Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

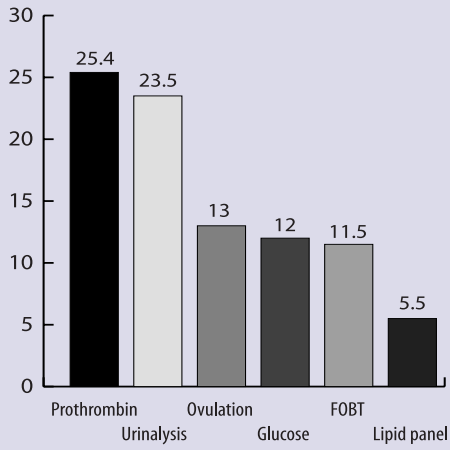
Established 1979

Waived Testing: What Does The Future Hold?

The U.S. market for CLIA-waived testing now represents some $1 billion in annual laboratory testing revenue and is growing at more than 20% per year, according to Charles Root, Ph.D., president of the consulting firm CodeMap (Barrington, IL). "A lot of labs think it's horrible, but you can't ignore waived testing. Technology is pushing it and technology always wins in the long run," says Root. The highest volume waived tests include prothrombin time (25.4 million tests/year) and urinalysis (23.5 million tests/year), according to Medicare Part B claims data.

Root says he's not predicting the demise of the traditional centralized lab, but he does see a growing number of time-sensitive routine tests gaining waived status and moving to the point of care. "Any test that's performed for the emergency department is a good candidate for waived testing," he says. However, he adds that advancing technology is also bringing extremely accurate and expensive new molecular tests to centralized labs.

High-Volume Waived Tests *(millions)*



Source: CodeMap based on 2003 Medicare Part B claims data

The key for traditional labs will be their ability to add new esoteric/molecular tests to their menus. This will help to compensate for the accelerating drain of routine tests moving to the point of care, according to Root. For more, see *Inside the Diagnostics Industry*, pp. 5-9.

Merck CEO Weighing Move Into Diagnostics

Richard Clark, age 59, who became chief executive at Merck & Co. (Whitehouse Station, NJ) six months ago, says the company is considering expansion into medical devices (implantable) and diagnostics. Clark announced this news at a private meeting with Wall Street analysts in New York City on October 28. Amy Rose, a spokeswoman for Merck, tells *DTTR* that Clark has made no decisions on potential new focus areas for the company, but will outline Merck's strategy in greater detail by year's end.

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▲ **Merck CEO Weighing Move Into Diagnostics,** *from page 1*

"Longer term we heard for the first time the potential for how Merck could envision itself as a company with businesses beyond pure pharma, to include devices and diagnostics as well," according to a research note written by Chris Shibutani, M.D., a JP Morgan analyst who attended the meeting. "Concretely, this could mean either acquisition or partnership with implantable devices or diagnostics businesses which align with disease areas (e.g., diabetes diagnostics, plus therapies)," wrote Shibutani.

News of Merck's interest in diversifying comes as the company faces declining earnings and a sagging stock price due to increasing competition from generic drugs and the withdrawal last year of its painkiller Vioxx, which had $2.5 billion in annual sales. The company faces more than 5,000 lawsuits from former Vioxx users and their families, who allege the drug caused heart attacks and strokes.

Despite Merck's recent setbacks, the company certainly has the financial wherewithal to potentially make big acquisitions in the diagnostics area. As of June 30, 2005, the company had a war chest of more than $13 billion in cash and short-term investments and was generating approximately $5 billion per year in free cash flow.

Merck at a Glance *($ millions)*

	First-Half 2005	First-Half 2004	% Chg
Revenue	$10,830	$11,653	-7
Pretax income	3,846	4,782	-20
Net income	2,091	3,387	-38
Free cash flow*	2,454	3,414	-28
Cash & securities	13,031	7,090	84
Long-term debt	5,672	4,692	21

*defined as operating cash flow minus capital expenditures
Source: Merck

Task Force Guidelines Raise The Bar On BRCA Testing

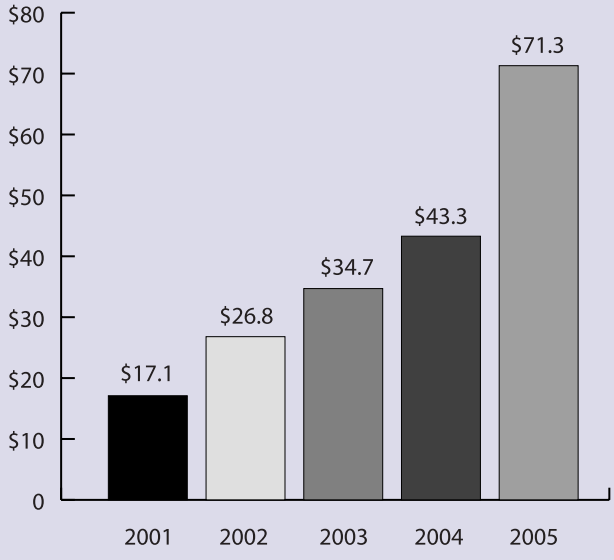
After reviewing all the studies on the BRCA1 and BRCA2 genes, the U.S. Preventive Services Task Force has issued guidelines for genetic testing for breast cancer. The guidelines emphasize the role of genetic counseling and seem to set a higher level of hurdles for determining who should get tested versus those in practice today. The findings were published in the Sept. 6, 2005, issue of the *Annals of Internal Medicine* and represent the first time the Task Force has issued guidelines on any type of genetic testing.

Abnormal BRCA1 and BRCA2 genes account for about 5% to 10% of all breast cancers. An average woman (without an inherited abnormal breast cancer gene) has about a 12% risk of developing breast cancer over her lifetime. Women who have an abnormal BRCA1 or BRCA2 gene have up to an 85% risk of developing breast cancer by age 70.

The Task Force guidelines say that women with an increased-risk family history should first be referred to a genetic counselor who will determine if genetic testing is appropriate. Many women with a family history of breast (and possibly ovarian) cancer can benefit from genetic counseling, but only some of these women will benefit from genetic testing, according to the Task Force.

The U.S. Preventive Services Task Force, sponsored by the Agency for Healthcare Research and Quality (Rockville, MD), is a group of health experts that reviews published research and makes recommendations about preventive healthcare. Its recommendations are considered the gold standard for clinical preventive services.

Myriad's Genetic Testing Revenue *($MM)*



Source: Myriad Genetics

For non-Ashkenazi Jewish women, the Task Force definition of increased-risk family history includes having two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 or younger; a combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; or a combination of both breast and ovarian cancer among first- and second-degree relatives. For women of Ashkenazi Jewish heritage, an increased-risk includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

About 2% of adult women in the general population have an increased risk as defined by the Task Force. And remember, the Task Force has recommended that these increased-risk women first go to a genetic counselor who would then evaluate whether genetic testing was appropriate.

Drawbacks to testing for the BRCA1 and BRCA2 genes, according to the task force, include: 1) Normal test results don't guarantee healthy genes. Some women that test normal may have an inherited form of breast cancer caused by an undiscovered gene; 2) An abnormal test result can trigger anxiety or depression, even though the result doesn't mean that a woman will definitely get cancer; and 3) Genetic testing is expensive—it costs about $300 to $3,000 (depending on the extent of the testing), and insurance companies don't routinely cover the genetic counseling that is done before and after the testing.

In contrast, the marketing material from Myriad Genetics (Salt Lake City, UT), which holds patents on the BRCA1 and BRCA2 genes and performs the related genetic testing strictly at its laboratory in Salt Lake City, suggests that any woman with one family member that has had breast or ovarian cancer is a candidate for genetic testing.

Myriad sells its test for the BRCA1 and BRCA2 genes under the trademark name BRACAnalysis at a price of $2,975 and markets the test through a 115-person sales force. In the fiscal year ended June 30, 2005, Myriad generated $71.3 million of revenue from genetic testing, an increase of 65% over the prior year. The majority of Myriad's genetic testing revenue comes from BRACAnalysis. A spokesman from Myriad did not return calls from *DTTR* seeking comment.

Point-Of-Care Firms Growing Nearly Twice As Fast As IVD Market

Worldwide revenues for 10 point-of-care diagnostic manufacturers grew by 12% to $792.3 million in the six months ended June 30, 2005, according to a tally of financial reports by *DTTR*. That's substantially higher than the 7% rate that the overall IVD industry recorded in the first half of this year (see *DTTR*, October 2005, page 4).

Although **Roche Diagnostics's** point-of-care business grew by only 4% to $421.7 million, six smaller companies grew by more than 20% each. **Hemosense** (San Jose, CA), which makes handheld blood coagulation monitoring systems for the management of warfarin medication, increased its revenue by 162% to $4.3 million in the six months ended June 30.

Matritech (Newton, MA), which makes a CLIA-waived rapid test for bladder cancer, grew by 55% to $4.8 million; **OraSure**, which makes rapid HIV and drugs-of-abuse tests, grew 44% to $23.4 million; **Cholestech** (Hayward, CA) grew 41% to $30.3 million; **Meridian Bioscience** grew 25% to $49.1 million; and **Biosite** grew 24% to $145.6 million.

Assuming that the 10 companies listed below represent 50% of the point-of-care testing market, *DTTR* estimates that annual worldwide revenue for this market is approximately $3.2 billion ($792.3 million multiplied by two and divided by 0.50 = $3.2 billion). Point-of-care test sales now represent 11% of the worldwide $28.2 billion IVD market.

DTTR estimates that the U.S. point-of-care-testing market is approximately $1.5 billion, including $1 billion from CLIA-waived testing and $0.5 billion from non-waived testing.

Worldwide Point-of-Care Revenue ($000)*

Company	Six Months ended 6/30/05	Six Months ended 6/30/04	% Chg
Roche Diagnostics (1)	$421,655	$405,438	4.0%
Biosite	145,610	117,539	23.9
Inverness Medical (2)	72,028	63,187	14.0
Meridian Bioscience	49,107	39,196	25.3
Quidel (3)	37,489	33,150	13.1
Cholestech	30,279	21,495	40.9
OraSure	23,399	16,292	43.6
Matritech	4,818	3,116	54.6
Hemosense	4,254	1,622	162.3%
Abaxis (4)	3,667	4,054	-9.5
10 cos., total	792,306	705,089	12.4
Estimated worldwide market	1,584,612	1,410,177	12.4

*Excludes self-monitoring blood glucose testing

1) for Roche's point-of-care business only; 2) for professional rapid diagnostics only, excludes Inverness's over-the-counter business; 3) excludes OraSure's cryosurgical business; 4) excludes Abaxis's veterinary diagnostics business

Waived Test Market Trends: What Does The Future Hold?

At G-2's recent Lab Institute conference in Washington, DC, Charles Root, Ph.D., gave a presentation focusing on the future of CLIA-waived testing. Below we highlight some of the key points Root made in his presentation and in a follow-up interview with *DTTR*.

Root noted that gaining waived testing status can make or break the success in the market for a point-of-care test. A test that is granted waived status by the FDA must be so simple and accurate as to render the likelihood of erroneous results negligible. There are no personnel qualifications for individuals who perform waived tests. Approximately 80% of all physician office labs are CLIA waived and therefore not eligible to perform more complex testing.

The factors that lead to physician office adoption of a waived test include clinical need for rapid results, patient convenience as far as not having to drive to a draw station, and the opportunity for physicians to make a profit, according to Root.

Waived Tests as % of Total Tests Performed

Test	CLIA Waiver	Total Part B 2003 Claims	Waived Penetration
Strep A antigen	March 5, 1996	0.5M	46%
Prothrombin time	Sept. 22, 1997	25.4M	37%
Influenza antigen	Oct. 4, 2000	NA	31%
Microalbumin	Nov. 9, 1995	0.5M	31%
Glucose (quantitative)*	April 27, 1995	4.6M	21%

NA=not available *excludes home use devices
Source: CodeMap based on 2003 Medicare Part B claims data

Waived tests that have reached the highest market penetration include strep A antigen, which now accounts for nearly half of all the 500,000 strep A tests performed for Medicare Part B recipients. However, it should be noted that the first waived throat-swab strep A test (made by Quidel Corp.) was cleared by the FDA in 1996, so penetration has not occurred overnight.

The first CLIA-waived prothrombin time test (ITC's ProTime device) hit the market in 1997, and it has taken eight years to reach 37% penetration for Medicare Part B. Other waived analytes that have achieved significant penetration over time include influenza, 31% of total Part B claims; microalbumin, 31% of 500,000 claims; and glucose, 21% of 4.6 million claims, according to an analysis by CodeMap.

Important New Waived Tests

Analyte	Manufacturer	Total U.S. Test Volume	Typical Reimbursement	Estimated U.S. Market
BNP	Biosite	15M	$40-60	$750M
Lithium	Akers Laboratories	12M	$10-20	$180M
TSH	ThyroTec	40M	$20-40	$1,200M
HIV 1/2	OraSure	17M	$15-25	340M

Source: *DTTR*

Important new analytes that have recently been granted waived status include b-type natriuretic peptide (BNP), blood lithium levels, thyroid stimulating hormone (TSH), and HIV 1/2. Each of these waived tests has the potential to reach penetration levels of 20% to 50%, although the transition from traditional lab to waived testing is a long-term process.

Four Test That Could Make A Big Splash In Waived Testing

BNP, lithium, TSH, ad HIV are among the tests expected to migrate to the point of care. However, the transition is likely to occur slowly over the next 5-10 years.

BNP (b-type natriuretic peptide) Testing: In August 2005, Biosite (San Diego, CA) received a CLIA waiver for its Triage BNP Test. BNP testing is used in the diagnosis and assessment of patients with symptoms of heart failure. Over the past three years, BNP testing has been the fastest-growing test in the lab industry. The overall BNP testing market in the United States is estimated at 15 million tests and is growing at more than 20% per year.

Biosite's Triage BNP Test is a handheld analyzer that provides results in about 15 minutes from a few drops of blood placed on a disposable cartridge. Biosite sells each cartridge for roughly $20; Medicare reimburses the test under CPT 83880 at $47.43. In the six months ended June 30, 2005, Biosite generated $98.8 million of revenue from the non-waived version of its Triage BNP Test, up 24% from $79.6 million in the same period a year earlier.

Currently there are no other diagnostic manufacturers with a waived BNP test, although Abbott is developing a point-of-care BNP test that will be run on its handheld i-Stat analyzers. (Abbott acquired i-Stat in January 2004.) The Abbott/i-Stat analyzer is likely to have a big impact when it gets a CLIA waiver (estimated 12 to 24 months time frame) for BNP testing. There are more than 10,000 Abbott/i-Stat handheld analyzers in use at hospitals and clinics in the United States today.

Lithium: In April 2005, the InstaRead Lithium Test made by Akers Biosciences (Thorofare, NJ) received waived status from the FDA. InstaRead is the first CLIA-waived system that allows psychiatrists to monitor the blood lithium levels of patients that have been prescribed lithium. The system uses finger-stick blood samples and provides results in two minutes.

Patients are treated with lithium for a variety of manic depressive disorders, including bipolar disorder, a lethal disease that can cause suicide if not properly treated. Testing is vital for the management of therapeutic effectiveness, as well as for the prevention of complications resulting from toxic levels of the drug that may decrease coordination or induce seizures or a coma. New patients generally have their blood tested every two weeks for lithium levels until the patient is stabilized; blood lithium levels are then monitored once per month.

The National Institute of Mental Health estimates that bipolar disorder affects more than two million American adults. Akers Laboratories estimates that 12 million lithium tests are performed each year in the United States at traditional laboratories that typically take two or more days to provide test results. The InstaRead test will allow psychiatrists and other mental health providers to get rapid information on a patient's blood lithium levels and adjust drug dosages accordingly in one office visit.

The test is distributed by ReliaLab (Basking Ridge, NJ), which charges $399 for the handheld, battery-operated analyzer and approximately $11 per test. Average reimbursement for lithium testing ranges from $10 to $20 per test; Medicare Part B covers the test under CPT 80178 at a national limit of $9.24 per test.

Thyroid Stimulating Hormone (TSH): In August 2004, the Thyrotest device, made by ThyroTec (Honey Brook, PA) became the first TSH test to receive waived

status from the FDA. Thyrotest provides a qualitative result (i.e., "yes" or "no" answer) for above normal levels of TSH.

TSH tests are used to screen for hypothyroidism (under-active thyroid). Insufficient thyroid hormone causes bodily functions to slow down. Symptoms include fatigue, mood swings, and depression. If untreated, hypothyroidism can eventually cause anemia, a low body temperature, and heart failure. Hypothyroidism is treated by replacing the deficient thyroid hormone with synthetic thyroid hormone through a drug prescription.

Thyroid diseases affect nearly 15 million people in the United States and more than half of those are undiagnosed, according the Thyroid Association of America. An estimated 40 million TSH tests are performed each year in the United States.

Thyrotest is a disposable credit-card sized test. It provides results in 10 minutes from a fingerstick sample of two drops of whole blood. The test is highly accurate (95.5% accuracy) and allows physicians to make immediate patient treatment decisions instead of waiting five to 10 days for results from a traditional lab.

ThyroTec markets the test to general practice, family practice, OB/GYN, and internal medicine physicians through a distribution agreement with Wampole Laboratories (Princeton, NJ). Thyrotest is sold to physician offices in packages of 20 tests each for a list price of $299, or $14.95 per test. Average reimbursement for TSH testing ranges from $20 to $40; Medicare Part B reimbursement is set at a national limit of $23.47 per test.

HIV Testing: In January 2003, the OraQuick device, made by OraSure Technologies (Bethlehem, PA) became the first HIV-1 antibody test for use on oral fluid, fingerstick, or venipuncture samples to receive waived status from the FDA. And in mid-2004, OraSure received waived status for a combined HIV 1/2 test.

The CDC estimates that there are approximately 1.2 million people in the United States with HIV, and some 25% to 30% of these people don't know they have it. This is partly because a large portion of the HIV population is transient, and after getting their blood drawn for testing at a traditional lab, they often don't return to their doctor's office or public health clinic to get the test result. Rapid tests like OraQuick eliminate this problem. Approximately 17 million HIV tests are performed by labs on an annual basis in the United States.

OraQuick is a toothbrush-sized disposable test that provides results in 20 minutes from a swabbed specimen of saliva, or fingerstick or venipuncture blood drop. The test allows physicians to make immediate patient treatment decisions instead of waiting three days or more for results from a traditional lab.

OraSure markets its HIV tests to physician offices and public health clinics through a direct sales force. In addition, Abbott Diagnostics has an exclusive agreement to market OraQuick to hospitals and a nonexclusive agreement to market to physician offices. Other vendors with waived HIV-1 blood tests include MedMira and Trinity Biotech.

OraQuick 1/2 is sold to physician offices at an average price of roughly $11 per test. Average reimbursement for HIV 1/2 testing ranges from $15 to $25; Medicare Part B reimbursement is set at a national limit of $19.17 per test.

A Quick History Of Waived Testing

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, establishing quality standards for all laboratories to ensure the accuracy and reliability of test results regardless of where the test was performed. Originally there were eight types of tests that were waived from CLIA; today there are approximately 50.

The greatest level of activity has taken place over the past seven years. Between 1998 and August 2005, there were 34 new analytes that received waived status.

Among the important new analytes or panels that Root believes could get waived status within the next few years are the complete blood count (CBC), basic metabolic panel, and cyclosporine, a frequent test for organ-transplant patients.

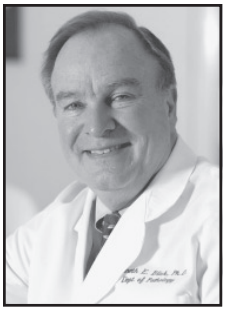
New Analytes Granted CLIA-Waived Status, 1998 Through 2005

Analyte	*Manufacturer*	*Date Waived*
B-type natriuretic peptide (BNP)	Biosite	August 26, 2005
Lithium	Akers Laboratories	April 22, 2005
Aspirin test (platelet aggregation)	Accumetrics	March 22, 2005
Trichomonas	Genzyme	March 16, 2005
Hemoglobin A1c	Bristol-Myers	Aug. 26, 2004
Thyroid stimulating hormone (TSH)	ThyroTec	August 18, 2004
Aspartate aminotransferace (AST)	Cholestech	June 18, 2004
HIV 1/2 antibodies	OraSure	June 25, 2004
Hemoglobin	EKF Diagnostic GMBH	Nov. 3, 2003
Respiratory syncytial virus (RSV)	Binax Inc.	Aug. 21, 2003
HIV-1 antibody	OraSure	Jan. 31, 2003
Albumin, urinary	Diagnostic Chemicals	Aug. 29, 2002
Morphine	Advantage Diagnostics	Feb. 19, 2002
Fern test	TCI	Dec. 5, 2001
Gastric PH	Beckman Coulter	Aug. 30, 2001
Semen (male infertility)	Embryotech Laboratories	Aug. 15, 2001
Collagen	Ostex International	July 30, 2001
Lactic acid (lactate)	KDK Corp.	July 27, 2001
Lyme disease	Wampole	June 19, 2001
Keytone, urine	Teco Diagnostics	April 30, 2001
Alanine Aminotransferase (ALT)	Cholestech	April 13, 2001
Follicle Stimulating Hormone (FSH)	Genua 1944 Inc.	Jan. 12, 2001
Luteinizing hormone (LH)	Inverness	Oct. 23, 2000
Influenza A/B	Quidel	Oct. 4, 2000
Estrone-3, glucuronide	Unipath	July 17, 2000
Six drugs of abuse*	Phamatech	April 19, 2000
Keytone, blood	Abbott Medisense	Feb. 25, 2000
Bladder cancer antigen	Bion Diagnostic Sciences	Feb. 4, 1999
Catalase, urine	Diatech Diagnostics	Feb. 4, 1999
Creatinine	Bayer	Oct. 27, 1998
HCG, urine	Bayer	Sept. 30, 1998
Amines	Litmus Concepts	March 25, 1998
Vaginal PH	Litmus Concepts	March 25, 1998
Ethanol (alcohol)	STC Technologies	Feb. 23, 1998

*included amphetamines, marijuana, cocaine, methamphetamines, opiates, and phencyclidine (PCP)

Source: *DTTR* from FDA files

Going All The Way With Lab Automation



Ken Blick, Ph.D.

On October 26, Washington G-2 Reports sponsored a national audio conference titled *Going All the Way with Lab Automation.* The conference featured insights from Kenneth Blick, Ph.D., professor and director of chemistry and immunoassay/endocrine laboratories at Oklahoma University Medical Center (OUMC), which went live with a total lab automation track system for chemistry at its core laboratory in March 2004. The core lab, which has 60 FTEs that perform 3.5 million reportable tests per year, is connected to three other nearby university hospitals through a pneumatic tube system. About two million tests are chemistry, and about 80% of these are being done on the automated track system.

Here are some of the highlights from the audio conference:

G-2 Reports: *How did you determine that OUMC was a candidate for lab automation?*
Blick: The average age of the core lab's medical technologists was 52, and growing test volumes had increased stress and turnover. We were also getting too many phone calls from doctors waiting for results and seeing greater competition from other hospitals. We had to plan for a lab of the future that would have to do more with less staff.

G-2 Reports: *Why TLA instead of front-end automation?*
Blick: Front-end automation is like putting lipstick on a pig. It's an incremental change that would have caused us to fail in four or five years. And we wanted to get rid of batch processing.

G-2 Reports: *How did you get the budget dollars from your hospital administration?*
Blick: You need to detail the projected financial savings and show a return on investment with a focus on equipment and reagent savings and not on FTE reductions. But there are other benefits that are harder to quantify. You should give your administrators a tour of the emergency department and show them the patients waiting for care, then show them the specimens that are waiting in racks at the laboratory. They've got to understand that late critical lab test results for things like potassium and troponin can cause delays in the emergency department.

G-2 Reports: *How did you select and contract with your automation vendor?*
Blick: We chose Beckman Coulter because their chemistry analyzers are fast and their automation system is open. We've got three LX 20's and a Bayer Centaur immunoassay analyzer connected to the track system. We pay by reportable test result.

G-2 Reports: *What are some pitfalls in installation to look out for?*
Blick: Interfacing our LIS to the automation system was the number one issue. Getting all the automation system rules and auto verification processes into the LIS was a slow and laborious process. Standardization of test tubes was another challenge; we went with lithium-heparin tubes. Nurses do nearly all of our phlebotomy at the patient's bedside and getting them to put the barcode labels on the tubes correctly was also a challenge. And don't expect things to go perfectly on day one. It will take three to four months to get comfortable with automation.

G-2 Reports: *What are some of the benefits OUMC has gotten from automation?*
Blick: We've eliminated the lab as a limiting factor for wait times in the emergency department. In terms of FTEs, we've increased our test volume by 10% in the past 18 months and not added any staff. In fact, we're now expanding our outreach business (currently 15% to 20% of core lab volume) with our freed-up FTEs. Without automation our lab would need an extra 18 FTEs.

The enhanced productivity has also allowed us to bring 20 tests in-house. Most of our new tests are endocrine: HGH, insulin for children, pediatric cortisols, etc. We also added several tumor marker assays including CA-125, and we've added high-sensitivity CRP and allergy testing. We recently added immunofixation testing as well.

The Core Lab at OUMC in Brief

Total annual reportable test volume:	3.5 million
Automated test volume:	1.6 million
Total FTEs:	60
Automation FTEs (analytical only):	3
Annual test volume per FTE:	58,333
Annual automated test volume per FTE:	533,333

Source: OUMC

Automation has also allowed us to shut down two hospital stat labs, which are now served by the core lab through a pneumatic tube system that can carry test tubes from the patient's bedside to the core lab in about two and a half minutes. In addition, our nurses are doing more point-of-care testing at the patient's bedside using i-Stat handheld analyzers. We currently have 46 i-Stats doing blood gases, electrolytes, ionized calcium, hematocrit, coagulation (PT, INR, ACT), glucose, BUN, and creatinine. We will probably bring that number to 60 soon. We also do point-of-care cardiac testing using Biosite. All point-of-care testing is coordinated by our lab staff.

There have been intangible benefits too. We have happier employees with less stress, less turnover, and better recruiting. And our phone now rarely rings from physicians wondering when they'll get test results.

Bayer Withdraws From Bidding For Boots

Bayer Group (Leverkusen, Germany) will not be buying the over-the-counter medicines business of Boots Group Plc. (Nottingham, England). In a press statement, Bayer said it withdrew from the bidding process because it was not willing to meet the prices offered by other bidders. The winning bid went to Reckitt Benckiser PLC, the Anglo-Dutch household products group, for a much better-than-expected 1.9 billion British pound sterling (US $3.4 billion). Bayer's initial interest in buying Boots's OTC business had set off speculation that the company might sell its diagnostics business to help pay for it (see *DTTR*, November 2005, pp. 1-2).

On a conference call with investors on November 9, Bayer's chief executive Werner Wenning said the company would continue to look at potential opportunities to strengthen its OTC medicines business. Bayer executives have not made any public comments regarding the future of the company's diagnostics business. However, *DTTR* hears that in a recent memo to employees, Wenning said that recent rumors that the diagnostics unit was being considered for sale were unfounded.

IVD Stocks Up 1%; Abaxis, Quidel Jump 25+%

Point-of-care testing stocks have been the best performing group within the IVD industry over the past few months.

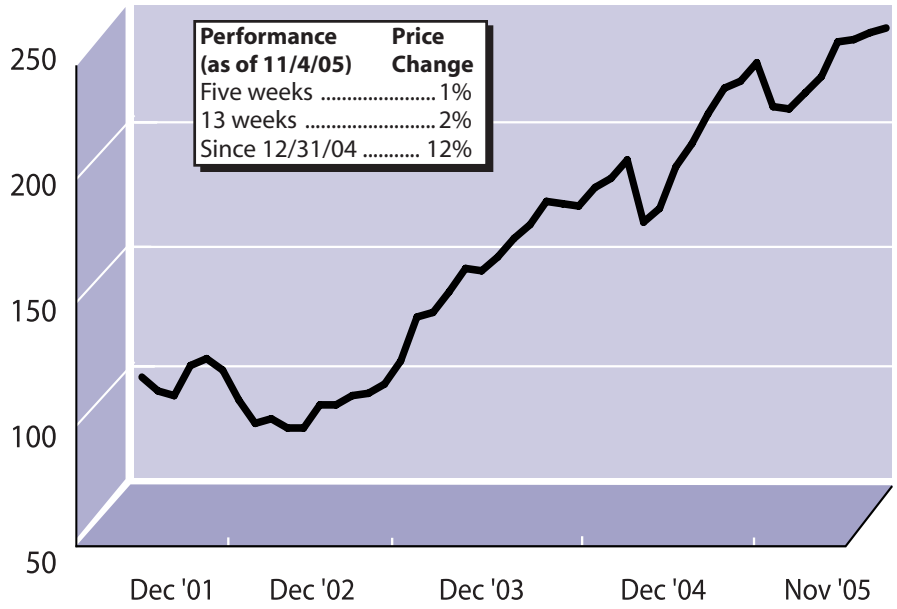
The 21 stocks in the G-2 Diagnostic Stock Index rose by 1% in the five weeks ended November 4, with 11 stocks up in price, one unchanged, and nine down. Year to date, the G-2 Index is up 12%, while the S&P 500 Index is up 1% and the Nasdaq is unchanged.

Abaxis Corp. (Union City, CA) was up 29% to $16.77 per share for a market cap of $334 million. In the quarter ended September 30, 2005, the company posted net income of $2.3 million, or 11 cents per share, up from $1.3 million, or 6 cents per share, in the prior-year period. Revenue rose to $17.4 million, up 28% from $13.6 million a year ago. Revenue from the company's Piccolo point-of-care system and reagents were up 69%; instruments sales totaled 139 units, up 132% year-over-year; reagent disc sales grew to 871,000 unites versus 706,000.

Quidel Corp. (San Diego, CA) was up 26% to $11.91 per share for a market cap of $391 million. The company, which makes rapid tests for influenza A and B, has benefited from growing concern over the avian flu virus. While its tests are not specifically designed to identify bird flu, some researchers have reported success in using Quidel's QuickVue test to detect the H5 strain of virus.

Third Wave Technologies (Madison, WI) fell 44% to $2.78 per share for a market capitalization of $114 million. The company reported disappointing results for the third quarter. Total revenue fell to $5.2 million from $10.5 million in the third quarter last year; net loss was $7.4 million, or ($0.18) per share, compared with net income of $24,000, or $0.00 per share.

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 21 IVD companies.

% Price Change, Five weeks ended 11/4/05

	Price	% Chg
UP		
Abaxis	16.77	29
Affymetrix	47.55	3
Beckman Coulter	54.61	1
Becton Dickinson	57.50	10
Bio Rad	59.98	9
Dade Behring	37.54	2
Digene	30.12	6
Meridian	21.57	4
OraSure	11.05	17
Quidel	11.91	26
Ventana	39.64	4
UNCHANGED		
Abbott Labs	42.57	0
DOWN		
Biosite	57.85	-6
Cytyc	26.14	-3
Cholestech	8.58	-15
Diagnostic Products	41.70	-21
Gen-Probe	44.01	-11
Inverness Medical	24.22	-9
Immucor	26.85	-2
Johnson & Johnson	60.88	-4
Third Wave	2.78	-44

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The Avian flu scare could just wind up being another Y2K nonevent, says Paul Offit, M.D., chief of the division of infectious diseases at the Children's Hospital of Philadelphia. Offitt tells *DTTR* that the H5 avian influenza has been around for 100 years or more and if it were going to mutate into a form that was contagious between humans, it would have done so by now. "It's a bird flu, and the species-to-species barrier is significant.

To date (as of November 6), the H5 avian influenza has killed 62 people in Indonesia, Thailand, Cambodia, and Vietnam (nearly all of whom worked in the poultry industry). It passes clumsily from birds to humans, but the virus can't yet pass from person to person. And it hasn't reached the United States.

However, although Offit sees little chance of a pandemic caused by the H5 virus, he says "there almost certainly will be a disastrous pandemic of some sort in the next 20 years. History guarantees one. And if we continue on our present course, the U.S. will not be prepared to handle it."

Offit says the problem is simple: The United States does not have the manufacturing capacity to produce 280 million doses of vaccine that would be needed to stave off an infectious disease pandemic. He notes that there are zero manufacturers of influenza vaccines in the United States. "We get our flu vaccines from three companies [Chiron, GlaxoSmithKline, and Sanofi-Aventis]. Even if we wanted to 'nationalize' an emergency vaccine program, it would be difficult. How can you nationalize an industry that isn't based in your country?" he asks.

He believes it's fear of litigation that is discouraging U.S. pharmaceutical companies from producing vaccines. "When the next pandemic happens, it will spread quickly. They've never been contained in the past. They only go away after a critical part of the population has either died or become immune," he warns.

Company References

Abaxis 510-675-6500

Akers Biosciences 856-848-8698

Biosite 858-455-4808

Children's Hospital of Philadelphia 215-997-5730

CodeMap 847-381-5465

Myriad Genetics 801-584-3600

OraSure 610-882-1820

ThyroTec 610-942-8971

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