Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

AACC Highlights: The Buzz Is Back At Abbott

After several years of weathering indifference from lab managers and directors, the buzz was back at the Abbott Diagnostics' booth at this year's AACC Clinical Lab Expo in Orlando, July 24 to 28. "We're definitely seeing more traffic this year. Two years ago I got lonely standing out here. The only customers that stopped by wanted to pound on me," Joe Nemmers, senior vice president of diagnostic operations at Abbott, told *DTTR*.

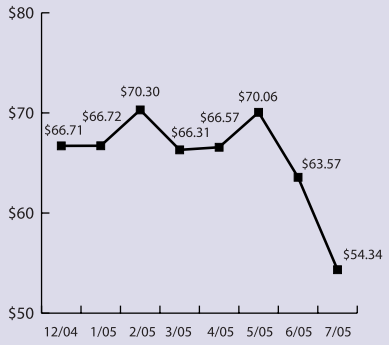
Nemmers says that while Abbott is still losing some market share in the United States, the company's worldwide centralized diagnostic business (chemistry, immunoassay, and hematology) posted a sequential increase in sales in the second quarter—the first time that's happened since 2000. And for the first time in more than four years, Nemmers expects Abbott to report a year-over-year gain in worldwide centralized diagnostic sales in the third quarter.

Among the bright spots has been the BNP testing market, which now represents $25 million of annual revenue after just 14 months of being added to the test menu for Abbott's AxSym system, according to Nemmers. He also cites 800 placements of Architect systems in the first half of 2005, bringing the total to 3,300 worldwide. For more on Abbott and other highlights from the AACC exhibit hall floor, *see pp. 3-4.*

Beckman Hammered On Weak U.S. Sales

Beckman Coulter shares plunged 15% on July 22 after the company reported lower-than-expected second-quarter profits and sales due to weakness at its U.S. diagnostics business. Beckman also slashed its full-year outlook as it shifts from sales-type leases to predominately operating-type leases. Finally, the company said it plans to lay off 350 employees, or about 3.5% of its 10,169 worldwide employees, as part of a restructuring that will combine two operating divisions (clinical diagnostics and biomedical research) into one unit. These moves represent the first major strategic decisions of the company's new chief executive Scott Garrett. ➥ *p. 2*

Beckman's Stock Price Plunge

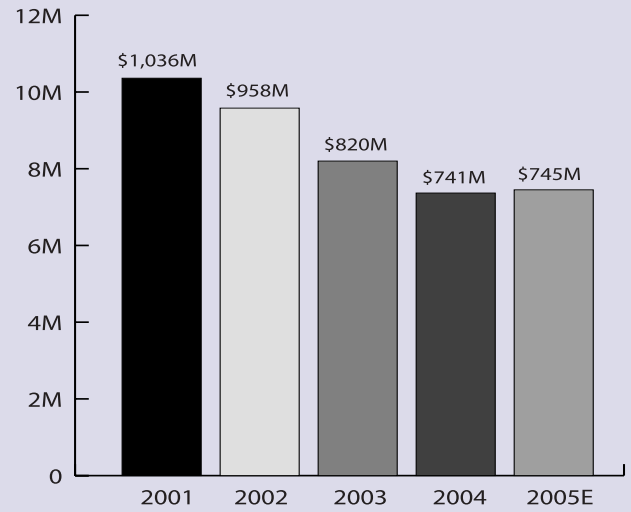


Source: *DTTR*

▲ **AACC Highlights: The Buzz Is Back at Abbott,** *from page 1*

Nemmers attributes a big portion of the fledgling turnaround at Abbott Diagnostics to the company's Architour trucks—customized semitrailers with working demos of Abbott's Architect systems on board. He says the company now has three Architour trucks on the road covering the eastern, central, and western United States. A fourth Architour truck displaying Abbott's total lab automation system will be on the road in a matter of weeks, according to Nemmers.

Abbott's Clinical Diagnostics Revenue* in USA



*excludes revenue from diabetes care (i.e., Medisense and TheraSense); E=estimated

Nemmers says each truck costs more than $100,000 to get on the road, but the investment is paying dividends. He says 75% of current sales closes for Abbott's Architect c8000, ci8200, and i2000 immunoassay systems in the United States are directly related to an Architour visit.

Is Abbott using heavy price discounting to close sales? "We're absolutely not using price to get market share. I'd like to know who told you that because they're wrong," answered Nemmers.

China Contract Represents Abbott's Largest Hematology Win

Abbott has announced that it has won a competitive bid to supply China's Ministry of Health with more than 550 Cell-Dyn 1800 hematology instruments. The contract represents the largest single order of Cell-Dyn 1800s in Abbott's history, says Joe Nemmers. Abbott currently has a total of more than 20,000 Cell-Dyn 1800s placed worldwide.

The contract represents part of China's efforts to upgrade the 1,000 hospital laboratories and clinics that treat infectious diseases. Instruments will be installed in hospitals located in 23 provinces throughout China, according to Nemmers.

He says the Chinese market now represents roughly $75 million in annual diagnostic sales for Abbott. Abbott has been growing in China at an average annual rate of about 35% for the past few years, he adds.

Olympus Nearing Jump Into Immunoassay Market

As Abbott regains its footing in the U.S. immunoassay market, Olympus America (Melville, NY) is preparing the launch of its new AU3000i automated immunoassay system. Stephen Wasserman, group vice president for diagnostic systems, anticipates the AU3000i will be on the market next spring. "We think we'll be a force to be reckoned with [in the U.S. immunoassay market]," told *DTTR* at the exhibit hall at AACC.

He says the AU3000i will be launched with an initial menu of about 15 tests in the cardiac, thyroid, and fertility areas. An initial targeted market will be the 750 to 800 lab customers (1,300 placements) in the United States that now use Olympus chemistry systems. "We want to capitalize on our reputation for reliability for uptime and reagent recalls," says Wasserman.

He notes that Olympus recently signed a licensing agreement with Bayer that will allow Olympus to develop a BNP test for the AU3000i.

Roche Ready to Begin Shipping AmpliChip CYP450

It's been about nine months since Roche Diagnostics gained FDA clearance to sell its AmpliChip CYP450 microarray in the United States. But actual commercialization of the product has yet to occur. Why the delay? Lonnie Shoff, senior vice president, applied science and molecular diagnostics at Roche, says the company is in discussion with payers on how the novel technology should be reimbursed. Without more info on what the level of reimbursement will be, she says it's difficult for Roche to negotiate pricing for the chips with its lab customers.

In Europe, Roche sells AmpliChip CYP450 for 400 euros (the equivalent of US $485). Despite the reimbursement questions, Shoff says Roche is ready to begin shipping the test in the United States and expects it to be commercialized before year's end. Shoff says Roche is also developing a number of other AmpliChip tests, including P53 (for various cancers) and a leukemia test.

The AmpliChip products may be Roche's answer to the patents that are beginning to expire on the company market-leading PCR technology. The foundational patents for PCR expired in March, and more will expire in the coming years. "The patent expirations may make PCR testing a little cheaper for homebrew lab testing, but the market is moving to real-time PCR, and those patents won't end for a long time," Sunil Hazaray, vice president of sales and marketing at Roche Molecular Diagnostics.

Bayer Diagnostics Is a Keeper

Quelling speculation of a spin out, Tony Bihl, newly promoted president of Bayer Diagnostics, tells *DTTR* that after a recent strategic assessment, Bayer has affirmed that its diagnostic division will continue to play a key role in the company's healthcare group. The mandate for Bayer's centralized diagnostics business is profitable growth, which is defined at pretax margins of 10% to 12%, according to Bihl.

Among upcoming product launches is the Centaur CP, an immunoassay system for low- to mid-volume labs, says Bihl. He says the system will be on the U.S. market later this year with an initial menu of approximately 30 tests, including thyroid, fertility, anemia, cardiac, and cancer tests. Within a year infectious disease testing, CA-125, CA 15-3, and her2/neu tests will be added, he notes.

Bihl adds that Bayer is interested in licensing technology so that it can develop tests for stroke and preecampsia.

UBS Survey: Abbott Still Losing Ground In Immunoassay Market

Despite the positive signs at the recent AACC convention, Abbott Diagnostics still has work to do when it comes to stanching the loss of share in the immunoassay market, according to the most recent lab vendor survey by UBS Investment Research.

The immunoassay portion of the June 2005 survey was completed by 323 labs. Eight percent (25/323) of respondents indicated that they have switched immunoassay vendors in the past three months or are planning to switch in the next six months. Of those respondents who have switched vendors in the past three months, 50% (6/12) switched from Abbott, and 25% (3/12) switched from Roche Diagnostics. This is the fourth consecutive quarter that Abbott has lost the most immunoassay customers based on the UBS surveys.

Beckman Coulter, which is encountering some difficulties itself (see page 1), seems to be benefiting the most from Abbott's troubles. Of those respondents that switched vendors, 17% (2/12) went to Beckman. UBS analyst Benner Ulrich said that one reason why Abbott may be having trouble winning immunoassay share back is because Abbott does not appear to be offering significant discounts. According to the survey, 68% of respondents (192/282) indicated that Abbott has not been giving discounts, 6% (17/282) reported 0-5% discounts, 9% (26/282) indicated 5-10% discounts, 10% (28/282)indicated discounts of 10-15%, and 7% (20/282) indicated discounts of over 20%.

Based on the survey results, the most important factor in influencing a customer's decision to switch is test menu, which was chosen by 19% (9/48) of respondents. This was closely followed by dissatisfaction with service (17% - 6/48).

UBS Survey Respondents that Switched from their Immunoassay Vendor

Vendor	*3Q04*	*4Q04*	*1Q05*	*2Q05*
Abbott	30%	53%	36%	50%
Bayer	13	11	9	8
Beckman Coulter	13	5	27	8
Dade Behring	20	5	0	0
Diagnostic Products	3	0	9	0
Olympus	0	0	9	0
Ortho-Clinical	3	0	0	0
Roche	7	16	9	25
Other	11	10	0	9
Total	100%	100%	100%	100%

Source: UBS Investment Research-Quarterly Lab Vendor Survey

Reasons for Switching Immunoassay Vendors

Vendor	*3Q04*	*4Q04*	*1Q05*	*2Q05*
Pricing	21%	21%	22%	10%
Broader test menu on new instrument	14	14	16	19
Unique features on new instrument	14	19	18	15
Higher throughput on new instrument	16	12	15	15
Dissatisfaction with service	16	16	14	17
Dissatisfaction with reliability of old instrument	7	9	9	13
Other ancillary services	2	2	1	2
Other	10	7	5	9
Total	100%	100%	100%	100%

Source: UBS Investment Research-Quarterly Lab Vendor Survey

Five Tests That Big Labs Should Consider Bringing In-House

Every big hospital and independent lab regularly checks its send-out test volumes, looking for opportunities to cut costs by bringing tests in-house. On average, bigger labs (i.e., more than 1 million billable tests/year) incur reference lab expenses that average more than $1 million per year and are growing by 5% to 10% per year, according to *Washington G-2 Reports Second National Esoteric Testing Survey*.

With this in mind, *DTTR* recently analyzed a number of tests that bigger labs frequently send-out and looked specifically for tests with strong volume growth trends, easily recognized clinical utility, and strong economics (i.e., low reagent costs relative to reimbursement). The short list we came up with includes allergy testing, lipoprotein subfraction testing, blood lead testing, homocysteine, and DNA-based testing for high-risk human papillomavirus (HPV) types.

Below we provide a thumbnail sketch on the clinical use and money-making potential for labs that chose to add these tests to their menus.

LDL Subfraction Testing

Heart disease is the number-one killer of both men and women in the United States. Each year, approximately 700,000 people in the country die from heart disease, according to statistics from the Centers for Disease Control and Prevention (CDC).

There is growing recognition among medical experts that the traditional routine cholesterol panel (total cholesterol, HDL, LDL, and triglycerides) used for screening heart-disease risk is limited in its effectiveness.

Low density lipoproteins (LDL) carry about 70% of the blood's cholesterol. These LDL particles are taken up by cells in the blood vessel wall and can be oxidized, which can lead to heart disease. This is why LDL is known as the "bad cholesterol."

The traditional cholesterol panel only tests for total LDL. However, total LDL can test "normal" even though there could be dangerous subfractions within the LDL, says Nehemias Muniz, Ph.D., director of the electrophoresis division at Quantimetrix Corp. (Redondo Beach, CA), which manufactures an LDL subfraction testing system named Lipoprint.

Five Tests to Bring In-House

Test	Reagent Cost	Medicare Reimbursement	Gross Profit*	Typical Ref. Lab Charge
Allergy panel (15 allergens)	$82.50	$109.50	$27.00	$120.00
Blood lead testing	5.60	16.91	11.31	8.02
DNA-based HPV (high-risk types)	25.00	49.04	24.04	65.63
Homocysteine	4.00	23.57	19.57	24.30
LDL subfractions	$15.00	$34.68	$19.68	37.00

*Gross profit=reimbursement minus reagent cost
Source: *DTTR*

Muniz says that people with small, dense LDL particles are at three times greater risk for heart disease even when they have normal traditional cholesterol screening levels.

He notes that here are drugs (Niacin and Fibrate) that can be

used to target LDL subfractions. "If physicians know the different levels of a patient's LDL subfractions, they can prescribe more accurate drugs," says Muniz.

A number of niche reference labs—LipoScience, Atherotech, Berkley Heart Lab—offer proprietary LDL subfraction tests at prices that average about $30 to $40 per test. But labs can also perform the test in-house using Quantimetrix's Lipoprint system.

Muniz says that there are approximately 60 labs in the United States using the Lipoprint system, which is the only LDL subfraction testing system cleared by the FDA. The company is adding an average of about one new lab customer every five weeks, he notes. National reference labs using the system include Mayo Medical Labs, ARUP Labs, and Quest Diagnostics. Regional labs using the system include Suburban Hospital (Bethesda, MD), Cognoscenti Health Institute (Orlando, FL), and Saint Luke's Hospital (Kansas City, MO).

Quantimetrix sells its desk-top Lipoprint system for $18,000; reagent kits are listed at $1,500 per 100 tests ($15 per test). LDL subfraction testing is reimbursed by Medicare under CPT 83716 at a national limit of $34.68 per test.

Blood Lead Testing

Federal law mandates that all children covered by Medicaid be tested for lead poisoning at age 1 and then again at age 2. In addition, all children that live in certain areas with a high concentration of houses built prior to 1978 (when all lead-based paints were taken off the market) are required to be tested. All told, the CDC estimates that four to five million people are tested for lead poisoning each year in the United States.

Lead poisoning can affect almost all parts of the body, including the central nervous system, kidneys, and reproductive organs. In children especially, it impairs cognitive development, which can lead to learning disabilities and behavioral problems.

Local labs frequently refer blood lead testing to one of the national reference labs, which charge an average of approximately $7 to $10 per test.

Instrument system options for bringing lead testing in-house include the handheld LeadCare rapid test system made by Magellan Biosciences (Chelmsford, MA). The system tests finger-stick blood samples and provides results in about three minutes.

Currently, there are about 450 labs and pediatric groups in the United States using the LeadCare system, according to Robert Rosenthal, Ph.D., chief executive at Magellan. He says the company sells the system for $1,890; reagent kits are listed at $269 per 48 tests ($5.60 per test). Medicare reimburses blood lead testing under CPT 83655 at a national limit of $16.91 per test.

Allergy Screening Panel (allergen-specific IgE antibody tests)

There are some 50 million people in the United States with some form of allergy that causes symptoms such as hives, dermatitis, rhinitis (nasal conges-

tion), red itchy eyes, asthma, or abdominal pain, according to Lorraine Damico, key account manager/senior product manager for Pharmacia Diagnostics (Portage, MI), which markets the ImmunoCap immunoassay system for allergy testing. She says most of these people are given broad-brush treatments, but never tested to find out exactly what is causing their allergic reactions.

Damico believes there is a huge opportunity for hospital outreach and independent labs to provide allergy panel testing to local physicians, especially ear, nose, and throat (ENT) specialists.

Pharmacia sells three different ImmunoCap systems ranging in price from about $22,000 to $235,000. The typical allergy screen tests for 15 allergens at a reagent cost of about $5.50 per allergen, or $82.50 per panel, according to Damico. Medicare reimburses each allergen test under CPT 86003 at a national limit of $7.30 per allergen, or $109.50 for a panel of 15 tests.

DNA-Based Testing for High-Risk HPV Types

Clinical studies have shown that human papillomavirus (HPV) is the cause of 99% of cervical cancer cases. DNA-based testing for high-risk HPV types has become the standard of care for follow-up testing for abnormal Pap tests.

In addition, the American College of Obstetricians and Gynecologists (ACOG) released guidelines in August 2003 recommending that women 30 years or older be offered the HPV DNA test in addition to their Pap smear and pelvic exam as a primary screen for cervical cancer.

Adoption of the ACOG guidelines had been moving slowly, but is sure to speed now that state laws are being enacted that require health insurers to pay for HPV testing. So far in 2005, three states—Texas, New Mexico, and Maryland—have passed laws requiring coverage of HPV testing as per the ACOG guidelines, and another 23 states have set up task forces to evaluate similar legislation.

Right now, Digene Corp. (Gaithersburg, MD) makes the only test cleared by the FDA for high-risk HPV types. Digene charges roughly $25 for its reagents, and HPV testing is covered by Medicare under CPT 87621 at a national cap of $49.04. Reference labs charge an average of $65.63 per HPV test.

In addition, Third Wave Technologies (Madison, WI) recently introduced analyte specific reagents for the same 13 high-risk HPV types in the Digene's test. Third Wave is selling the reagents for approximately $30 per test.

Homocysteine

Homocysteine is a cardiac marker used to determine if a person is at high risk of heart attack or stroke. Homocysteine can also be elevated in patients who are folate-deficient or Vitamin B12-deficient.

There are, as of yet, no established guidelines for homocysteine testing, and routine screening has not been recommended by any professional organizations. But Robert Hoffman , Ph.D., president of A/C Diagnostics (San Diego,

CA), believes that someday homocysteine levels will be screened on a routine basis just like cholesterol.

Right now, Abbott Laboratories is the market leader in sales of homocysteine tests. A/C Diagnostics has also developed a homocysteine test that has been FDA-cleared for use on the Hitachi 912 clinical chemistry system. And Hoffman says A/C will soon seek clearance of its homocysteine test on a portable system it has developed.

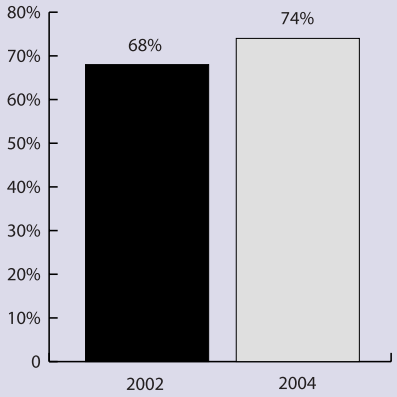
Hoffman says A/C will be able to give the portable system away to hospital labs and then charge under $5 per homocysteine test reagents. "We are ready to compete on price, and we will not be undersold," says Hoffman.

Meanwhile, Hoffman, who is also a professor in the department of surgery at the University of California (San Diego), says that patent issues raised by Competitive Technologies (Fairfield, CT) don't hold water. Competitive Technologies has been licensing its patented technology for homocysteine detection to companies like LabCorp, Axis Shield, and Diagnostic Products Corp. But Hoffman believes those patents are not defendable because of related work by Japanese researchers that was published in the early 1980s. "We know all the prior art. Competitive Technologies received its patents after the published work of Dr. Soda Kenji, so its patents are invalid," according to the opinion of Hoffman.

The Challenges in Reducing Send-Out Test Volumes

Seventy-four percent of labs surveyed late last year said they are actively seeking to expand their testing menus and reduce send-out tests to reference labs, according to *Washington G-2 Reports Second National Esoteric Testing Survey*. This compares with 68% from our last survey in 2002. The most commonly cited tests that labs said they expect to add to their menus in 2005 included folate, HCV viral load, hepatitis C antibody, vitamin B12, CA-125, B-Type Natriuretic Peptide (BNP), and cystic fibrosis (genetic analysis).

Percentage of Labs Actively Seeking to Broaden Their Esoteric Test Menus, 2002 vs. 2004



Note: For 2004 survey: n=190 labs (including 144 hospital labs, 34 independent labs, and 12 physician office labs (POLs) and other labs)

For 2002 survey: n=171 labs (including 148 hospital labs, 20 independent labs, and 3 physician office labs (POLs) and other labs)

Thirty-nine percent of respondents from our 2004 survey said the main reason why they don't expand their esoteric testing menus is "low test volumes do not justify bringing in-house." The second most commonly cited reason (16%) was "budget constraints/lack of capital to purchase necessary equipment." Survey results for 2004 were very similar to those from our 2002 survey.

What is the biggest barrier your laboratory faces in expanding its esoteric testing menu?

	2002	2004
Low test volumes do not justify bringing in-house	46%	39%
Budget constraints/lack of capital to purchase necessary equipment	16%	16%
Inadequate reimbursement from Medicare and/or managed care payers	16%	11%
Esoteric testing reagents are too expensive	10%	11%
Difficulty in hiring laboratory staff with necessary expertise	9%	9%
Not enough space	3%	9%
Other reason	0%	5%

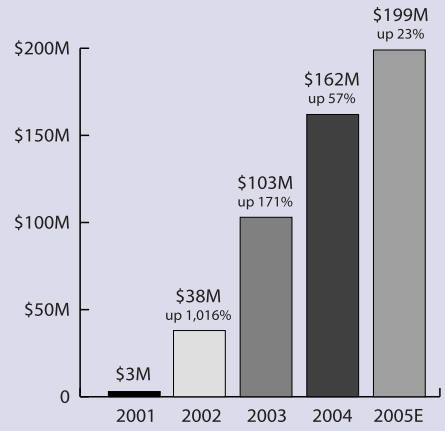
Source: *Washington G-2 Reports Second National Esoteric Testing Survey*.

Big IVD Makers Eating Away At Biosite's BNP Testing Market

In the past few months several more major diagnostic manufacturers have secured licensing agreements to either B-type natriuretic peptide (BNP) or NT-proBNP—two markers used to help diagnosis congestive heart failure. In April, BioMerieux (Marcy l'Etoile, France) gained nonexclusive rights to Roche Diagnostics NT-proBNP marker, and in July, Response Biomedical (Vancouver, Canada) signed a similar agreement. There are now seven companies that either have a NT-proBNP test on the market or are developing one.

Meanwhile, Bayer Diagnostics recently gave licensing rights to its BNP marker to Olympus for use on the company's new Olympus AU3000i, which is currently scheduled for release in 2006 in the United States. There are now five IVD manufacturers licensed by either Bayer or Biosite (San Diego, CA) to use a BNP marker.

Biosite's Annual BNP Sales



E=estimated; Source: Biosite and *DTTR*

Up until two years ago, Biosite had the BNP testing market to itself. From 2002 to 2004, Biosite's BNP testing revenue jumped from $38.1 million in 2002 to $162 million in 2004 for an annualized increase of more than 100% per year. But added competition from Bayer, Abbott, Roche, and Dade is now cutting into that growth.

Based on reported sales for the six months ended June 30, 2005, *DTTR* estimates that Biosite will increase its BNP sales by "only" 23% this year to approximately $199 million.

The other story playing out in congestive heart failure testing is the battle between the BNP marker and the NT-proBNP marker. Those on the BNP side (i.e., Biosite, Bayer, Abbott, Beckman, and Olympus) argue that their tests measure the actual hormone that gets elevated in patients suffering from congestive heart failure, while NT-proBNP measures a precursor peptide.

Meanwhile, the advocates of NT-proBNP (i.e., Roche, Dade, etc.) say that quantities of NT-proBNP are directly proportional to its biological counterpart BNP and in close correlation with the severity of heart failure. In addition, they say the measurement of NT-proBNP is not affected by therapy with Natrecor (nesiritide), a synthetic form of BNP used in the treatment of heart failure.

Taking Sides in the Congestive Heart Failure Testing: BNP vs. NT-proBNP

BNP	***NT-proBNP***
Axis-Shield/Abbott Diagnostics	BioMerieux
Bayer Diagnostics	Dade Behring
Beckman Coulter	Diagnostic Products Corp.*
Biosite	Nanogen*
Olympus*	Ortho-Clinical Diagnostics* Response Biomedical* Roche Diagnostics

*Has licensing agreement, but test is not yet on the U.S. market

Source: *DTTR*

▲ **Beckman Hammered on Weak U.S. Sales,** *from page 1*

For the quarter ended June 30, Beckman's net income fell to $47.7 million, or 73 cents per share, from $58.3 million or 88 cents per share, a year earlier; revenue grew 3.6% to $618.8 million. (Revenue was up just 2% after adjusting for currency fluctuations.)

The company's strongest area was immunodiagnostics: third-quarter revenue up 11.7% to $138.8 million (up 9.7% after currency adjustments). Its weakest area was routine chemistry: third-quarter revenue down 4.5% to $168.3 million (down 5.8% after currency adjustments).

Lab customers love Beckman's instruments and service, but this is not showing up on the company's bottomline.

In terms of geography, Beckman's greatest strength was in Europe: third-quarter revenue up 10.9% to $183.1 million (up 6.9% after currency adjustments). Asia sales grew 2% to $75 million (up 0.5% after currency adjustments). Revenue from the Americas' region was up 0.6% to $360.7 million (flat after currency adjustments).

On a July 22 conference call, CEO Scott Garrett said U.S. sales were hurt by a slowdown in automation purchases due to the growing range of new competing systems. An increase in the percentage of instruments placed on operating-type leases (OTL) also negatively impacted sales, he said.

Beckman currently generates approximately 50% of its revenue from sales-type leases (STL), 30% OTLs, and 20% from cash sales. This compares to Dade Behring, which has approximately 25% STLs, 50% OTLs, and 25% cash sales.

Because of the revenue recognition requirements of the new lease model, Garrett said reported sales and earnings will be lower in the near term. But he eventually expects to see stronger sales and earnings growth rates.

As a result of the changes, Beckman has cut its full-year 2005 earnings outlook (before one-time charges) to between $2.55 and $2.90 a share from a prior range of $3.51 to $3.61. It now expects sales of $2.41 billion to $2.46 billion. Wall Street analysts on average had been expecting a profit of $3.56 per share on revenue of $2.59 billion.

Beckman's weak revenue gains, particularly in the U.S. market, are surprising given that the company has consistently scored well on satisfaction surveys gathered by Washington G-2 Reports (see *DTTR*, December 2004, pages 1-3) and UBS Investment Research (*see page 4 of this issue*).

Beckman's Second Quarter in Brief *($ millions)*

	Revenue	Reported Growth %	Constant Currency Growth %
Routine chemistry	$168.3	-4.5	-5.8
Immunodiagnostics	138.8	11.7	9.7
Hematology	132.1	4.8	3.4
Total clinical diagnostics	439.2	2.9	1.4
Biomedical research	179.6	5.3	3.3
Total Beckman Coulter	$618.8	3.6	2.0

Source: *DTTR* from Beckman Coulter

IVD Stocks Rise 7%; Quidel Jumps 48%

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 7% in the four weeks ended July 29, with 13 stocks up in price and eight down. Year to date, the G-2 Index is up 9%, while the S&P 500 Index is up 2% and the Nasdaq is flat.

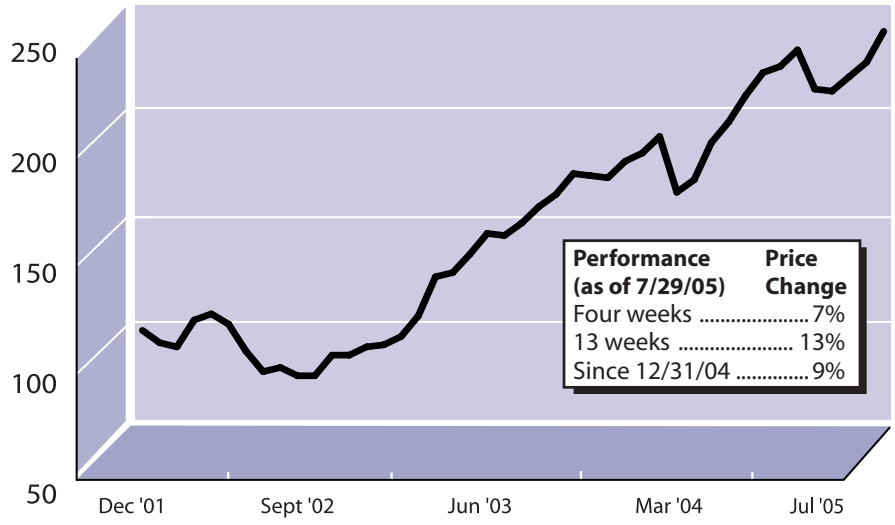
The rapid test manufacturers led the upward rise in IVD stocks in July:
Quidel (San Diego), which makes rapid tests for pregnancy, Strep A, and influenza, jumped 48% to $7.10 per share for a market capitalization of $227 million. The company reported that second-quarter revenue was up 7% to $14.8 million, compared with total revenues of $13.8 million for the second quarter of 2004. The net loss for the second quarter of 2005 narrowed to $1.7 million, or $0.05 per share, compared with a net loss of $2.3 million, or $0.07 per share, for the second quarter of 2004.

Meridian Bioscience (Cincinnati), which makes rapid tests for respiratory, gastrointestinal, and parasitic infectious diseases, was up 24% to $24.99 per share for a market cap of $395 million. Meridian reported third-quarter sales of $25,421,000, a 39% increase over the same period of the prior fiscal year and an all-time record for any quarter in the company's history; net income increased 62% to $3.5 million, or $0.22 per share.

Cholestech (Hayward, CA), which makes a point-of-care cholesterol testing system, was up 21% to $11.26 per share for a market cap of $166 million. The company posted revenue of $15.1 million for its fiscal first quarter ended June 24, 2005, compared to $9.6 million for the first quarter of the prior year. Net income was $1.6 million, or $0.11 per share, versus a net loss of $345,000, or $0.02 per share.

Meanwhile, **Beckman Coulter** shares were down 21% in the four-week period, including a 15% drop on July 22 (*see page 1*), to $54.34 per share for a market cap of $3.4 billion.

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 7/29/05

UP	Price	%Chg
Abaxis	12.48	10%
Bio Rad	60.03	5
Biosite	55.09	5
Cholestech	11.26	21
Cytyc	24.96	6
Dade Behring	75.80	11
Diagnostic Products	56.46	22
Digene	29.09	14
Gen-Probe	44.09	10
Meridian	24.99	24
OraSure	10.78	17
Quidel	7.10	48
Third Wave	4.65	1
DOWN		
Abbott Labs	46.63	-5
Affymetrix	46.69	-10
Beckman Coulter	54.34	-21
Becton Dickinson	55.37	-1
Immucor	27.47	-22
Inverness Medical	27.15	-6
Johnson & Johnson	63.96	-4
Ventana	42.96	-1

G-2 Insider

Don't miss the **23rd Annual Lab Institute: T*ransformational Forces Reshaping Labs,*** October 19-22, 2005, at the Crystal Gateway Marriott, Arlington, Virginia. This year's Institute features some of the lab industry's most influential business and government leaders, including:

Stephen S. Raab, M.D., from the University of Pittsburgh's School of Medicine, will explain how a focus on quality measurement and process improvement can affect the high costs associated with lab/pathology errors.

Daniel Levinson, HHS Inspector General, will gauge the OIG's top priorities for the healthcare sector and provide an update on the OIG's proposal on Part B lowest charges.

Lindsey Graham, U.S. Senator (R-SC), will discuss what's behind the epic national debate on reforming Social Security and the implications for Medicare.

Ken Freeman, former chief executive of Quest Diagnostics and managing director at Kohlberg Kravis Roberts & Co., will identify which market forces are having the biggest impact on today's healthcare environment.

Myla Lai-Goldman, M.D., executive vice president at LabCorp, will discuss the challenges and opportunities for clinical labs as the molecular revolution gains speed.

Newt Gingrich, former Speaker, U.S. House of Representatives, will talk about the major challenges facing the U.S. healthcare system and the importance of building a national database of electronic medical records.

In all, the Lab Institute conference will feature over 35 presentations and panel discussions from more than 50 laboratory experts and government officials. For a complete program go to *www.g2reports.com* or call 800-401-5937, x2.

Company References

Abbott Labs 847-937-6100

A/C Diagnostics 858-654-2555

Beckman Coulter 714-871-4848

Biosite 858-455-4808

Digene 301-944-7000

Magellan Bioscience 978-856-2345

Meridian Bioscience 513-271-3700

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