



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. V, No. 3/November 2004

CONTENTS

TOP OF THE NEWS

Labs targeting molecular diagnostics	1
Quest to market CellSearch	1-2

PARTNERSHIPS/VENTURES

Update on North Carolina blood banking venture	2-3
--	-----

REIMBURSEMENT NEWS

Immunoassay FOBt fees headed to \$22	4
--	---

INSIDE DIAGNOSTICS INDUSTRY

Web-Connectivity Potpourri Tips from Spectrum Labs	5-6
What's next for Atlas?	7
Case study on ALS in Kansas	8

FINANCIAL NEWS

Glucose testing market rebounds	9
FDA clears Perkin Elmer newborn screen	10
IVD stocks up 11%	11

G-2 INSIDER

Lab industry growing at 6-7%	12
------------------------------------	----



Established 1979

Labs Targeting Molecular & Gene-Based Testing For Growth

Fifty-two percent of labs envision that molecular and gene-based testing will be their "hottest" business line over the next few years, according to an online survey of attendees of Washington G-2 Reports' recent Lab Institute. This represents a significant increase from the 41.6% of labs that selected molecular and gene-based testing in a similar survey conducted by Washington G-2 at the Lab Institute two years ago.

These survey results suggest an increasingly competitive environment for the big national reference labs: Quest Diagnostics, LabCorp, Mayo, ARUP, and Specialty Labs. The survey also points to an opportunity for reagent vendors positioned to help hospitals and independent labs bring advanced testing technologies into their labs.

The next most frequently cited area for growth was outreach testing, which garnered 26% versus 26.8% in 2002. This year's Lab Institute conference drew a record crowd of 600 attendees, vendors, and speakers. The 2004 survey was completed by between 123 and 140 attendees (depending on the question asked). *For more survey details, see page 8.* 🏠

What is the "hottest" business line you envision for your lab over the next few years?

	2004	2002
Molecular & gene-based testing	52.0%	41.6%
Outreach testing	26.0%	26.8%
Point-of-care testing	10.6%	12.6%
Anatomic pathology	6.5%	6.3%
Direct-access testing	4.9%	7.9%
Other	0.0%	4.7%

For 2004 survey: N=123 (57% hospital labs and academic medical centers; 27% independent labs; 16% other)
Source: Lab Institute Surveys, October 2004 and 2002

Quest Diagnostics To Market CellSearch

Quest Diagnostics (Teterboro, NJ) has signed an exclusive deal with Veridex LLC (Warren, NJ), a Johnson & Johnson subsidiary, to be the only national commercial reference lab to offer Veridex's CellSearch test for identifying and counting circulating tumor cells in blood samples from metastatic breast cancer patients. Quest says the test will become available by the end of September to physicians nationwide through its esoteric testing lab, Nichols Institute (San Juan Capistrano, CA). The agreement covers all areas of cancer as the test label is expanded for additional uses. Veridex can market the test to academic-based medical centers, but not other commercial reference labs (e.g., LabCorp, Specialty Labs, Mayo, ARUP, Genzyme Genetics, Esoterix). ➡ p. 2

Smaller labs are fearful that the exclusive contracts Quest and LabCorp have with test developers will lead to higher reference lab expenses. But exclusive deals have had little impact in the lab market so far.

▲ Quest Diagnostics To Market CellSearch, from page 1

Circulating tumor cells are present in the blood when a primary cancer sheds tumor cells into the circulatory system. Cancer metastasis occurs when circulating tumor cells begin to grow in distant locations in the body. Knowing the number of circulating tumor cells in the blood can help oncologists make decisions about patients' treatment earlier than previously possible.

Financial terms of the agreement were not disclosed nor was pricing for the test. However, *DTTR* expects Quest to offer the test at a list price in the range of \$300 to \$400. A Quest spokesman would only tell *DTTR*, "We are currently talking to private payers about reimbursement, and we anticipate that private payers will be interested in covering the test."

The CellSearch test was developed by Immunicon (Huntington Valley, PA); Veridex markets the test to labs under an exclusive worldwide distribution agreement. For full background on CellSearch, see last month's issue of *DTTR*, pp. 1, 5-8.

Over the past few years, the two biggest commercial reference labs (Quest and LabCorp) have signed a number of distribution agreements with the developers of new testing technologies, but most have had little impact in the lab market place. The most successful to date has probably been the nonexclusive agreement the big labs have with Atherotech (Birmingham, AL), which sells a proprietary lipoprotein subfraction test for helping predict risk of cardiovascular disease. Atherotech says it is currently performing more than 60,000 tests a month, which is double what the company was processing during the same period a year ago, largely because of the Quest and LabCorp marketing partnerships. 🏠

National Commercial Reference Lab Distribution Agreements

Lab	Company	Date	Test Market	Agreement	Financial Terms
LabCorp	Exact Sciences	7/11/2001	colorectal cancer	exclusive	Up to \$75M milestones to Exact, 20% royalty
Quest	diaDexus	11/26/2001	osteoporosis	exclusive	Upfront fee, milestones, and royalties to diaDexus
LabCorp	Myriad Genetics	12/4/2001	cancer, hypertension	exclusive	LabCorp gets 10-30% marketing fee
LabCorp	Celera	10/2/2002	Alzheimer's, cancer	non-exclusive	NA
LabCorp	Correlogic	11/6/2002	ovarian cancer	semi-exclusive	Signing fee, milestones, and royalties to Correlogic
Quest	Correlogic	11/6/2002	ovarian cancer	semi-exclusive	Signing fee, milestones, and royalties to Correlogic
LabCorp	Atherotech	7/7/2003	lipid profiles	non-exclusive	NA
Quest	Atherotech	7/7/2003	lipid profiles	non-exclusive	NA
Quest	Enterix	5/19/2003	colorectal cancer	semi-exclusive	NA
LabCorp	BioPredictive	10/21/2003	liver fibrosis	exclusive	NA
Quest	Veridex	9/20/2004	cancer	semi-exclusive	NA

Source: *DTTR* from Quest, LabCorp, and UBS Investment Research

Community Blood Center Of The Carolinas Update

A group of 10 hospitals in North Carolina has spent \$4.7 million to develop their own blood center and gain independence from the Red Cross.

One year ago, *DTTR* highlighted a group of 10 hospitals in North Carolina who—unhappy about the price of blood and inflexibility of the American Red Cross (ARC)—decided to start their own blood processing center with the aim of becoming fully self-reliant for blood products (see *DTTR*, October 2003, pp. 1, 5-8). The hospitals named their new venture Community Blood Centers of the Carolinas (CBCC). Although it's had its share of growing pains, Tom Hassett, group vice president of Carolinas HealthCare System, says CBCC is now providing its hospital owners with more than half of their blood needs.

More specifically, Hassett, who served as CBCC's interim executive director for its first year of operation, says the venture is currently collecting and manufacturing 36,000 units of blood per year, or 60% of the 10 hospitals' total annual need of 60,000 units. The ARC still supplies the remaining 40%, or 24,000 units, but Hassett says CBCC is attracting more and more donors each week.

CBCC, which currently has 31 employees, opened the doors to its 31,000-square-foot freestanding building in Charlotte in January 2003, and a few weeks later it held its first community-based blood drive at Pillowtex Corp. in Cocord, North Carolina. Hassett says CBCC has now organized blood drives at more than 300 companies, churches, malls, and other locations. Laboratory testing is contracted out to Blood Service Labs (Dallas).

In addition to collections, CBCC handles the "manufacturing," or separation of each donation into platelets, plasma, and red blood cells. CBCC works under an FDA license held by Virginia Blood Services (Richmond), an independent blood bank that serves 20 hospitals in Virginia and served as an advisor in the formation of CBCC.

Hassett says CBCC has been successful in its blood drives because it has been willing to perform them onsite at corporations. "Companies have responded because we're not taking their employees away from work," he says. Companies and donors also appreciate the fact that all collected blood is used at local hospitals and is not shipped to other parts of the country. In addition, he says CBCC has a strong focus on service and conducts a donor satisfaction survey immediately after each blood draw. So far, he says, CBCC has scored an average satisfaction rating of 4.7 on a scale of one to five.

The biggest challenge CBCC had has been building name recognition. Hassett says CBCC was initially funded with \$3.2 million from its 10 hospital owners, which include Carolinas Healthcare System, Gaston Memorial Hospital, Northeast Medical Center, and Piedmont Medical Center. However, the hospitals had to inject another \$1.5 million into CBCC largely due to the unexpected high cost of marketing to attract donors. But Hassett says CBCC has stabilized its finances and is expected to be operating on a breakeven basis by the end of the current fiscal year (ends Sept. 30, 2005).

"If we had the choice to do it all over again, we would," says Hassett. Furthermore, he tells *DTTR* that a group of hospitals in the Triad region of North Carolina just completed a feasibility study on creating their own blood center, while another group in the western part of the state has begun examining the potential as well.

Meanwhile, Debbie Estes, communications director for ARC's Carolinas Blood Services Region, tells *DTTR* that ARC has made some changes in the way it operates to address concerns of hospitals. For example, about one year ago, ARC began allowing hospitals to purchase non-leukocyte-reduced blood nationwide. Non-leukoreduced blood is \$30 to \$40 cheaper per unit, and the ARC's unwillingness to offer it had been a major complaint of hospitals. But years of inflexibility and the apparent success of CBCC may mean that ARC will face the challenge of a growing number of hospitals that bring blood banking inhouse, observes *DTTR*. 🏠

Immunochemical FOBT Reimbursement Headed To \$22

Beckman Coulter is the clear market share leader in the traditional FOBT market. This position should give it a big headstart for introducing its new immunochemical FOBT.

After hiking Medicare reimbursement for immunochemical fecal occult blood tests (iFOBTs) from \$4.54 to \$18.09 effective Jan. 1, 2004, the Centers for Medicare and Medicaid Services (CMS) says that it "expects" to put in place another raise to \$22.22 effective next year. The news came to IVD vendors in a general letter from CMS sent out in August.

Test-maker Enterix (Falmouth, ME), had been arguing its case to CMS for higher reimbursement over the past six months. Enterix was pressing for a \$28 Medicare reimbursement rate, but the second expected hike will still be short. As a result, Enterix, which is headquartered in Australia, has scaled back its U.S. sales and marketing to a bare-bones staff. Among the casualties is Craig Sands, who had served as chief executive of Enterix for about one year. Enterix distributes its iFOBT, named InSure, through a distribution agreement with Quest Diagnostics. However, even with reimbursement at \$22.22 per test, the Enterix executives had said their margins would be razor thin. Now most of Enterix's fulfillment services will be provided to Quest from Australia.

Meanwhile, Beckman Coulter (Fullerton, CA) says it's aiming to relaunch its immunochemical fecal occult blood test (iFOBT) on November 1. The test was formerly known as FlexSure and was on the market between 1997 and 2001, but an inability to get adequate reimbursement from insurers and Medicare led Beckman to withdraw the product. FlexSure is being relaunched under the brand name Hemocult ICT.

David Bull, marketing manager for occult blood tests at Beckman, tells *DTTR* that Hemocult ICT will be profitable at either the \$18.09 or \$22.22 levels. The CLIA-waived test will be marketed primarily to physician offices. The selling price to physicians after distributor markups is expected to be in the range of \$14 to \$16 per three-slide test, he says.

Finally, Exact Sciences (Marlborough, MA), which makes the Pre-Gen Plus DNA test for detecting colon cancer, says it is unlikely to reach its accession goal of 10,000 tests for 2004. So far this year (through September), Exact has recorded accession volume of slightly more than 3,000 tests. Benner Ulrich, analyst at UBS Investment Research, estimates that approximately 5,000 PreGen-Plus tests will be accessioned in 2004, but Exact will receive payment on less than half. Ulrich says barriers to gaining market traction include the low demonstrated sensitivity (PreGen-Plus at 52% versus 85% to 90% for colonoscopy) and high cost (list price of \$795). 🏠

Some Tips On Connecting With Your Docs Via The Web



David Moore



Karen Yoemans

On September 9, Washington G-2 Reports sponsored a national audio conference titled *Web-Based Connectivity: How Labs Can Get the Biggest Bang from Their Buck*. The conference featured two executives, David Moore and Karen Yoemans, from Spectrum Laboratory Network (Greensboro, NC), which is one of the most Web-enabled laboratories in the nation.

Spectrum is a for-profit venture owned by High Point Regional Health System and Moses Cone Health System. Spectrum, which has approximately 700 FTEs, manages six inpatient labs plus a freestanding core lab in Greensboro. Over the past three years, Spectrum has invested more than \$6 million to connect all 38 of its patient service centers and more than 400 physician clients to its Web-based system (from Atlas Medical Software) for test orders and results reporting. Spectrum now receives more than 60% of its accessions via the Web, either through Web browsers or direct Internet connections with physician offices. Spectrum currently maintains five server computers onsite and will soon add two more.

Here are some highlights from the audio conference:

What's the biggest mistake you see other labs making when they purchase, install, and begin marketing a new Web-based system?

"They try to run before they can walk," said Moore. Some labs are spending a lot of money on servers and systems, when they'd be better off starting with an ASP model. "If you are only adding one new physician office to the system per week, then you're probably better off having the Web vendor host the system. At some later point it will become cost effective to bring the system inhouse, advised Moore. He suggested the crossover mark would be roughly 50 connected offices each sending in 5- 10 accessions per day.

What benefits has Spectrum received from its investments in the Web?

Moore said that of the total 48,000 accessions Spectrum receives each week, 66% are ordered via the Web and have an average of less than 10 data-entry errors per week. Furthermore, there are zero errors between what is ordered by the physician office and which tests the lab performs, according to Moore.

As a result, Moore said that Spectrum has been able to reduce its days sales outstanding (aka, days in accounts receivable) from 62 days at yearend 2002 to 48 days at yearend 2003 to 42 days currently.

In addition, Moore says that Spectrum has been able to save 40 FTEs in its accession processing and order entry staff. Overall, he estimates that Spectrum earns back \$2 for every \$1 it invests in its Web-based system.

How should a lab evaluate Web-system vendors?

Moore and Yoemans cited numerous criteria, including: 1) Does each step of the order-entry process make sense, or does the user need to go backward and forward between pages and retype data? 2) Can the vendor clearly explain the

methods by which it interfaces its system with various office management systems? 3) How does the Web system get test orders into the LIS, and how are results transferred into the Web system? 4) Is the system scalable? Can the vendor show you labs using their system with five physician office connections as well as 50 connections? 5) How long does the vendor keep test results on the server, and is there a cost for retrieving historical results?

What's the minimum size physician practice that Spectrum will connect to the Web?
 Yoemans said the cut off is 8-10 specimens per day, or approximately \$5,000 per month in lab business. She said physician offices with this level of test volume will typically be connected using existing PCs at the office and a Web browser. Spectrum supplies larger practices with dedicated PCs and a direct interface to Spectrum's lab.

What can a lab give to a physician office that uses a Web-based system without crossing the inducement line?

Spectrum buys a PC, keyboard, label printer, and Internet connection for its larger clients, according to Yoemans. She said Spectrum programs the PCs so that they can only be used to place lab orders and view results. Spectrum also has its clients sign forms under which they agree to use the equipment solely for lab purposes.

What are three key selling points to physicians to convince them to use the Web?

Yoemans answered: 1) The lab gets correct billing information the first time, so we don't have to call your office asking for clarification; 2) Web-based order entry will automatically fill in demographic information on requisitions; and 3) physicians can pull up test results anywhere they have Internet access.

After a Web connection is made, how does a lab ensure that a physician office uses the system?

"They have to like the system. It needs to be quick and easy to use," answered Yoemans. For example, she said the customized Atlas system used by Spectrum

allows for touch-screen ordering (just like an ATM machine), and orders can be completed by physician staff in less than 20 seconds. Next, she said it's necessary for a lab's field service staff to spend as much as a week training a physician office on how to use the system. "They need to get a hands on feel for the system....They need to feel comfortable with it," she said.

Yoemans noted that Spectrum monitors the percentage of requisitions it receives via the Web each day for all clients that are connected. If usage drops off at a particular client, then a field service representative meets with that client and resells and retrains them on the system. 🏠

Spectrum at a Glance*

Headquarters/core lab:	Greensboro, NC
Chief executive:	Nate Headley
Chief information officer:	David Moore
Sales & marketing director:	Karen Yoemans
Market area:	NC, SC, GA, VA, TN
Employees:	700 FTEs
Est'd net revenue, 2004:	\$90M
Weekly accession volume:	48,000
Physician clients connected to Web:	400
PSCs connected to Web:	38
% accessions ordered via Web:	66%
LIS vendor:	Antrim/Sunquest
Web-based order entry/results vendor:	Atlas
Internet data transfer platform:	HyperSend/Hilgraeve

*Figures do not include recent acquisition of Medex Regional Laboratories, which has approximately 310 FTEs and \$25 million in annual net revenue. Source: DTTR from Spectrum

What's Next For Atlas Medical?

After a shaky start (1999-2002), which featured the failure of several vendors and big financial losses for “early-adopter” labs, it now appears that Web-based order entry/result reporting is actually beginning to catch hold. One of the leading Web vendors is Atlas Medical Software (Calabasas, CA), which markets the LabWorks system for Web-based order entry/result reporting. Atlas was originally founded by brothers Robert, age 48, and Steven Atlas, 46, as a healthcare information technology consulting firm back in 1989. In the mid-1990s, the company switched its focus toward the development of Web-based connectivity systems, and the first version of LabWorks was launched in 1995.

Today, Atlas has 78 employees and LabWorks is installed and running at 37 laboratories across the country, including Sunrise Medical Labs (Hauppauge, NY), Memphis Pathology Laboratory, LabNet of Ohio, and Spectrum Lab Network (see pp. 5-6). For perspective on what's next for Atlas and Web-based lab communications, *DTTR* recently interviewed Robert Atlas, president and chief executive, of the company that bears his name. Here are some highlights:

More and more labs are now connecting with their physician clients through the Web, and physicians are actually making use of the technology.

DTTR: *What makes Atlas different from other Web vendors?*

ATLAS: We have a truly proven system. We're the only system out there with clients that have driven 50 to 60 to 70% of their test orders into the lab. Of the 37 “live” clients we have, all are receiving orders over the Web except for one.

DTTR: *Why won't the biggest LIS vendors, Cerner and Mysis (Sunquest), succeed in Web-based connectivity and beat out smaller independent vendors like Atlas?*

ATLAS: Our system is more flexible when it comes to linking labs with physician offices and the rest of the outside world. We also have an advantage in multi-lab systems that use different LIS systems. I'd also point out that Atlas is profitable. We're going to still be around five years from now.

DTTR: *What are some of the mistakes you see labs making when they select a Web vendor?*

ATLAS: They're not asking the right questions. For example, “Can the lab update patient demographic and insurance information on their own or can this only be done by the vendor?” If the latter is the case, then labs are giving up a big piece of control that can lead to outdated patient files. In general, labs need to carefully consider the flexibility of Web systems and how easily they can be integrated with other systems outside of their organization.

DTTR: *What drives physician adoption of the Web?*

ATLAS: The ease of use of the system and the mindset on the part of the lab that they are going to make adoption happen. A system has to be so easy to use that a user can sign on for the first time and immediately understand it, and entering orders has to be a quick process.

DTTR: *What's next for Atlas?*

ATLAS: Later this year we'll be introducing handheld order entry on Pocket PCs and then on the Palm O/S. Overall, I'm anticipating that LabWorks will grow from 37 installed customers to 55 over the next 12 months. 🏠

Do Physicians Really Need The Web?



Ed Harned

Physician demand for Web connectivity to their lab is a lot like the public's demand for four-wheel-drive SUVs, according to Ed Harned, president of Affiliated Medical Services Lab (AMSL-Wichita, KS). Most people have no real need for a four-wheel-drive vehicle, but they desire one anyway. Physicians are the same way with Web connectivity, he said. Harned's comments came during his presentation at Washington G-2 Reports' recent Lab Institute conference in Arlington, Virginia, Sept. 29-Oct. 2.

"After a 10- or 12-hour day of seeing patients, how many physicians do you think go home, log onto the Internet, and start viewing lab test results?" Harned rhetorically asked. He said the need for physician access to Web-based results during the workday is questionable as well, given that AMSL makes specimen pickups at its largest clients three times per day and reports results back using traditional systems (printers, auto-dial fax, etc.) within a few hours of pickup. "Nonetheless, some physicians feel they've just got to be connected to the Internet," he noted.

Harned says AMSL was compelled to begin offering Web-based order entry/results reporting after a competing lab from Florida entered his market and began using Web connectivity as a selling tool to attract physician clients. "A good salesperson can spin the Internet so that they can take away a good customer....I'd hate to be out there without the ability to tell physicians we can't hook them up to the Internet," he said.

So, in early 2003, AMSL introduced a Web-based system made by LabPortal.com (Chantilly, VA), which is a subsidiary of Quest Diagnostics. AMSL has given its new Web system the moniker of "LabStar." AMSL processes approximately 2,000 requisitions per day and is currently receiving 25% to 30% of its orders and sending out 50% of results via the Web.

Despite the tenuous benefits that Web-based order entry/results reporting provides to physicians, Harned said there has been a real paybacks to AMSL. At the top of the list is the automatic generation of advanced beneficiary notices (ABNs) at the moment a physician office places an order over the Web. "Now we're getting ABNs in and we're getting them signed....This alone has made it all worthwhile," he said.

Other benefits include an estimated 40% reduction in administrative FTEs for Web-based lab orders; decreased spending on paper forms; and a reduced threat of client attrition to competitors.

Among the factors labs should consider when choosing a Web vendor is the ability of the system to print out bar codes that can be read by your lab's LIS, according to Harned. This is especially important if your lab has front-end automation, he said. He also highlighted the need for an easy interface with your lab's LIS and the physician office management systems used by your clients. In Harned's opinion: "The best solution is an LIS with a Web portal as an embedded feature." Finally, he warned labs not to underestimate the time and training needed to get each physician client to learn and use a new Web system. 🏠

AMSL invested roughly \$200,000 to purchase its web system and get it up and running. AMSL also pays monthly service fees based on the number of physicians that sign on and use the system each month.

▲ Labs Targeting Molecular & Gene-Based Testing, from page 1

“There are 40,000 genes in the human body. Understanding what each one does may be complex, but it’s finite,” Randy Scott, Ph.D., chief executive of Genomic Health (Redwood City, CA), told Lab Institute attendees in a keynote presentation titled *The Next Big Bang in Diagnostic Lab Technology: Implications of Genomic Profiling*. “The time required to fit the pieces in a finite puzzle decreases rapidly as one approaches the solution,” said Scott. He predicted an acceleration in the rate that molecular disease is understood as each year passes and the puzzle is put together. This will provide big opportunities for diagnostic makers and labs, according to Scott.

What is the biggest challenge that “cutting-edge” test developers will face when launching their products?

Reimbursement from Medicare and managed care	81.9%
Government regulation	10.2%
Physician acceptance/education	7.1%
Consumer education/acceptance	0.8%

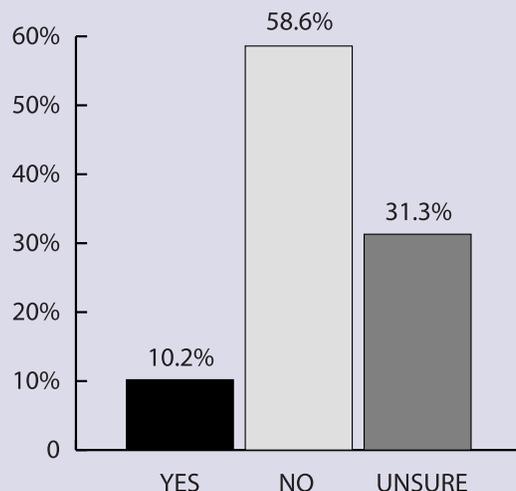
N=127

Source: Lab Institute conference attendees, October 2004

And what is the biggest challenge that “cutting-edge” test developers will face when launching their products? The answer by far is “reimbursement from Medicare and managed care,” according to Lab Institute attendees. A whopping 81.9% choose reimbursement as the biggest challenge, followed by government regulation at 10.2%. Only 7.1% choose physician acceptance/education, and consumer education/acceptance barely registered with just 0.8%.

Meanwhile, Lab Institute survey respondents were clearly opposed to the notion of patenting human genes. Almost 59% said diagnostic companies should not be allowed to patent human genes that they have discovered. Only 10.2% were for gene patents, and a significant 31.3% were unsure on the issue. 🏠

Should diagnostic companies be allowed to patent human genes that they have discovered?



Source: Lab Institute conference attendees, October 2004

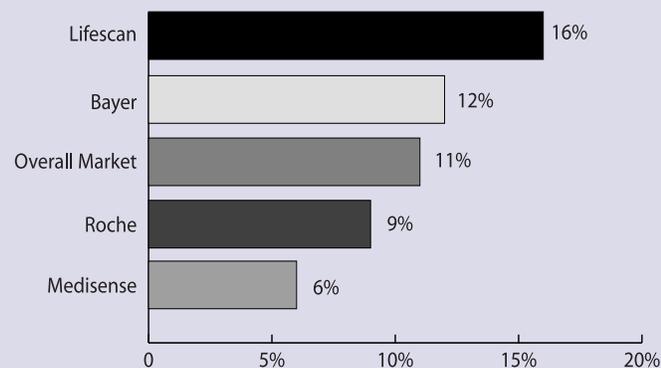
Self-Testing Blood Glucose Market Rebounds To 11% Growth Rate

After posting growth of only 5% last year, the worldwide self-monitoring blood glucose (SMBG) market has rebounded back to a double-digit growth rate. In the six months ended June 30, 2004, the four largest SMBG vendors reported combined revenue of \$2.548 billion, up 11% from the same period a year earlier. This is up substantially from the 5% growth rate posted for full-year 2003.

The fastest-growing vendor in first-half 2004 was Johnson & Johnson’s **Lifescan** (Milpitas, CA), which reported 16% growth to reach worldwide sales of \$820 million. Lifescan’s fastest growth was in the United States, up 18% to \$455 million.

Next fastest was **Bayer Diagnostics** (Tarrytown, NY), which grew its worldwide SMBG business by 12% to reach \$378 million (\$311 million euros). Bayer's SMBG business was led by its Ascensia line, which grew by 16% to \$357 million.

Growth Rates for Leading SMBG Vendors*



*excludes the effect of currency changes and acquisitions
Source: DTTR from company reports

Meanwhile, **Roche Diagnostics** (Basel, Switzerland) increased its Accu-Chek line by 9% to \$1.011 billion (1.288 billion Swiss francs). After adjusting for its \$1.2 billion acquisition of TheraSense in April 2004, Abbott's **MediSense** business (Bedford, MA) grew by 6% to \$339 million.

Amylin Moves Closer to Approval for Diabetes Drug Symlin

Despite the rebound in the SMBG market, storm clouds are on the horizon. Specifically, the biopharmaceutical company Amylin Pharmaceuticals (San Diego) is moving closer to getting its diabetes drug Symlin to the

market. On September 20, Amylin announced that it had responded to questions from the FDA concerning the company's application to market the drug.

The company said it has received two "approvable" letters for the treatment thus far and that it expects a response from the agency within six months. An approvable letter is issued by the FDA when the agency feels submitted data is encouraging but lacks certain specifics needed for marketing approval.

Amylin's Symlin is a once-per-month glucose control therapy for Type II diabetes, the most common form of diabetes, which typically develops in adulthood and is closely linked to obesity. The drug utilizes sustained release technology to control blood sugar levels over the course of a month. 🏠

Symlin could greatly reduce the number of glucose tests performed by diabetics.

FDA Clears Perkin Elmer Newborn Test Kit

Approximately four million babies are born each year in the United States, and every state mandates testing for PKU, with some states requiring as many as 30 additional newborn screening markers.

Perkin Elmer (Wellesley, MA) has received clearance for the world's first FDA-approved testing kit used to test for metabolic disorders in newborns. The kit, called the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, analyzes more than 40 disease markers with a heel-stick blood sample, including phenylketonuria (PKU), sickle cell anemia, congenital hypothyroidism, and galactosemia. Currently, most laboratories test for metabolic disorders using "homebrew" methods.

Perkin Elmer is the leading supplier to newborn screening laboratories, according to spokesman Dan Sutherby. He says that Perkin Elmer currently generates approximately \$55 million per year from the sale of newborn screening test supplies.

The nation's largest newborn screening laboratories include Mayo Medical Labs (Rochester, MN) and Pediatrix Screening (Bridgeville, PA). Laboratories performing Perkin Elmer's full panel of 40 newborn disease markers are expected to charge payers approximately \$100, according to Sutherby. He would not disclose the price of the test kit, which will be on the market in about three months. 🏠

IVD Stocks Rise 11%; Third Wave Leaps 54%

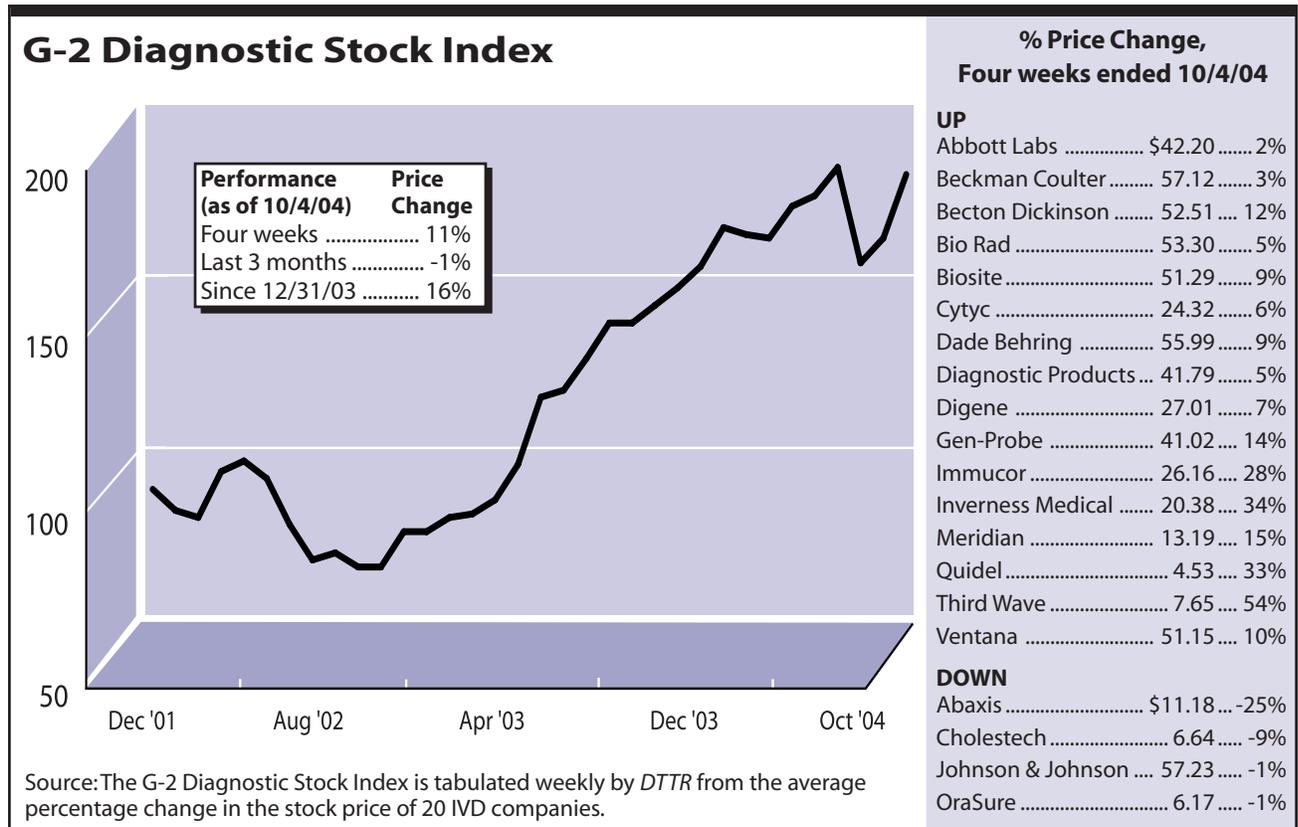
The 20 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 11% in the four weeks ending October 4, with 16 stocks up in price and four down. Year to date, the G-2 Index is up 16%, while the S&P 500 Index is off 2%, and the Nasdaq is down 3%.

Third Wave Technologies (Madison, WI) jumped 54% to \$7.65 per share for a market cap of \$310 million, which is approximately 5.6 times the company's current annual run rate of \$56 million. Recent news includes a new contract with TriCore Reference Laboratories (Albuquerque, NM), an independent reference lab owned by the University of New Mexico, Presbyterian Hospital, and St. Vincent's Hospital.

Under the new contract, TriCore is using Third Wave's Invader HCV genotyping reagents to perform homebrew assays that identify all six genotypes of the hepatitis C virus. TriCore, which has approximately 700 employees and roughly \$65 million in annual revenue, provides outreach testing services in New Mexico, Texas, Arizona, Colorado, and Nevada.

Other labs using Invader HCV include Spectrum Laboratory Network and UCLA Medical Center (Los Angeles).

Separately, Third Wave says it plans to introduce an HPV detection product for its Invader system by year's end. 🏠



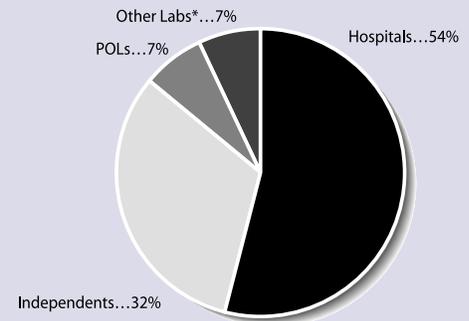
Laboratory Industry Revenues Top \$40 Billion

National spending on clinical laboratory testing services, including anatomic pathology, grew by an annual rate of 6.8% in the three years ended Dec. 31, 2003, to reach \$40.1 billion. This marks a substantial increase from the estimated 1% annual growth rate for the preceding three years (1998-2000).

In terms of market share, hospitals performed \$21.5 billion of testing for a 54% market share, followed by independent labs at \$13 billion (32% share); and POLs and "other labs," each at \$2.8 billion (7% share).

Despite the accelerated growth of the past three years, the rate of increase of spending on laboratory testing still lagged behind spending trends for most other healthcare sectors. For example, the Centers for Medicare and Medicaid Services (CMS) projects that spending on hospital care grew by 7.8% annually between 2000 and 2003; physician service expenditures grew by 7.9% per year; and prescription drug spending grew by 14.9%.

Laboratory Industry Market Share by Revenue, 2003



*includes nursing homes, home health agencies, ambulatory surgery centers, etc. Source: *Lab Industry Strategic Outlook 2005: Market Trends & Analysis*

Company References

- Affiliated Medical Services
Lab 316-265-4533
- Amylin 858-552-2200
- Atlas Medical 800-333-0070
- Community Blood Center
of the Carolinas
704-972-4700
- Enterix 207-781-4990
- Exact Sciences 508-683-1200
- Immunicon 215-830-0777
- Spectrum Laboratory
Network 336-664-6100
- Third Wave Technologies
608-273-8933
- Veridex 877-837-4339

These are just some of the findings from Washington G-2 Reports new market research report **Lab Industry Strategic Outlook 2005: Market Trends & Analysis**. This definitive business planning report contains 200+ pages of facts and figures on the Nation's \$40+ billion lab industry and has been written by Jondavid Klipp, editor of *Laboratory Industry Report* and *Diagnostic Testing & Technology Report*. Single copy: \$795, G-2 subscribers; \$995, non-subscribers. For ordering information, visit our Website, www.g2reports.com or call 1-212-629-3679. 🏠

DTR Subscription Order or Renewal Form

Subscription includes 12 monthly issues, e-mail Alerts, annual company index, newsletter binder, plus exclusive savings on other G-2 publications and programs

YES, enter my subscription at the regular rate of \$419/yr

or

YES, as a current subscriber to the **National Intelligence Report, Laboratory Industry Report, or G-2 Compliance Report**, enter my subscription at the special subscriber rate of \$319/yr

Please Choose One:

Check enclosed (payable to Washington G-2 Reports)

American Express VISA MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company _____

Address _____

City _____ St _____ Zip _____

Phone _____ Fax _____

e-mail address _____

Return to:

Washington G-2 Reports,
3 Park Avenue, 30th Floor,
New York, NY 10016-5902
Tel: (212) 629-3679
Website: www.g2reports.com

For fastest service:

Call (212) 629-3679
or fax credit card order
to (212) 564-0465

11/04

Note: subscribers outside the U.S. add a \$50 postal surcharge

Subscribers are invited to make periodic copies of sections of this newsletter for professional use. Systemic reproduction or routine distribution to others, electronically or in print, is an enforceable breach of intellectual property rights. G2 Reports offers easy and economic alternatives for subscribers who require multiple copies. For further information, contact Randy Cochran at 212-576-8740 (rcochran@ioma.com).

© 2004 Washington G-2 Reports. All rights reserved. Reproduction in any form prohibited without express permission. Reporting on commercial products is to inform readers only and does not constitute an endorsement.

Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1111 14th St NW, Ste 500, Washington DC 20005-5663. Tel: 202-789-1034. Fax: 202-289-4062. Order line: 212-629-3679. Website: www.g2reports.com

Publisher: Dennis W. Weissman. Managing Editor: Jondavid Klipp, labreporter@aol.com

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 200.