories and chief medical officer, says all areas are still growing. "I thought molecular genetics was starting to level off, but it really isn't. There are more tests on the horizon. We have seen some of our high-volume molecular tests start to level off a bit. That's not because the demand is down, but because some of our clients are bringing them in-house."

This is a trend that ARUP supports. Ashwood says, "We like our clients to set up tests, if they have the volume to support doing them themselves, we support that." He also notes that ARUP has increased its growth every year by getting new clients, not by acquisition.

Although viral load testing for Hepatitis C and HIV is a particularly large section of ARUP's test volumes, newer infectious disease tests, including enterovirus and tuberculosis, are also performing well, with a lot of classical microbiology being replaced by molecular techniques. Additionally, with many states having started newborn screening projects, ARUP has seen increased demand for confirmatory tests for conditions such as galactosemia.

New tests with more automation are always being brought on board. ARUP is utilizing its third generation of viral load tests, and Ashwood notes that they're still changing. "We fully expect the FDA will approve a new version of the HIV viral load test this coming year, which will probably force labs to get it. It's always improving, and it's always getting better."

He adds that one of the most laborious aspects of molecular testing is extracting nucleic acid. There is automation for this in existence, but it's typically scaled for pharmaceutical companies and not appropriate in size for clinical laboratories. "That's changing," Ashwood says. "There's going to be some mid-range automation that I think clinical labs are going to find very useful."

ARUP Molecular Laboratories

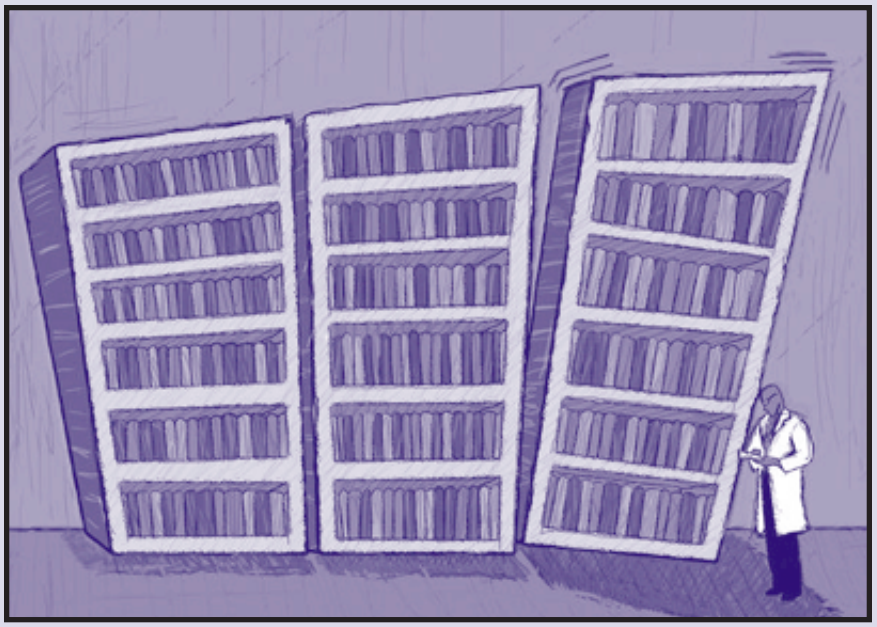
- Molecular Infectious Diseases
- Molecular Genetics
- Molecular Oncology
- Sequencing

One area of molecular diagnostics that is rare, but in which Ashwood believes there may be growth, is sequencing—trying to determine the differences in base pair sequences in whatever relevant gene is being studied. The problem with sequencing is an abundance of information and a lack of clarity about how to interpret it. For instance, ARUP will sequence the entire cystic fibrosis (CF) gene if asked to. Ashwood says, "We find variations and then the big question is: Is that variation significant enough to cause disease? Oftentimes we don't know the answer to that question. The science isn't far enough along to know."

Bringing The Interpretation Of Molecular Tests To The Physician

With approximately 20,000 peer-reviewed journals publishing about two million articles each year worldwide, it is impossible to keep up with the amount of scientific information produced every day. In the area of clinical diagnostics, this can lead to molecular-based tests being offered within months of the original paper being published. Domnita Crisan, M.D., Ph.D., laboratory director of molecular pathology at William Beaumont Hospital (Royal Oak, MI), notes that the original paper on JAK2 testing was published in the summer of 2005, and the test is being brought online this year in her laboratory. "There is a pretty fast transition from research to clinical testing in some areas."

Molecular diagnostics is also opening up whole new worlds of information. Human beings have somewhere between 20,000 to 30,000 genes. A typical gene has about 2,000 changes that can be correlated with different phenotypes out of approximately 4,000 neutral changes. Steve Sommer, M.D., Ph.D., laboratory director for the City of Hope National Medical Center Clinical Molecular Diagnostic Laboratory (Duarte, CA), says, "Do the math. That's about 132 million changes that need to be interpreted. The information content in molecular diagnostics is literally orders of magnitude greater than it is with other types of testing. Within a generation, the information from molecular diagnostics may be greater than all the medical information today. Each gene is its own world."



As a result, in some cases, the information provided by a test can be so comprehensive that it requires more thorough and nuanced interpretation. "We have to really evolve the sophistication of our reports," says Myla Lai-Goldman, M.D., executive vice president and chief scientific officer and medical director of LabCorp (Burlington, NC). "For example, if you look at an HIV genotype report, it's quite a sophisticated report in terms of taking a look at the viral genotype and matching it up in terms of the drugs given. It really provides a profile that's individualized for that patient's regimen. Many molecular tests are going to require an evolving type of information system that we deliver."

Edward R. Ashwood, M.D., senior vice president and director of laboratories for ARUP Laboratories (Salt Lake City, UT), specifically mentions cystic fibro-

"The information content in molecular diagnostics is literally orders of magnitude greater than it is with other types of testing," says Steve Sommer, M.D., Ph.D. "Within a generation, the information from molecular diagnostics may be greater than all the medical information today. Each gene is its own world."

sis (CF) testing. Because CF is a complex disease associated with over 700 potential gene mutations, interpreting test results can be problematic. Typically, laboratories offering the CF assay actually test for about the most common 25 gene mutations. But Ashwood suggests that the laboratory really needs to know more about the patient and what the physician is looking for. "Before you even get to what tests are offered, you really have to start with what question the physician is trying to answer when dealing with a molecular test or a test for CF. Are they trying to confirm a diagnosis in a patient who appears to be affected? Are they trying to provide risk information for couples that want to become pregnant and want to know their risk of having an affected child? Are they dealing with a family that already has an affected child and the mother is now pregnant with another baby and it's a case of prenatal diagnosis? Are they dealing with a male who is infertile and trying to figure out exactly why? There are all these complicated questions, and the laboratory hardly ever knows why the doctor wants the test." This is not unusual and will probably grow worse as molecular-based tests comprise larger and larger proportions of laboratory test menus.

Mary Lowery Nordberg, Ph.D., associate professor and director of molecular pathology at Louisiana State University Health Sciences Center in Shreveport, regularly educates physicians on molecular diagnostics. "We are the people who actively teach the medical school. I'm teaching the medical students this. They rotate through the laboratory. They're seeing how molecular is used clinically. I also send out FAQs and Web mails for my clinicians and do a lot of in-services. We spend a lot of time on physician/patient education."

Nordberg also notes that physicians coming out of medical schools and residencies are very savvy about molecular diagnostics and are looking for it. "But just because we didn't offer it two months ago, doesn't mean we won't soon."

Finally, genetic counselors are a critical tool in the interpretation of molecular diagnostic results. Lai-Goldman notes that LabCorp has always had genetic counselors working in the laboratories to assist physicians in test ordering or in test interpretation. "Our molecular scientists are also involved in much of that as well. We find that early on there's a lot of educational support. As physicians get accustomed to the specific tests and the test results, they become a bit more independent," she says. "We're going to use whatever electronic tools that are available. Many of our tools will be online in addition to having genetic counselors available. It's an important area, and we're going to need to educate physicians." Lai-Goldman also emphasizes the need to develop novel reports and tools that physicians can personalize for individual patients.

Not only will this be necessary, it will be part of the value-added service a laboratory can provide to clinicians. For Sommers, "It's not just about providing a technical result. At the end of the day, those laboratories that are going to do well are those that physicians feel can advise them about the implications of the test for their specific patient. Physicians, no matter how specialized, cannot keep up with the rate of information that's being generated in the larger and larger number of genes that are relevant to their practice."

SACGHS Task Force Wrestles With Challenges Of Pharmacogenomics

"There obviously needs to be some coordination between the drug companies and the test developers. These are two separate groups that are not typically working together today. We need to figure out ways to encourage that coordination."

With the goal of considering and further developing approaches for addressing challenges in pharmacogenomics, the SACGHS Pharmacogenomics Task Force met for the third time as part of the SACGHS general meeting held earlier this year. In the process of defining the broad areas for the focus of its forthcoming recommendations, the task force reviewed the state of federal efforts in pharmacogenomics and how these efforts can be most effective in an area where private enterprise plays a dominant role.

The group divided its survey of federal efforts into eight major issue/need areas defined by SACGHS: research and development, clinical practice, infrastructure, oversight, education, surveillance, coordination, and ELSI (ethical, legal, and social issues).

"As we heard presentations over the last year, it became obvious that there is still a lot of research to be done in this area," task force chairperson Emily Winn-Deen, Ph.D., said at the meeting. In the area of research and development, the specific needs identified included novel research teams, evidence on effectiveness, and pharmaco-economic models. Another priority: "What it might take to get some of the [drugs] that are already on the market into studies that would result in the data that you need to decide if there should be a pharmacogenetic test," Winn-Deen said. "And then there obviously needs to be some coordination between the drug companies and the test developers. These are two separate groups that are not typically working together today."

Barriers to Integration of Pharmacogenomics in Clinical Practice

- ❑ Lack of evidence relevant to clinical practice
- ❑ The cultures in medical specialties
- ❑ Lack of awareness of both providers and the public
- ❑ Lack of coverage and reimbursement

Source: SACGHS Pharmacogenomics Task Force

Another key challenge discussed by the group was how to ensure that research and development efforts in pharmacogenomics are translated into clinical practice. "You could have great science, but if you don't understand how to change clinical practice, then there won't be the end result, which is the desired result, which is to improve health care."

The translational aspect is particularly challenging given the breadth and depth of this ever-evolving area of medicine. "Pharmacogenetics means several different things," said Debra Leonard, M.D., Ph.D., chairperson of the SACGHS Task Force on Patents and Access. "One is it's getting the right drug for the right variant that's associated with disease, like Herceptin and HER-2/neu. The

other is getting the right dose of a drug that will be effective, but you want to get to therapeutic and not to toxic levels."

The task force noted several existing barriers to integrating pharmacogenomics into clinical practice, including the lack of evidence to help clinicians interpret and use pharmacogenomic data. "You can't just say, 'Well this SNP is associated with better response to drug X,'" said Winn-Deen. "You have to provide information that the clinician needs to translate that. Does that mean that you give a different dose to different patients based on their genotype? Does it mean that you don't give that drug or you only give it to a certain subset? You have to provide that guidance to them and teach them how to use it."

Also highlighted was the differing level of receptivity to pharmacogenomics among medical specialties. Oncologists, for example, tend to be more open to learning about and applying pharmacogenomics, while other specialties are usually more set in their ways and less willing to experiment.

Another component is educating those who have the tests and get a handle on the issue of consent. "We need to educate patients so that [pharmacogenomics] is not some strange word that they hear and they get a test, but they don't know really what that means or how the data is going to be used," said Winn-Deen. "Are they going to have to give informed consent for pharmacogenomics testing or is this outside of the realm of the informed consent world?"

Priorities for Federal Oversight of Pharmacogenomic Testing

- ❑ Guidance on the use of pharmacogenomics in the FDA review process
- ❑ Improved coordination between regulators and the industry
- ❑ Guidance needed on labeling changes

Source: SACGHS Pharmacogenomics Task Force

Finally, the group discussed the challenges related to infrastructure and oversight, which are particular concerns given the volume of data that pharmacogenomic tests can generate. In terms of infrastructure, the task force noted the need for electronic health records and data standards. For example, once someone is genotyped for the purpose of formulating drug or dosing decisions, "there's a need to figure out how to make sure that that test information stays with you over your lifetime," said Winn-Deen.

The issue of oversight is perhaps the most complex: Who decides how and when pharmacogenomics should be utilized? The FDA's new guidance document on the necessary steps to getting a pharmacogenetic test approved is a step in the right direction. However, Winn-Deen noted, "What we don't have yet is a guidance document that says under what circumstances will a test be required, under what circumstances will there be a labeling change in a drug. If a test comes on the market, does that go back and affect a drug that's already there?"

NorDx Sees Growth In Molecular Testing For STDs And Looks To Expand

The majority of NorDx's molecular testing utilizes analyte-specific reagents (ASRs) or major brand kits.

NorDx Laboratory, a private, nonprofit laboratory owned by the MaineHealth health system, has been offering molecular-based testing for just over six years. Although reimbursement continues to be a problem for this area in general, NorDx has experienced rapid growth in molecular testing, particularly with its tests for sexually transmitted diseases (STDs). The lab is now planning to expand its diagnostic offerings with molecular tests for infectious diseases and cancer biomarkers.

A full-service laboratory, NorDx processes approximately 23 million samples annually and employs 376 FTEs. Of those 23 million samples, approximately 29,000 are for molecular-based tests. About 20,000 of the molecular tests are for sexually transmitted diseases (STDs), and the rest are for non-STD molecular-based tests. Of the 376 FTEs, approximately 100 are in technical areas—medical technologists and laboratory technicians. Three medical technologists work in the molecular pathology area, and one medical technologist works in the microbiology laboratory on molecular-based tests. They share a supervisor and a Ph.D.-level staff member. Gross revenues for the regional laboratory are approximately $36 million. The gross revenue from molecular-based tests is $995,503.

NorDx's 17 patient service centers throughout southern Maine. Its 30,000 square-foot headquarters is in Scarborough.

Stan Schofield, president of NorDx, notes that half of its business is with four hospitals for capitated services. That is to say, the hospitals pay NorDx approximately $22 million for testing performed, then bill patients and third-party payers independently. "We have a kind of interesting financial model here that can make it tough to do comparison. How big are we? If it's gross dollars that are billed for services—even though I don't bill for them—we're a $110 million organization. If it's straight things I can bill for on outreach, well, that's not a good number. What's my cost structure? About $32 million."

The majority of its molecular testing utilizes analyte-specific reagents (ASRs) or major brand kits. Schofield notes that it does not perform home brews, although there is a small percentage of tests that are ASR-based that have been modified.

NorDx began offering molecular-based testing in 1999/2000 with STD tests. It had one technologist working molecu-

lar at that time. It added cystic fibrosis, FISH, Hepatitis C Virus (HCV), HIV, and HPV in 2001 and 2002. Its largest area of growth is in STDs. Schofield calls growth of existing tests "organic growth" and says it is about 6% annually. Adding new tests skews the average upward.

The NorDx test menu is fairly straightforward, with tests for Factor V (Leiden), Prothrombin gene mutation, hereditary hemochromatosis, ApoE (for cardiac, not Alzheimer's disease), lipoprotein lipase, and cystic fibrosis (CF).

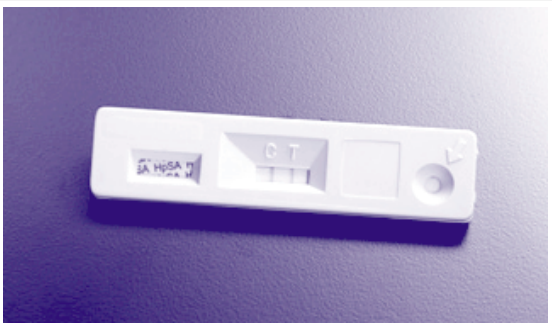
Under its cancer diagnostics areas, it offers HER-2/neu, bladder cancer screening, BCR-ABL, p53, MSI (microsatellite instability), and human papillomavirus (HPV). NorDx is currently planning to bring on cytomegalovirus (CMV), herpes simplex, and BK (virus) for kidney transplant studies by the end of this summer. It is also looking at ZAP-70 for colon cancer, CD56, CD57, and p16.

Schofield believes the biggest problem currently facing molecular diagnostics is poor reimbursement. "I think we're well behind the curve for reimbursement given the complexity of the testing and medical value. It's determined by fiscal intermediaries—there are 58 around the country. Their medical review boards and medical appropriateness and standard of care boards determine reimbursement, but it almost has to be Medicare-approved before anybody else will touch it these days. They tag it investigational research or not-standard-of-care or experimental so they don't have to pay for it. It's hugely disproportionate."

FDA Grants CLIA Waiver Status To Meridian's Ulcer Test

Meridian Bioscience (Cincinnati, OH) has received CLIA waiver status from the FDA for its ImmunoCard STAT! Helicobacter pylori Stool Antigen (HpSA) test. The rapid immunoassay diagnoses Helicobacter pylori infection, which is the cause of most peptic ulcers and is also associated with late-onset stomach cancer and non-ulcer dyspepsia. H. pylori is believed to infect approximately one-third of the United States population, and peptic ulcer disease results in more than $6 billion in healthcare costs annually.

Indicated for diagnosing H. pylori infection as well as for monitoring patient response to therapy, the ImmunoCard STAT! HpSA test uses patented technology similar to that of Meridian's Premier Platinum HpSA test, an ELISA assay that the FDA recently cleared for use in children and adults (see *DTTR*, May 2006, p. 2). Both tests use stool specimens and as immunoassays, have the advantage over blood tests of being able to detect active H. pylori infection.



Meridian Bioscience's ImmunoCard STAT! HpSA test, a rapid, one-step enzyme immunoassay that detects H. pylori antigens in human stool.

Having received CLIA waiver status for the test, the company now plans to "immediately expand its distribution partnerships to increase access into physicians' office and clinic markets," according to Meridian President and Chief Operating Officer John Kraeutler.

Genomic Health Plans Oncotype DX-Style Colon Cancer Assay

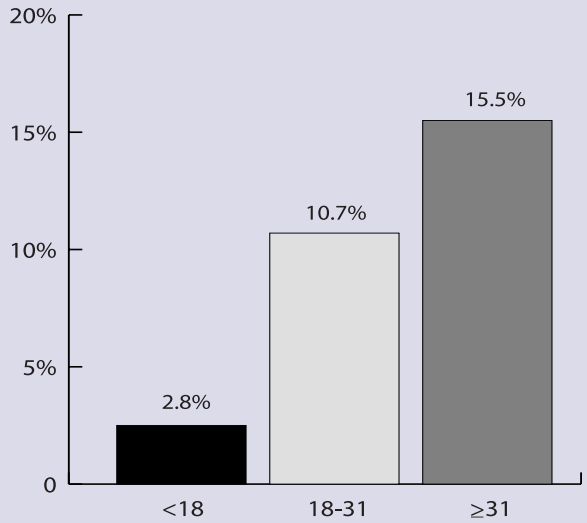
A study presented at the 42nd annual meeting of the American Society of Clinical Oncology (ASCO) in June used the same RT-PCR technology applied in Genomic Health's Oncotype DX test to identify genes associated with the prognosis of patients with stage II and stage III colon cancer treated with surgery. The promising study kicks off what Genomic Health Chief Medical Officer Steven Shak, M.D., calls "a rigorous clinical development path to develop a reliable test service for predicting recurrence and response to chemotherapy in colon cancer."

"Moving forward, we expect to follow a rigorous clinical development path, as we did with Oncotype DX, conducting multiple studies to develop a reliable test service for predicting recurrence and response to chemotherapy in colon cancer," said Genomic Health's Steven Shak, M.D.

Conducted by researchers at the National Surgical Adjuvant Breast and Bowel Project (NSABP; Pittsburgh, PA) and Genomic Health (Redwood City, CA), the study demonstrated that tumor gene expression at the time of diagnosis is clearly associated with the likelihood of subsequent recurrence in colon cancer patients.

Two other presentations at the ASCO meeting reported the results of studies on the clinical utility of Oncotype DX, Genomic Health's 21-gene expression test service designed to predict the likelihood of breast cancer recurrence. The first study evaluated the tumor expression of 192 genes to predict responses to docetaxel, a highly effective chemotherapeutic to which many patients are resistant. Study co-author Jenny Chang, M.D., described its results as a "molecular blueprint for docetaxel-sensitive breast cancers" that could lead to a predictive test that would rule out resistant patients. The other study analyzed the economics of Oncotype DX, using information from more than 1,300 patients to demonstrate the lower toxicities and reduced costs associated with treatment guided by the test.

Risk of Death from Breast Cancer at 10 Years*



*In estrogen-receptor (ER)-positive patients

Source: Habel et al. (2006) *Breast Cancer Research* 8:R25.

The predictive value of Oncotype DX was further bolstered by the publication of a new clinical study in the peer-reviewed journal *Breast Cancer Research*. The population-based study, conducted by Kaiser Permanente, found a statistically significant correlation between the Oncotype DX Recurrence Score and breast cancer survival in nearly 5,000 lymph node-negative breast cancer patients not treated with chemotherapy. They also found that the Recurrence Score was strongly associated with risk of breast cancer death among estrogen receptor (ER)-positive patients not treated with tamoxifen and among ER-negative patients. These associations remained after accounting for tumor size and grade, and the Recurrence Score identified a larger subset of patients with low risk of breast cancer death than either of those standard prognostic indicators.

IVD Stocks Drop 7%; Abaxis And Biosite Slump

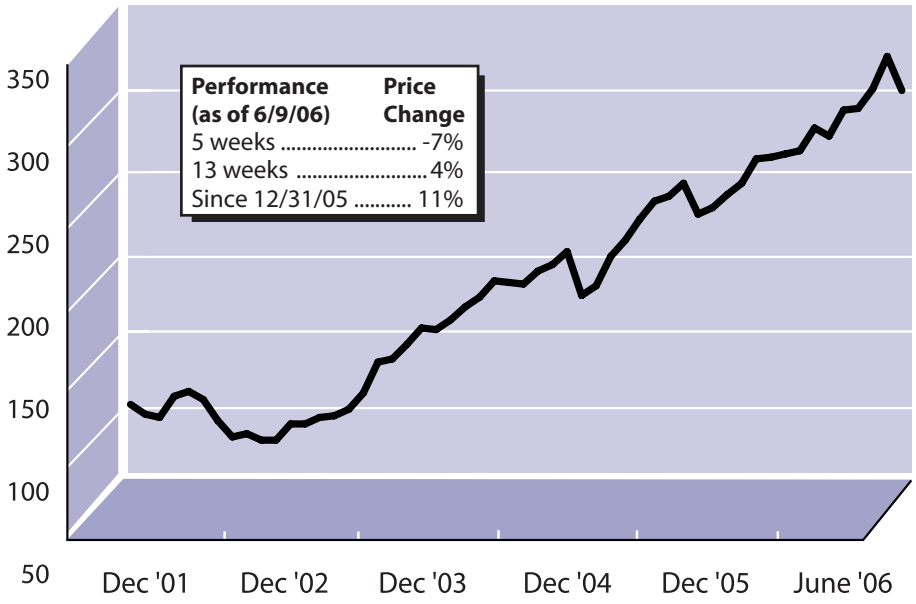
The 22 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 7% in the five weeks ended June 9, with 17 stocks down in price, one unchanged, and four up. Year to date, the G-2 Index is up 11% while the S&P Index is unchanged and the Nasdaq is off 3%.

Abaxis (Union City, CA) fell 27% to $17.71 per share for a market cap of $319 million. The point-of-care blood analysis system manufacturer announced recently that it has discontinued its veterinary products distribution agreement with Henry Schein (Melville, NY), the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets. This distribution channel accounted for about 14% of Abaxis' total business for the most recent fiscal year.

Best known for its Triage brand of rapid diagnostics, **Biosite** (San Diego, CA) was down 24% to $43.65 per share for a market cap of $735 million. Biosite shares fell to their lowest levels since 2004 on the news that the company plans to withdraw its application for premarket approval (PMA) application for the Triage Stroke Panel. The application, which was submitted in January of 2005, was on hold with the FDA. Planning for a new clinical trial and another regulatory application is underway.

The biggest gainer in the five-week period was **Cholestech** (Hayward, CA), which was up 12% to $14.11 per share. The company recently reported quarterly revenue of $17.6 million, up 16% from last year, for the fiscal year ended March 31, while full year revenue was $64.1 million, up 21% from last year. The company attributed the gains to higher average sales prices of its blood test systems and greater manufacturing efficiencies.

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 22 IVD companies.

Avg. % Price Change, 5 weeks ended 6/9/06

	PRICE	% CHG
UP		
Abbott Labs	$43.00	1%
Cholestech	14.11	12
Dade	38.29	2
Johnson & Johnson	61.38	5
UNCHANGED		
Diagnostic Products	57.81	0
DOWN		
Abaxis	17.71	-27
Affymetrix	26.82	-7
Bayer	41.57	-9
Beckman Coulter	54.82	-2
Becton Dickinson	59.52	-5
Bio-Rad	64.93	-8
Biosite	43.65	-24
Cytyc	24.82	-5
Digene	37.73	-12
Gen-Probe	50.51	-11
Immucor	17.77	-11
Inverness Medical	29.90	-2
Meridian	23.39	-11
OraSure	8.43	-10
Quidel	9.92	-12
Third Wave	2.90	-3
Ventana	45.23	-7

G-2 Insider

Applied Biosystems Gets Personal . . . Applera Corporation-owned Applied Biosystems (Foster City, CA) has agreed to acquire Agencourt Personal Genomics (APG; Beverly, MA), a privately held developer of genetic analysis technologies. The cash transaction, valued at about $120 million, is expected to close in the third quarter of this year.

What's in it for Applied Biosystems? APG's novel, high-throughput approach to DNA and RNA analysis. The technology, which uses parallel fluorescence sequencing by stepwise ligation, should complement current Applied Biosystems platforms. Applications for the APG system include medical sequencing, high throughput gene expression, and high throughput genotyping. The technology can also use "paired-end" reads, which are helpful in such genomic applications as whole genome sequencing. Applied Biosystems, which has an installed base of approximately 180,000 instrument systems worldwide, anticipates that it will place initial systems with customers next year.

"After conducting a thorough evaluation of more than 40 companies and academic research groups, we have concluded that APG's technology is both tested and commercializable," said Applied Biosystems President Catherine M. Burzik. "We believe it should be able to address the goal of dramatically reducing the cost of sequencing without sacrificing quality."

APG was incorporated in January of 2005 as an entity of Agencourt Bioscience, a provider of genomic services and nucleic acid purification products that was acquired in May of 2005 by Beckman Coulter. Since then, Beckman Coulter has owned 49% of APG, with 51% owned by other shareholders, including APG management.

Company References

Abaxis 510-675-6500

Applied Biosystems 650-638-5800

ARUP 801-583-2787

Biosite 858-805-4808

Centers for Disease Control 800-311-3435

Chembio 631-924-1135

Cholestech 510-732-7200

Genomic Health 650-556-9300

Meridian Biosciences 513-271-3700

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