Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

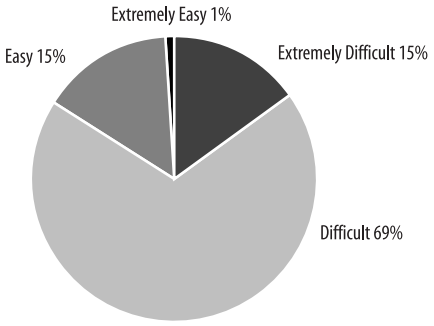
Labor Shortage Continues To Push Labs Toward Automation

A whopping 84% of labs say that finding and hiring medical technologists is either difficult (69%) or extremely difficult (15%), according to a survey conducted in early September by Washington G-2 Reports. Fifteen percent said finding MTs was easy, and only 1% said it was extremely easy.

The survey, which was completed by 188 labs, helps explain why the adoption of lab automation continues to accelerate. Since our last survey of vendors 15 months ago (see *DTTR*, June 2004, pp. 1, 5-8), 190 hospitals and independent labs in the United States have installed some form of automation, ranging from front-end only to total lab automation (TLA), raising the total number to more than 500 labs.

Meanwhile, our surveys and interviews with lab directors and managers indicate that there has been a revival of interest in total lab automation track systems. After initial stumbles, glitches, and outright failures (e.g., Lab-Interlink), TLA placements are on the rise. For more details, see *Inside the Diagnostics Industry*, pp. 5-10.

How difficult is it for your lab to find and hire medical technologists?



N=188 (130 hospital labs; 37 independent labs; 14 other labs; 5 POLs; 2 pathology groups)
Source: Washington G-2 Lab Automation Survey, September 2005

FDA Clears Third Wave Pharmacogenomics Test; Will The Test Be Available To All Labs?

Third Wave Technologies (Madison, WI) has received FDA clearance for its pharmacogenomic test, Invader UGT1A1 test. The test has been shown to help predict which patients will respond to Pfizer's colon cancer drug Camptosar, which is known generically as irinotecan, and future data could link it to other drugs. But the big question on the minds of a number of independent esoteric testing labs is whether or not they'll get access to the test. *DTTR* hears that Third Wave is contemplating a licensing deal with at least one of the two major commercial labs (Quest Diagnostics and LabCorp) that would give them exclusive access to the test.

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▲ **Will Third Wave Share Its Test?** *from page 1*

The Invader UGT1A1 test is cleared for use to identify patients who may be at increased risk of adverse reaction to Camptosar detecting and identifying variations in the UGT1A1 gene, which makes an enzyme that helps metabolize drugs. The differences in the gene affect how much medicine enters the blood stream. Higher levels of the drug in the blood can lead to more side effects. Camptosar has been relabeled to include dosing recommendations based on a patient's genetic profile.

As part of its clearance application to the FDA, Third Wave submitted an outside study of 66 colon cancer patients taking Camptosar that found those with a certain variation in the UGT1A1 gene had a higher risk of toxicity. The study found the Third Wave test to be 100% accurate compared to DNA sequencing, the standard for genotype determination.

In a news release, the FDA said the approval of the Third Wave test could provide colorectal cancer patients with significant medical benefit. Approximately 150,000 new cases of colorectal cancer are diagnosed each year in the United States. The question is will Third Wave allow every molecular diagnostics lab to offer the test, or just the top one or two? A Third Wave spokesman would only tell *DTTR* that the company was considering several different distribution options, but had not made a decision yet.

Correlogic Awarded Patent; Gets Equity Investment From Quest

Correlogic Systems (Bethesda, MD) has been awarded a patent for its invention, *A Process for Distinguishing between Biological States Based on Hidden Patterns from Biological Data* ("hidden patterns"), by the US Patent and Trademark Office. The patent is based on the concept that subtle patterns of changes occurring in the body, including those reflected in serum, urine, and secretions such as saliva and perspiration, can be used to identify disease and other biological conditions. The patent is co-owned by Correlogic and the Public Health Service, which has licensed its commercialization rights exclusively to Correlogic.

The first application of Correlogic's hidden patterns technology has been for the early detection of ovarian cancer. This test, which has been dubbed OvaCheck, looks for subtle changes in patterns among the tens of thousands of proteins, protein fragments, and metabolites in the blood. A computer software program is then used to identify these hidden patterns. Correlogic is in the process of trying to convince the FDA that OvaCheck can be marketed as a "homebrew," or laboratory developed test. Correlogic is also using its hidden pattern technology to develop tests for prostate, breast, and pancreatic cancers and to distinguish recurrence/remission of Wegener's disease.

Quest Diagnostics and LabCorp are the only labs licensed to market OvaCheck. In addition, Quest recently purchased an ownership stake in Correlogic. The exact terms of the investment have not been disclosed.

LipoScience Lands Deal With LabCorp For Heart Disease Test

LipoScience (Raleigh, NC) has signed an agreement to have LabCorp (Burlington, NC) market its NMR LipoProfile test, a proprietary "homebrew" test that uses NMR (nuclear magnetic resonance) spectroscopy to measure the number of dangerous LDL particles that build up in the arteries and cause heart disease.

Under the nonexclusive contract, LabCorp will market LipoProfile and testing will be performed at LipoScience's CLIA-certified lab in Raleigh, North Carolina. LipoScience currently markets LipoProfile through agreements with a number of small regional labs across the country. LipoScience sells the test at a list price of $91 and Medicare reimburses the test under CPT codes 82465 and 83716 for a total of $40.76.

Earlier this year, LipoScience signed an agreement with Varian Inc. (Palo Alto, CA), which makes scientific instruments, to codevelop an FDA-cleared NMR system for use in clinical laboratories. The lead application will be the LipoProfile test.

Richard Brajer, president of LipoScience, says the agreement with Varian represents a new strategic direction for LipoScience under which its clinical laboratory will act more as an incubator for new test development.

The company's clinical business has been under pressure from competing labs that also market specialized tests that go beyond measuring standard LDL-cholesterol levels. For example, Atherotech (Birmingham, AL) markets a proprietary test called the Vertical Auto Profile (VAP) through a distribution agreement with Quest Diagnostics (Lyndhurst, NJ). And Quantimetrix (Redondo Beach, CA—see *DTTR*, September, pp. 5-6) sells an FDA-cleared LDL subfraction test system called Lipoprint.

Brajer says LipoProfile measures the number of LDL particles in the blood, whereas competing tests measure particle size. He points to recent published studies (e.g., *Current Atherosclerosis Reports.* 2004; 6:381–387 and *Circulation*. 2005; 111:3465-3472) that have shown that LDL particle number may be a more important parameter than LDL size in assessing coronary artery disease and events.

Biosite Gets CLIA Waiver For BNP Test

After more than two years since filing its initial request with the FDA, Biosite (San Diego, CA) has finally received a CLIA waiver for its Triage BNP Test. This new status opens the door for use at some 80,000 physician office laboratories that are licensed to perform only CLIA-waived tests. 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 hand-held 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 its Triage BNP Test, up 24% from $79.6 million in the same period a year earlier.

Most of the major IVD manufacturers have nonwaived BNP tests on the market for use in centralized labs, including Roche, Bayer, Beckman (through partnership with Biosite), Abbott, and Dade. Abbott is also developing a point-of-care BNP test that will be run on its hand-held i-Stat analyzers. (Abbott acquired i-Stat in January 2004.)

Worldwide IVD Sales Up 7% In First-Half 2005

Worldwide IVD sales grew by 7.2% (excluding the effect of currency changes and acquisitions) to $14.2 billion in the six months ended June 30, 2005, according to an exclusive analysis by *DTTR* of the financial reports from the 15 largest reagent manufacturers. Our estimate assumes that the 15 largest companies held an 85% share of the market with the remaining 15% held by hundreds of smaller companies.

The 7.2% growth rate for 2004 marks a significant acceleration from the average 5% growth recorded in 2003 and 6% in 2004. The fastest-growing large IVD company was **Biosite** (San Diego, CA), which recorded a 23% increase in revenue to $145.6 million for the first half of 2005. Next was **Johnson & Johnson** (New Brunswick, NJ), including Ortho-Clinical Diagnostics and Lifescan, which grew 16% to $1.7 billion. **Becton Dickinson** (Franklin Lakes, NJ) also posted a double-digit sales gain for its diagnostic business, up 10% to $638 million.

The slowest-growing IVD companies were **Gen-Probe** (San Diego, CA), up 2.5% to $142 million, and **Beckman Coulter** (Fullerton, CA), up 3% to $857 million.

Top 15 IVD Manufacturers' Worldwide Revenue *($ millions)*

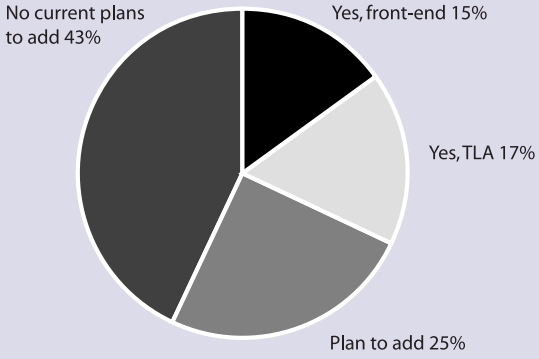
Company	Revenue Six Months ended 6/30/05	Revenue Six Months ended 6/30/04	Reported % Chg	Adjusted % Chg*	Market Share
Roche Diagnostics[1]	$2,905	$2,832	2.6%	5.0%	20%
Abbott Diagnostics[2]	1,844	1,607	14.7	7.0	13
Johnson & Johnson	1,696	1,439	17.9	16.0	12
Bayer Diagnostics	1,246	1,163	7.1	9.0	9
Beckman Coulter[3]	857	816	5.0	3.0	6
Dade Behring	836	770	8.6	6.0	6
Becton Dickinson[4]	638	565	12.9	10.0	4
BioMerieux[5]	506	490	3.4	4.0	4
Sysmex[6]	364	326	11.8	NA	3
Bio-Rad Labs[7]	307	283	8.4	4.8	2
Diagnostic Products	238	217	10.1	6.1	2
Olympus[8]	198	178	11.0	NA	1
Cytyc Corp.[9]	177	161	9.9	9.0	1
Biosite	146	118	23.9	23.0	1
Gen-Probe	142	138	2.9	2.5	1
Top 15 total	12,099	11,101	9.0	7.4	85
Other IVD companies	2,135	1,959	6.0	6.0	15
Total IVD Market	$14,234	$13,060	8.6%	7.2%	100%

*Adjusted % change excludes effect of currency changes and acquisitions and divestitures
(1) Roche revenue excludes applied science segment. (2) Abbott's adjusted % growth includes impact of i-Stat and TheraSense acquisitions. (3) Beckman revenue excludes biomedical research segment. (4) Becton Dickinson revenue includes diagnostic systems and flow cytometry. (5) BioMerieux revenue excludes industrial application sales. (6) Sysmex revenue is based on company forecast for the fiscal year ending March 31, 2006. (7) Bio-Rad revenue excludes life science segment. (8) Olympus' revenue is for diagnostic systems only (excludes microscope business) and is based on company forecast for the fiscal year ending March 31, 2006. (9) Cytyc's revenue excludes sales from surgical products (i.e., Novacept). Source: *DTTR* from company financial reports

G-2 Survey Shows High Marks For Lab Automation

Thirty-two percent of the 188 labs that responded to the Washington G-2 Lab Automation Survey said they have some form of automation, including front end only (15%) or total lab automation track system (17%). Another 25% of surveyed labs said they plan to add automation within the next 12 months, while 43% said they have no current plans to do so.

Do you have a lab automation system



Source: *Washington G-2 Lab Automation Survey*, September 2005

Average volume among surveyed labs with TLA was 7.6 million reportable test results per year. Those with front-end automation performed an average of 5.2 million reportable tests per year.

Labs with automation overwhelmingly said that it had lived up to their expectations. Thirty-nine percent said lab automation had "absolutely yes" lived up to expectations, another 36% said "mostly yes," and 22% said it was "satisfactory." Only 3% said lab automation had not lived up to expectations.

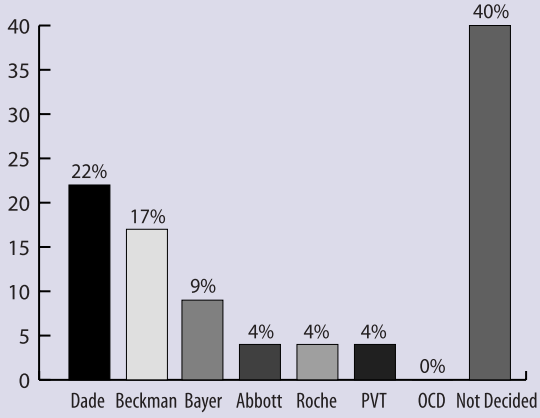
Did lab automation live up to your expectations?

	Front-End	*TLA*	*Combined*
Absolutely yes	37%	41%	39%
Mostly yes	37%	34%	36%
Satisfactory	22%	22%	22%
No	4%	3%	3%

Source: *Washington G-2 Lab Automation Survey*, September 2005

In terms of market share for installed systems, Beckman Coulter led in the survey labs with a 42% share, followed by Bayer Diagnostics and Roche Diagnostics with 15% each. Tecan had a 7% share; Dade Behring, 5%; Ortho-Clinical Diagnostics, 3%; and Abbott Diagnostics, 2%. Other vendors had a combined 10% share, including MDS Autolab, Lab-Interlink, Olympus OLA, and SAIC.

Whose automation system will you add?

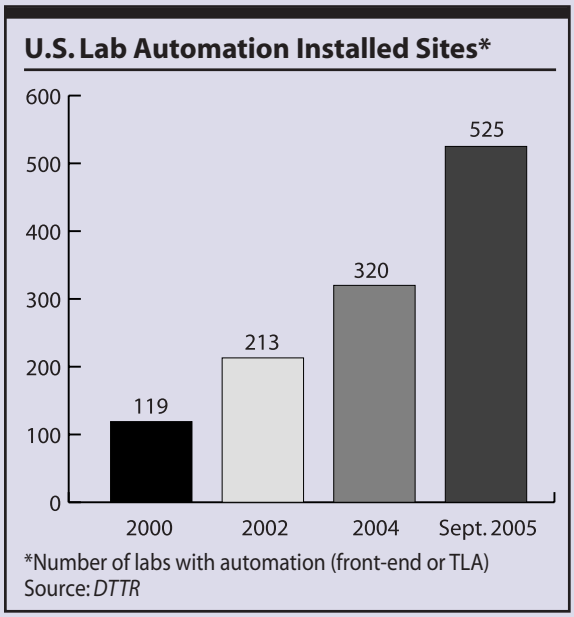


Source: *Washington G-2 Lab Automation Survey*, September 2005

Among the surveyed labs that plan to add automation within the next 12 months, 22% said they had chosen a system from Dade, followed by Beckman with a 17% share. Bayer had a 9% share of planned installations and Abbott, Roche, and PVT LabSystems each had 4%. Forty percent said they had not yet made a decision on which vendor to use.

For a closer look at what's happening with lab automation, *DTTR* interviewed five top vendors plus five labs that use automation. The most consistent piece of advice was to review all your laboratory processes before installation and make changes where necessary to eliminate bottlenecks and optimize the use of automation. Here's more of what they had to say:

Of the 525 labs in the United States that have some form of automation, nearly one-half use a system from **Beckman Coulter** (Fullerton, CA). Beckman has installed its automation at 250 labs in the United States, according to **Ron Berman**, worldwide director of product management for automation and information systems. Recent installations include Carilion Health System (Roanoke, VA), El Camino Hospital (El Camino, CA), and Ventura Community Hospital (Ventura, CA). Beckman's average customer is a 300-bed hospital and about one out of four also have Beckman's LH1500 for hematology automation, he notes.



Berman says the level of interest in automation is at an all-time high. His advises labs to do detailed benchmarking, design, and implementation studies so they can properly evaluate expected and realized gains in productivity. "You can't just put in an automation system and new analyzers and expect things to happen, and choosing a vendor is about more than price," he says.

By year's end, Berman says Beckman will launch a new automation system, named "Automate," that will be aimed at 100-bed hospitals. At the front-end, system will centrifuge, decap, and aliquot, and, at the backend it will map and sort samples.

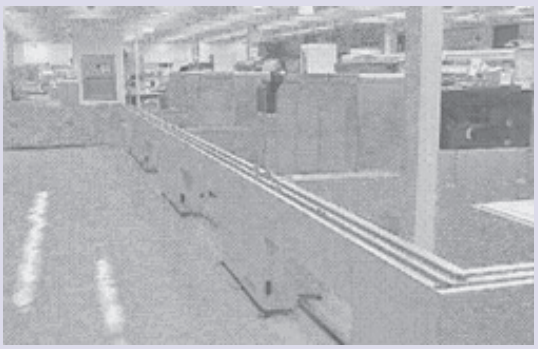
David Hornbeck, division director, laboratory services, at **Suburban Hospital** (Bethesda, Maryland), says his lab installed Beckman track automation systems for chemistry and hematology in July 2004 for two primary reasons: 1) outreach testing volumes were growing at nearly 20% per year; and 2) recruiting lab employees to keep up with the volume gains was difficult.

Hornbeck says Suburban's laboratory is now performing 1.5 million billable chemistry and hematology tests per year with 20 FTEs. Prior to automation, Suburban was performing approximately 1.1 million billable chemistry and hematology tests per year with 29 FTEs.

He advises other labs thinking about automation to make sure their pre-analytical processes will mesh with any new automation system they may have under consideration. Test tube bar codes can be especially tricky, he notes. "Make sure your current barcode will work perfectly with what the automated line requires. There are different languages for bar codes, and the label positioning on your test tube is critical," says Hornbeck.

Although some glitches were encountered during installation, Hornbeck is pleased with the productivity gained through the track system. "It's one of the greatest advancements in laboratory testing," he says. And adds, "It takes guts and appropriate analysis to go to your hospital administration and ask for the

OUMC Lab Automation System



big investment that track systems require, but to do the frontend only is a waste of time. Why would any lab want to set up a half-a-million-dollar piece of equipment [i.e., front-end system] that still needs $26-an-hour MTs to walk a specimen all over the laboratory?" he asks.

"In my opinion, doing lab automation on a piece meal basis is a lousy solution. You won't get the full benefits unless you do total lab automation. Anyone that thinks you can dabble is just not getting it," says **Ken Blick, Ph.D.**, professor and director of chemistry at **Oklahoma University Medical Center** (OUMC).

The core lab at OUMC began installing Beckman's total lab automation track system for chemistry in November 2003 and went live in March 2004. At the same time, a $1 million pneumatic tube system for real-time transportation of test tubes was installed connecting the core lab to three nearby university hospitals and a VA hospital. Another track for hematology is in the process of being installed. Automation of coagulation and urinalysis is slated for late 2006/early 2007.

Blick says the TLA and the tube system have allowed OUMC to close satellite labs that were once maintained at the three university hospitals. All testing is now either performed at the core lab or at the bedside by nurses using handheld, point-of-care analyzers made by Abbott/i-Stat or Biosite.

Blick says the core lab, which operates 24/7, has 60 FTEs that are currently performing a total of 3.5 million reportable test results per year. About two million tests are chemistry, and about 80% of these are being done on the automated track system. During a typical day, the core lab has about three FTEs "running" the analytical aspects of the track system, according to Blick. "We have the capacity to do even more tests without having to bring on additional employees," he adds.

Blick notes that the average age of the core lab's employees is 52 years old and that hiring new ones is difficult. "The medical technologist's job is changing. There's a growing need for MT's with expertise in information systems, robotics, and quality control for walk-away instruments and point of care," he adds.

In summary, Blick says, "We're now getting critical results to doctors quicker and without error. Automation has helped our lab get a lot more respect at the hospitals."

Roche Diagnostics (Indianapolis) has installed its automation systems at approximately 105 labs in the United States, according to **Chris Bosler**, director of marketing for centralized diagnostics. Recent installations include Community Hospital (Munster, IN), Ohio Health-Riverside (Columbus, OH), and New York Methodist Hospital (Brooklyn, NY). Bosler says Roche is scheduled to complete another 15 installations by year's end.

Of Roche's 105 installations, only four are for total lab automation. Roche's MPA (modular pre-analytical) system is the company's most popular automation solution, says Bosler. "Hospitals have moved away from the massive capital investments associated with total lab automation," he says.

Bosler believes Roche is differentiated because it's the only company that designs, builds, and sells its own automation system. "Others aren't as seamlessly integrated," he says.

What can labs do to get the most out of lab automation? "All of the steps that come before specimens are loaded onto a rack need to be rethought and optimized to gain the most efficiency. This includes everything from the containers you use to how specimens are collected, labeled and identified, accessioned, and tracked," answers Bosler. Because you're adding more power and higher throughput, labs also need to rethink how they will review and release their test results," he adds.

Tamara Wilfinger, vice president of system laboratories at **St. John Health System** in Michigan, got off on the wrong foot for its first attempt at lab automation. Because it had OCD Vitros and Eci instruments in use, the core lab at St. John chose Lab Interlink as its lab automation vendor in 2000. After numerous delays, the Lab-InterLink system was installed and set to go live at St. John in late 2003. Then the day before Thanksgiving, Lab-InterLink fired all its employees and went out of business.

Wilfinger says OCD, which had distributed the Lab-InterLink system under the "enGen" trademark, gave a full refund back to St. John. She notes that other labs that had contracted directly with Lab-InterLink weren't so lucky.

But the experience didn't turn St. John off to the idea of lab automation. Wilfinger says the St. John lab system, which includes a core lab at St. John Hospital and Medical Center plus five rapid response labs, was struggling to keep up with an outreach program that was growing at 12% to 15% per year. (Currently St. John performs a total of 12.4 million billable tests per year of which 56% is from outreach.)

The second time around, St. John chose Roche's MPA system. The contract was signed in May 2004, the system plus two chemistry and one immunoassay instrument were delivered to the lab in September, and St. John went live on Dec. 16, 2004 (as scheduled).

Wilfinger says the Roche system was chosen because it had a small footprint that had the capacity to handle the projected growth at St. John for the next four years. She says that approximately four million billable tests are currently running through the automation on an annual basis. The biggest benefits have included an average 25% to 30% reduction in turnaround time. "You have no idea how quiet and low profile the system is. We used to have techs hurrying to get work done," she notes.

Wilfinger's advice to other labs considering automation: 1) make sure your vendor provides a strong project manager; 2) plan for future growth; 3) plan how all your lab processes should be changed to make the most out of automation; 4) lease your automation and instruments if your test volumes are growing rapidly; and 5) get a lot of people in the lab involved in the project: LIS manager, outreach manager, lab director, chief techs, etc.

Larry Siedlick, president of **Sunrise Medical Laboratories** (Hauppauge, NY), says Sunrise went live with front-end automation, with archiving from Roche, in November 2003. Siedlick says one of the biggest benefits has been the ease of finding archived specimens. He says Sunrise, which has 285 FTEs and tests 4,000 to 4,500 specimens per day, used to have three FTEs devoted to finding specimens, but now has just one. Siedlick's advice to other labs: 1) pick an experienced vendor; and 2) review all your processes before installation of automation to make sure you'll get the optimum use out of the new system.

Dade Behring (Deerfield, IL) has its StreamLab automation system installed at 38 sites worldwide, including 20 in the United States. Recent installations include Ingalls Memorial Hospital and Overlook Hospital.

In addition, **Chris Christopher**, vice president of global solutions for Dade, says the company expects to begin installation of its new Dimension Lynx System, targeted at medium-volume laboratories. The Lynx features sample sorting, decapping capability for multiple tube sizes, throughput of up to 300 tubes per hour, and a small footprint of 12 feet by 12 feet, he notes.

Ultimately Christopher sees automation expanding from sorting, transporting, and testing specimens to managing more of the back-end reflex testing, results reporting, and sample management and disposal. "It won't be long before the entire process after the doctor orders the test is automated," he predicts.

Abbott Diagnostics (Abbott Park, IL) has installed its Tecan Genesis FE500 preanalytical workstation at approximately 36 labs in the United States. The Genesis FE500 is manufactured by Tecan Group (Zurich, Switzerland) and distributed by Abbott on a nonexclusive basis.

Abbott plans on launching its Accelerator Automated Processing Systems *(APS)* in late late 2005/early 2006, says Keith Chaitoff, senior director of automation, informatics, and consulting. He says the Accelerator APS can decap, centrifuge, sort, and archive between 300 tests and 600 tests per hour, depending on the configuration. He adds that unlike the Genesis FE500, Accelerator APS will be highly customizable.

Chaitoff says information technology is playing an increasing role in automation, particularly at the backend. He notes that Abbott will begin commercialization of its Accelerator Decision Manager software system within the next few weeks. Decision Manager connects a lab's LIS to its instrument systems and uses algorithms and decision rules for auto release of test results to physicians.

As for the outlook for total lab automation, Chaitoff says, "The market continues to move away from traditional track systems."

Meanwhile, **Annabelle Brameshuber**, a spokeswoman from **Tecan Group**, tells *DTTR* that the company has a total of 40 Tecan Genesis FE500 preanalytical workstations installed in the United States. She notes that in addition to Abbott, Tecan has distribution agreements with Dade Behring and Bayer Diagnostics.

Michele Zwickl, marketing manager for automation for North America at **Bayer Diagnostics** (Tarrytown, NY), says Bayer has its lab automation installed at approximately 85 sites in the United States.

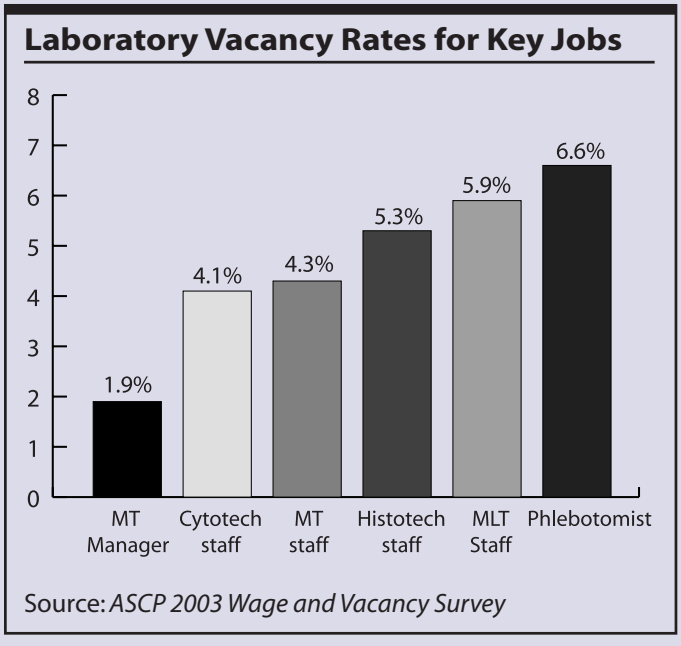
Zwickl says total lab automation is alive and well and notes that Bayer's worldwide placements of lab automation systems are increasing at an annual rate of more than 35%. "We believe TLA will become a necessity in most laboratories across the nation," she adds.

The biggest benefit Bayer's lab automation products offer to labs is quick turnaround time for patient results because the company's track and its analytical engines are fast and have the menu to support over 130 assays on a single platform, according to Zwickl.

Her advice on automation: "Be ready to relook at your process and make the changes necessary to the process. Do not try and just automate your current process."

An Update on the Lab Personnel Shortage

The American Society for Clinical Pathology (Chicago, IL) released results from their *2003 Wage and Vacancy Survey* earlier this year. The survey, which was based on responses from 1,682 hospital, independent, and other labs, showed that vacancies for lab positions had generally declined, while average salaries across all lab positions had risen about 5% to 6%.



However, despite the increase in wages and decrease in vacancies, 46% of labs reported problems in recruiting qualified staff. Staff level medical technologists (MTs), medical laboratory technicians (MLTs), and phlebotomists were hardest to fill. On average it took from three to 12 months to fill any vacancy, according to the survey.

The survey authors said lower vacancy rates may be the result of several trends, including 1) the use of more noncertified staff to fill positions that once required certification; and 2) after budget cuts or lengthy recruitment searches, budgeted positions were simply being eliminated.

IVD Stocks Flat; Third Wave Climbs 19%

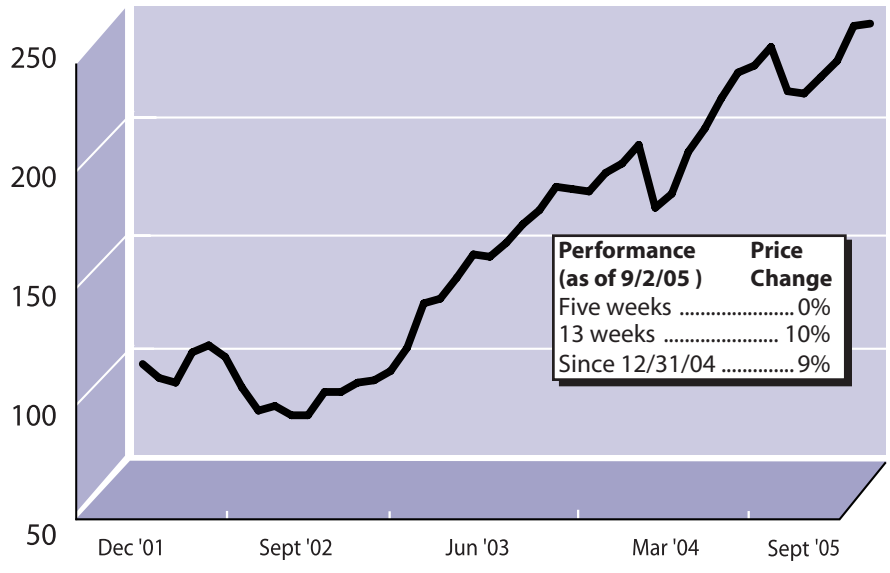
The 21 stocks in the G-2 Diagnostic Stock Index were unchanged in the five weeks ended September 2, with 10 stocks up in price and 11 down. Year to date, the G-2 Index is up 9%, while the S&P 500 Index is up 1% and the Nasdaq is down 2%.

Third Wave Technologies (Madison, WI) rose 19% to $5.53 per share for a market capitalization of $230 million. The company recently received FDA clearance for its pharmacogenomic test, UGT1A1 Molecular Assay (*see page 1*).

Quidel Corp. (San Diego, CA) was up 21% to $8.58 per share for a market cap of $280 million. The company recently announced that it has acquired the immunochemical Fecal Occult Blood Test (iFOBT) from Alfa Scientific Designs (Poway, CA). Quidel says this FDA cleared and CLIA-waived test will be marketed to healthcare professionals as the QuickVue iFOB test. The immunochemical fecal occult blood test category represents a large market opportunity for Quidel as over 50 million fecal occult blood tests are sold annually through medical/surgical distributors in the United States. In addition, Medicare reimbursement rates awarded immunochemical fecal occult blood tests (CPT 82274 at $22.22) over the traditional Guaiac-based fecal occult blood tests (CPT 82270 at $4.54) are significantly higher.

Meanwhile, **Immucor** (Norcross, GA), which makes instrument systems for blood donor screening, fell 14% to $23.68 per share for a market value of $1.1 billion. On August 26, the company reported that the Securities and Exchange Commission had launched a formal investigation into payments made by its Italian unit in October 2003 to physicians associated with government hospitals. Then on August 29, Immucor reported that its chief financial officer, Steven Ramsey, resigned, and the company revised its previously issued results for at least two quarters to account for unrecorded bonuses.

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, Four weeks ended 9/2/05

UP	Price	% Chg
Affymetrix	$49.24	5
Beckman Coulter	57.15	5
Biosite	60.11	9
Cytyc	25.15	1
Digene	30.32	4
Gen-Probe	47.45	8
Inverness Medical	27.48	1
Meridian	17.45	5
Quidel	8.58	21
Third Wave	5.53	19
DOWN		
Abaxis	11.76	-6
Abbott Labs	45.15	-3
Bio Rad	55.80	-7
Becton Dickinson	53.60	-3
Cholestech	9.85	-13
Dade Behring	37.31	-2
Diagnostic Products	53.94	-4
Immucor	23.68	-14
Johnson & Johnson	63.57	-1
OraSure	9.47	-12
Ventana	40.52	-6

G-2 Insider

Digene Corp. (Gaithersburg, MD) says it has launched direct-to-consumer TV advertisements for its HPV test for cervical cancer in two new cities. The 30-second spots began airing in early September in Boston and Chicago and are supplementing the company's ongoing national magazine campaign (*People*, *Ladies Home Journal*, *Redbook*, etc.).

Digene says the success of its initial TV advertising campaign in Atlanta, Baltimore, and Philadelphia (see DTTR, April 2005, page 12) led to its expansion into Boston and Chicago. Charles Fleischman, president of Digene, says the company is choosing cities where HPV test reimbursement is high, where it has good sales rep coverage, and a strong major laboratory partner presence. Digene spent $1.6 million on its initial TV ads in three cities and has spent another $3.7 million on magazine advertising through October.

Digene had originally contracted the physician-office marketing of its HPV test to PDI Inc. (Pharmaceutical Detailing Inc.—Saddle River, NJ) in 2003. But after one year, Fleischman says it became clear that this strategy was not optimizing HPV test sales, so Digene brought its sales and marketing inhouse and began advertising directly to consumers. The company currently employs 55 sales reps that market to physicians and another 15 reps that focus on labs.

In the fiscal year ended June 30, 2005, Digene says its revenue from HPV test sales in the United States increased by 34% to $77.3 million. The company sold a total of 3.6 million HPV tests in fiscal 2004 at an average of about $21.47 per test.

Company References

Abbott Labs 847-937-6100
Beckman Coulter 714-871-4848
Biosite 858-455-4808
Correlogic 301-214-4030
Dade Behring 847-267-5300
Digene 301-944-7000
Immucor 770-441-2051
LipoScience 919-212-1999
Roche Diagnostics 317-521-2000
Third Wave 608-273-8933
Varian 650-213-8000

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