Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Molecular Diagnostics Migrating To Local Labs

More and more community hospitals and regional independent labs are either building new molecular diagnostics labs or expanding existing capabilities, while academic medical centers are now frequently transferring their molecular testing research capabilities into commercial enterprises, an informal *DTTR* survey of eight molecular lab directors around the country shows.

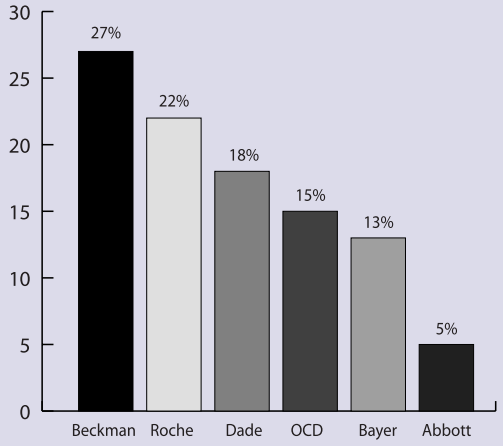
Molecular tests frequently being added to menus include cystic fibrosis genetic analysis, Fragile X, Bordetella pertussis, and Factor V. The benefits include: 1) greatly reduced turnaround times; 2) savings of as much as $100 or more per test; and 3) improved service levels and prestige for existing outreach programs. Among the biggest challenges is finding and hiring experienced molecular pathologists and medical technologists.

For profiles of the molecular testing operations at eight local labs, see *Inside the Diagnostics Industry*, pp. 5-9.

Beckman And Roche Offer Best Value, Says G-2 Survey

Of the six biggest reagent vendors, Beckman Coulter offers the best value (i.e., service plus price), according to an independent survey of 182 labs conducted by Washington G-2 Reports. Beckman was selected as "best value" by 27% of survey participates, followed by Roche Diagnostics at 22%. In the middle are Dade Behring, 18%; Ortho-Clinical Diagnostics (OCD), 15%; and Bayer Diagnostics, 13%. Meanwhile, Abbott Diagnostics was selected by only 5% of labs, suggesting that lab customers may not have forgotten the company's past troubles with the FDA. For more survey details see pages 2-3.

Which major reagent vendor offers the best value *(i.e., service plus price)?*



N=182. Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

▲ **Beckman Offers Best Value,** *from page 1*

Washington G-2 Reports' *First National Reagent Vendor Survey* was sent out via e-mail on Oct. 26, 2004, to approximately 4,000 lab directors, managers, and supervisors throughout the nation. In all, 182 survey forms were completed and returned for a response rate of 5%. Among the survey respondents, 138 were from hospital labs, 33 from independent labs, and 11 from physician office labs.

Survey Demographics

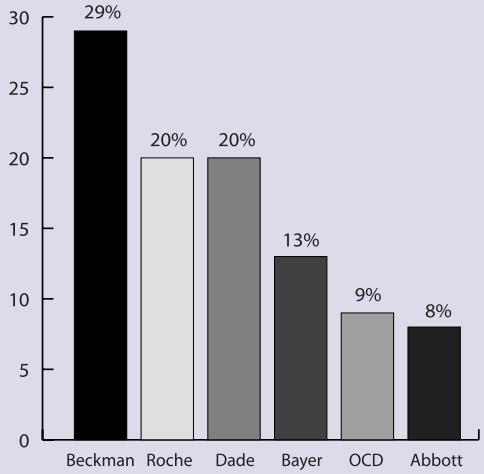
Total survey responses	182 labs
Average annual test volume:	2,315,086
Average annual test volume growth:	6-7%
Average percentage of lab budget spent on reagents:	28.1%

Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

Survey respondents were geographically disbursed. Twenty one respondents came from the Northeast region (ME, NH, VT, MA, NY, CT, RI, NJ); Forty two from the mid-Atlantic (PA, MD, OH, DE, WV); twenty one from the Southeast (VA, NC, SC, GA, FL); twenty five from South Central (TX, LA, MS, AL, OK, AR, TN); thirteen from Central (KS, MO, NE, IA); forty two from North Central (MN, WI, MI, IN, KY, IL, SD, ND); twenty nine from the West (CA, NV, UT, AZ, NM, CO, HI); and nine from the Northwest (WA, OR, ID, MT, WY, AK).

Overall, the average lab in our survey performed 2.3 million tests per year and grew its volume by 6 to 7% over the past 12 months. More specifically, the 138 hospital labs in the survey had average annual volume of 2.2 million tests and reported growth of approximately 6% per year. The 33 independent labs had average annual volume of 3.3 million tests with growth of approximately 7%, and the 11 POLs reported average annual volume of 624,500 tests with growth of 3%.

Which major reagent vendor offers the lowest prices?



N=182; Note: percentages don't add to 100% because of rounding
Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

The overall average percentage of lab budget spent on reagents was 28.1%. More specifically, hospital labs in the survey spent an average of 29% of their budgets on reagents; independent labs, 24%; and POLs, 38%.

Beckman Coulter was cited by 29% of all survey participants as having the lowest prices, while Roche and Dade were each at 20%. Looking strictly at the 138 hospital lab survey participants, 31% said Beckman had the lowest prices; Roche and Dade Behring were each at 22%; OCD, 12%; Bayer, 10%; and Abbott, 4%.

Roche was cited by 26% of all survey participants as being the most responsive to answering questions and fixing problems. Beckman was second at 23%, followed by Dade at 18%. Looking strictly at the 138 hospital lab survey participants, 26% said Roche was the most respon-

sive; Beckman, 24%; Dade, 20%; OCD, 17%; Bayer, 11%; and Abbott, 1%.

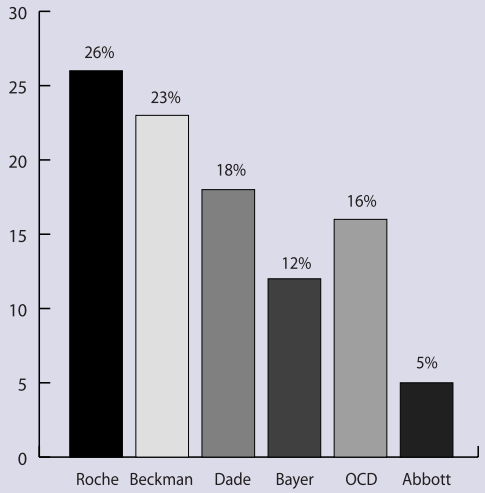
Beckman was cited by 28% of all survey participants as the reagent vendor that sells the most reliable instruments and reagents, followed by OCD at 23%. Looking strictly at the 138 hospital lab survey participants, 26% said Beckman was the most responsive; OCD, 25%; Roche, 21%; Dade, 19%; Bayer, 8%; and Abbott, 1%.

Twenty-eight percent of all survey participants selected Beckman as having the most technologically advanced instrument systems; Roche was second with 19%. Among the 138 hospital lab survey participants, 29% said Beckman was the most technologically advanced; Dade, 19%; Roche and OCD were tied at 18%; Bayer, 14%; and Abbott, 2%.

In summary, Beckman was selected as the top major reagent vendor for four out of five of the categories in the survey, including best value, lowest prices, most reliable instruments, and most technologically advanced instruments. Roche got top honors in one category: most responsive to answering questions.

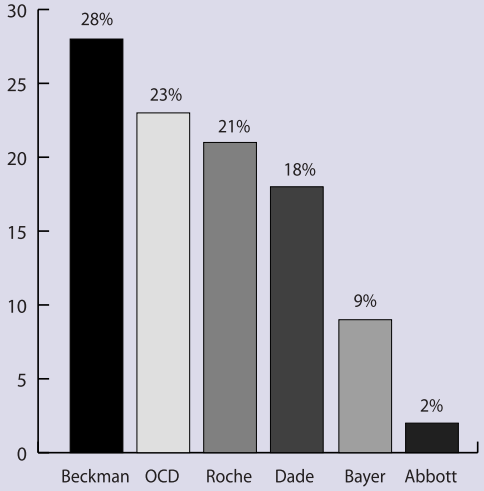
If you would like more details about Washington G-2 Reports' *First National Reagent Vendor Survey* contact *DTTR's* editor, Jondavid Klipp, at *labreporter @aol.com*.

Which major reagent is the most responsive to answering questions and fixing problems?



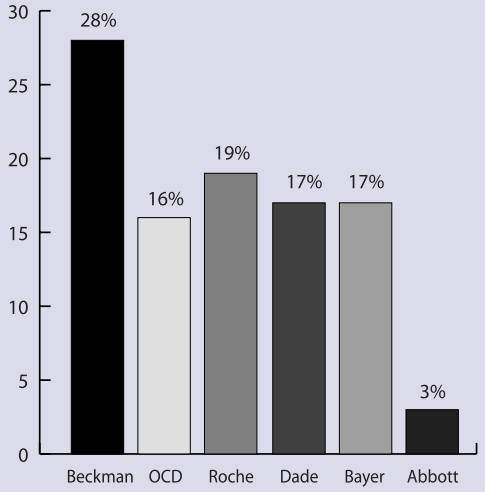
N=182; Note: percentages don't add to 100% because of rounding
Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

Which major reagent sells the most reliable instruments and reagents?



N=182; Note: percentages don't add to 100% because of rounding
Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

Which major reagent has the most technologically advanced instrument systems?



N=182. Source: Washington G-2 Reports' *First National Reagent Vendor Survey*

Ductal Lavage Not Effective For Detecting Breast Cancer, Says Study

Ductal lavage is not an effective method for detecting breast cancer, according to a new study led by researchers at Northwestern Memorial Hospital that appears in the October 20 issue of the *Journal of the National Cancer Institute*.

"This study raises serious questions about the utility of ductal lavage as a cancer detection test and shows us that women should not be offered ductal lavage as a method of breast cancer detection. Mammography and physical examination remain the most effective methods of early detection," said the study's lead author Seema Khan, M.D., interim director of the Lynn Sage Comprehensive Breast Center and surgeon at Northwestern Memorial Hospital (Chicago). However, Khan noted that "ductal lavage does remain promising as a method for obtaining more information about the level of breast cancer risk."

A spokesman from Cytyc Corp., which owns and markets the FDA-cleared ductal lavage procedure, tells *DTTR* that the study's findings aren't surprising given that ductal lavage is not designed, approved, or marketed for breast cancer detection. Rather, he says, it's designed for risk assessment.

Ductal lavage involves the use of a microcatheter to extract cells that have been shed from the lining of milk ducts from the breast of healthy women. These specimens are then sent to a lab for cytologic analysis for abnormalities. Cytyc acquired the ductal lavage technology through the $176 million purchase of ProDuct Health in November 2001. But after three years, the procedure has failed to generate significant revenue and is only in use at a handful of surgical centers around the country. Cytyc says it's now in the process of recruiting patients for a five-year study—Serial Evaluation of Ductal Epithelium—that it hopes will bolster the scientific data behind the procedure.

Roche's Madaus Leaving To Join Millipore

Martin Madaus, age 45, has resigned as president of Roche Diagnostics (Indianapolis) to become chief executive of Millipore Corp. (Billerica, MA), no later than Feb. 1, 2005. A Roche spokeswoman says that Heino von Prondzynski, head of Roche's global diagnostics operations, will oversee the U.S. operations until Madaus' successor has been found.

Madaus had led Roche's U.S. diagnostics business, which employs approximately 4,000 people and has annual revenue of more than $1.7 billion, since January 2004. Prior to that, he was vice president of business development for Roche Molecular Diagnostics.

Millipore, which was founded in 1954, has been a pioneer in developing membrane technology in filtration, purification, and sterilization equipment for medical use. The company has 4,200 employees, annual revenue of $1 billion, and is located in a suburb of Boston.

Molecular Diagnostics Going Local

An increasing number of hospitals and academic medical centers are developing or enhancing their molecular testing menus. Here's a quick look at what eight such labs are doing:

Mark Micale, Ph.D.

Mark Micale, Ph.D., F.A.C.M.G., became director of the Center for DNA Diagnostics at **Mercy Integrated Laboratories** (MIL-Toledo, OH) in August 2003. At that time, MIL was performing molecular tests for infectious disease. Micale was hired with the go-ahead to build a full-scale clinical genetics lab. In late 2003, MIL opened a cytogenetics lab, and this past summer it added DNA testing capabilities.

Micale says MIL acquired state-of-the art equipment to support its two genetics labs, which employ a combined seven people. "The outlay for building a full-service genetics lab is between $250,000 and $500,000 depending on your scope of service," says Micale. The initial test menu in MIL's molecular diagnostics lab included Factor V Leiden, Factor II, hereditary hemochromatosis, and MTHFR testing. More recent additions include cystic fibrosis genetic screening and DNA parentage testing. And Micale expects to add Y chromosome microdeletion and Prader-Willi/Angelman Syndrome methylation testing by year's end. Molecular oncology capabilities will be added next year, along with additional genetic tests, he says.

Molecular testing volume is currently running at approximately 2,000 tests on an annualized basis. MIL is part of Mercy Health Partners, and its new molecular diagnostic lab will ultimately serve all five Mercy hospitals in the Northwest Ohio region plus affiliated physician clinics. MIL is also marketing the service to its outreach clients and other hospitals as well, says Micale.

"We've gained carry over routine business from physician offices since we've opened our genetics lab. They don't want to fill out three or four requisitions from different labs, and they want reports that look similar for all their lab tests. A major selling point is our consultative service. It's harder for doctors to reach someone to talk with at a national lab. I give my pager and office number to our clients, and they can call me directly anytime," says Micale.

Gregory Tsongalis, Ph. D.

Gregory Tsongalis, Ph.D. became director of molecular pathology at **Dartmouth-Hitchcock Medical Center** (Lebanon, NH) in February 2004 with the mandate of modernizing and expanding Dartmouth-Hitchcock's existing molecular diagnostics lab. Tsongalis was formerly with Hartford Hospital in Connecticut where he directed the lab to an annual test volume of approximately 40,000 molecular diagnostic tests per year from a small number of Southern blot based tests when he first arrived in 1994.

Among the first changes Tsongalis made at Dartmouth-Hitchcock was to shift its Southern blot testing from radioactively-labeled DNA probes to the newer chemilumenesence method. Tsongalis says the switch helped eliminate the large

For more on molecular testing be sure to listen in on Washington G-2's next audio conference: **Building a Molecular Diagnostics Lab: Practical Advice from Two Experts Who have Been There and Done That** *on December 7. Go to* www.g2reports.com *for more details.*

cost of disposing radioactive material, improved employee safety, and decreased turnaround times for Southern blot tests to one week versus two to three weeks.

When he first arrived, Tsongalis says the molecular lab at Dartmouth-Hitchcock was performing approximately 7,000 tests per year with a menu that included B & T cell gene arrangement studies for lymphoma, Factor V, Factor II, MTHFR, Bordetella pertussis, and HSV as well as genetic testing for Fragile X and Prader-Willi/Angelman Syndrome. He anticipates a 10% to 20% annual increase in overall test volumes as the laboratory continues to expand its menu.

Since he has arrived, Tsongalis has added viral load testing for HIV and hepatitis C and is in the process of validating tests for hepatitis C genotyping and quantitative tests for cytomegalovirus (CMV) and BCR/ABL. Tsongalis estimates that a routine lab that's adding a molecular diagnostics menu of five or six tests could require as little space as 300 square feet and a capital budget for instrumentation of less than $100,000. "It's not nearly as expensive as getting a new chemistry system," he notes.

Tsongalis says the savings for each test brought inhouse can be substantial. For example, he says reference labs typically charge between $200 and $500 for hepatitis C genotyping, but it can be performed for less than $100 if brought inhouse. "The national reference labs need to take a close look at their pricing. When you get greedy, you lose business," he adds.

Dartmouth-Hitchcock will, of course, offer its new molecular tests to its own hospitals and the Dartmouth-Hitchcock Clinic (a network of more than 900 primary and specialty care physicians located throughout New Hampshire and Vermont). But Tsongalis says there are also plans to market the molecular testing services to the Dartmouth-Hitchcock Alliance, a regional network of 13 hospitals in New Hampshire, Vermont, and Massachusetts.

Jay Schamberg, M.D.

Jay Schamberg, M.D., general manager of **ACL Laboratories** (West Allis, WI and Chicago, IL), expects a big boost to ACL's routine and molecular testing volumes in Illinois beginning next year. That's because it's bringing inhouse capitated lab contracts with eight Advocate Health Care physician-hospital organizations (PHOs) now served by Quest Diagnostics.

ACL Laboratories is jointly owned and operated by Advocate Health Care, the largest health system in Illinois, and Aurora Health Care, the largest health system in Wisconsin. ACL manages the labs at 22 Advocate and Aurora hospitals plus about 70 physician clinics. Current annual volume totals 14 million tests, including 15,000 molecular tests.

The eight contracts cover the lab work for 175,000 patients and will add between two million and four million annual tests to ACL. To handle the increase, ACL has built a new 75,000 square-foot freestanding lab in Rosemont, Illinois, immediately adjacent to Chicago's O'Hare Airport. The new facility includes 700 square feet for ACL's molecular diagnostics lab.

ACL currently performs about 18 different molecular tests, including HIV and hepatitis C viral load, herpes simplex, and B-cell gene arrangement. Tests that

will soon be added include Bordetella pertussis, cystic fibrosis genetic analysis, and T-cell gene rearrangement.

Schamberg advises hospitals seeking to add molecular testing capability to hire an experienced scientist to manage the effort. "Some vendors say they have FDA-approved platforms, but in all likelihood you'll be dealing with ASRs and will need a doctoral-level individual with appropriate training," he says.


Andrea Ferreira-Gonzalez, Ph.D.

Andrea Ferreira-Gonzalez, Ph.D., director of the molecular diagnostics laboratory at **Virginia Commonwealth University Health System** (VCUHS-Richmond), says the ability to provide molecular tests has been a marketing plus for VCUHS's routine outreach business. Given the choice, she says physicians prefer to have a test performed locally because it's easier for them to get in touch with a pathologist to answer questions.

The molecular diagnostics lab at VCUHS, which goes by VCU Molecular Diagnostics, takes up 6,400 square feet of space and employs 18 people, including eight that perform clinical testing and seven who are focused on validation of new assays for different clinical applications, such as microarray technology and pharmacogenetics. Annual test volume is 15,000, excluding Chlamydia/gonorrhea, and is growing by 20% per year, according to Ferreira-Gonzalez.

VCU Molecular Diagnostics currently offers approximately 20 tests, including HIV and hepatitis C viral load and genotyping, Her-2/neu, Fragile X, Factor V, cystic fibrosis genetic analysis, and B & T-cell clonality. New tests being considered for menu expansion include CYP450 microarrays for determining a patient's metabolism for prescribed drugs and bacterial identification through gene sequencing, according to Ferreira-Gonzalez.


Jerry Baldwin, M.D.

Jerry Baldwin, M.D., physician executive partner at **MeritCare Laboratory Services** (MLS-Fargo, ND), says his lab became a Roche Molecular Center of Excellence this past spring. In return for choosing Roche as its main molecular diagnostics vendor, MLS gets free supplies for the validation of new molecular tests it adds to its menu plus first-in-line treatment for new tests introduced by Roche, according to Baldwin.

MLS operates one molecular diagnostics lab at MeritCare Main Campus and MeritCare South University—these two sites, along with MLS, are each part of MeritCare Health System. The current molecular test menu at MLS includes Chlamydia/gonorrhea, Group A strep, Bordetella pertussis, Factor V Leiden, and Factor II polymorphism. MLS is looking to add four more tests to the menu: herpes simplex, Group B strep, cytomegalovirus, and MRSA, according to **Sandra Matthey, M.T.**, executive partner at MLS.

MLS has four lead technologists who validate, implement, and train other lab staff on each new molecular test. Matthey says that because nearly all of the molecular tests are sold as analyte-specific reagents (ASRs), there is a strong need for interaction with other molecular lab professionals.

Roche is limited in the technical advice it can give, but it has introduced MLS to other Roche Molecular Center's of Excellence that can share information. In

addition, Matthey says that Mayo Medical Labs, the reference lab for MLS, has been very cooperative in providing technical advice. "The technology is improving, but it's not yet push button and walk away…Setting up a molecular diagnostics lab takes a big commitment," she adds.

Matthey says MLS's physician clients have been very appreciative of the lab's efforts to expand its molecular diagnostics menu. The one exception has been Group A strep; some physicians still prefer the traditional rapid tests that they can do in their offices. MLS currently performs about 8,000 molecular tests per year, but that figure will grow to 40,000 after full implementation of molecular-based Group A strep testing, says Matthey.

Thomas Williams, M.D.

Thomas M. Williams, M.D., director, genetics and cytometry, **TriCore Reference Laboratories** (Albuquerque, NM), says the ability to offer molecular diagnostics promotes a stronger relationship with TriCore's physician office clients.

TriCore is an independent reference lab owned by the University of New Mexico, Presbyterian Hospital, and St. Vincent's Hospital. TriCore has a total of about 800 employees, including 18 at its molecular diagnostics lab. TriCore provides outreach testing services throughout New Mexico, Colorado, and western Texas.

Williams says the molecular diagnostics lab at TriCore currently performs about 132,000 tests per year, and its menu includes more than 20 different tests, including cystic fibrosis genetic analysis, hereditary hemochromatosis, genotyping and viral load testing for HIV and hepatitis, DNA-based HPV testing, and HLA allele identification for transplant patients.

Williams says the decision to add a test to the menu is based on a number of factors, including: 1) clinical utility; 2) ease of adding onto existing instrument systems; 3) potential testing volumes; 4) cost savings versus sending out; and 5) potential educational value to pathology residents and fellows at University of New Mexico's School of Medicine for which Williams is a professor of pathology.

Tests expected to soon be added to TriCore's menu include Fragile X, an expanded cystic fibrosis screen that will look for 40 to 50 gene mutations (up from 33 with current test), and quantitative real-time PCR assays to detect chimeric gene transcripts in leukemias and lymphomas.

Given that Albuquerque lacks a big biotechnology industry base, Williams says that one of the biggest challenges is finding medical technologists with backgrounds in molecular biology/diagnostics.

David Ziemba, M.D.

"The most important piece of advice I can give to hospitals building a molecular diagnostics lab is to proceed slowly. Start with one or two tests and add more over time. You don't want to overwhelm your techs or instrumentation," advises **David Ziemba, M.D.**, medical director for the labs at St. Luke's Hospital and Tobey Hospital, which, along with Charlton Memorial Hospital, are part of the **Southcoast Health System** in southeastern Massachusetts.

Ziemba speaks from experience. This past summer, he oversaw the opening of a molecular diagnostic lab at St. Luke's Hospital. The initial test menu included

viral load testing for HIV and hepatitis C, and Digene's DNA-based HPV test. In September, an immunohistochemistry lab with six tests was added, including tests for Her-2/neu, estrogen/receptor, progesterone/receptor, EGFR for determining Erbitux prescriptions, H. pylori for gastroesophageal reflux disease (GERD) patients, and cytokeratins expression for prostate cancer evaluation.

The new molecular diagnostics lab serves the three Southcoast hospitals as well as their outreach program. Current volume totals 1,200 to 1,300 tests per month and is growing rapidly, according to Ziemba. Among the tests that Ziemba expects to add soon include the UroVysion FISH test for diagnosing bladder cancer recurrence and a reflex FISH test for Her-2/neu scores of 1+ or 2+.

He says molecular testing has been a boon to Southcoast's outreach program. "We're able to turnaround tests for HIV, HCV, and HPV within 24 to 48 hours and tests for ER and PR receptors and Her-2/neu in less than 24 hours versus waiting a week for results from a reference lab. We're allaying patient anxiety and allowing doctors to rapidly institute therapies," explains Ziemba.

Jane Rachel

Jane Rachel, MT (ASCP), M.A., who manages the molecular diagnostics lab at **St. Luke's Hospital** (Kansas City, MO), advises new molecular diagnostics labs to start off with real-time PCR technology rather than conventional PCR because it's the way all PCR-based testing is moving. "It's much less complex technically, the instruments are smaller, and it's much quicker overall," notes Rachel.

The molecular lab at St. Luke's, which performs some 25,000 tests per year, has a current menu of 13 tests, including cystic fibrosis genetic analysis, HIV and hepatitis C viral load testing, Factor V, and CMV quantification, according to Rachel. Tests expected to be added soon include DNA-based HPV, MRSA, and vancomycin-resistant enterocci (VRE).

Regarding cost savings, Rachel notes that it costs St. Luke's a little over $100 for each quantitative test for HIV, hepatitis C, or CMV that it performs inhouse, or less than half what the reference labs charge. "The real limiting problem to growing our molecular lab is finding employees with expertise," says Rachel.

A Snapshot of Eight Molecular Diagnostics Labs

Laboratory	Annual Molecular Test Volume	Expects to bring Inhouse	Primary Reference Lab
ACL Laboratories	15,000	Bordetella pertussis, cystic fibrosis, T-cell gene rearrangement	ARUP, Quest
Dartmouth-Hitchcock	7,000	HCV genotyping, CMV quantification, and BCR/ABL quantification	Mayo
Mercy Integrated Labs	2,000	Y chromosome micro deletion Prader-Willi/Angelman Syndrome	ARUP
MeritCare	8,000	herpes simplex, Group B strep, CMV, MRSA	Mayo
Southcoast Health System	15,000	UroVysion FISH, reflex FISH test for Her-2/neu	Specialty Labs
St. Luke's Hospital	25,000	DNA-based HPV, MRSA, VRE	Mayo
TriCore Reference Labs	132,000	Fragile X, expanded CF screen, chimeric gene transcripts	ARUP
VCU Molecular Diagnostics	15,000	CYP450 microarray, bacterial identification by gene sequencing	LabCorp

Source: *DTTR* from labs

What's Next For The National Reference Laboratories?

In the five years ended December 2003, the national market for esoteric testing services, including gene-based tests, cancer diagnostics, and other esoteric tests, has grown by an average of 15% to 20% per year, reaching $3.7 billion in 2003, according Washington G-2 Reports' *Lab Industry Strategic Outlook Report**. This includes about $2.3 billion of esoteric testing business sent out by hospital laboratories and $1.4 billion from independent labs and physician offices.

Washington G-2 Reports defines the esoteric testing market as those tests that are too complex and too low in volume to be performed within a hospital or routine independent lab plus, similarly complex tests sent out by physician offices. It should be noted that a precise definition of esoteric testing is difficult because as test volumes increase and automation improves for a particular esoteric test, it eventually becomes more routine in nature.

The growth in the esoteric testing market has been a boon for the national reference labs. The profit margins at Quest Diagnostics, LabCorp, Mayo Medical Labs, ARUP Labs, Genzyme Genetics, etc. have all been fattened by an unusually strong wave of high-margin molecular tests that have been introduced to the market over the past few years, including viral load testing and genotyping for HIV and hepatitis C, cystic fibrosis genetic analysis, and DNA-based HPV testing.

Top Esoteric Testing Labs by Estimated Annual Revenue *($MM)*

	2003	Market Share
Quest Diagnostics	$1,000	27%
LabCorp	889	24%
Genzyme Genetics	246	7%
Mayo Medical Laboratories	200	6%
ARUP Laboratories	190	5%
Specialty Laboratories	120	3%
Esoterix	107	3%
US Labs	54	1%
Athena Diagnostics	50	1%
Focus Technologies (lab services only)	40	1%
Prometheus Labs (lab services only)	40	1%
AmeriPath	39	1%
Myriad Genetics	35	1%
Pathology Partners	35	1%
ViroLogic	33	1%
Bio Reference Labs	31	1%
Total, 16 labs	3,109	85%
Other labs	546	15%
Grand total	$3,655	100%

Source: *Lab Industry Strategic Outlook 2005*

But as more and more local labs build and expand their molecular diagnostics capabilities they are: 1) reducing their send-out volumes to the national reference labs; and 2) competing in the market for esoteric-testing business from physician offices and smaller hospitals. As a result, *DTTR* believes the growth rate for the esoteric testing market (i.e., send outs to the national reference labs) is slowing down to the 10% to 15% range and pricing is starting to drop as well.

The national reference labs are now scrambling to find their next growth driver in esoteric testing. *DTTR* believes the next big thing could be either DNA microarrays (in particular, Roche's AmpliChip) or Correlogic's protein-pattern recognition system, but commercial launch of each product has been delayed a year and counting by the FDA.

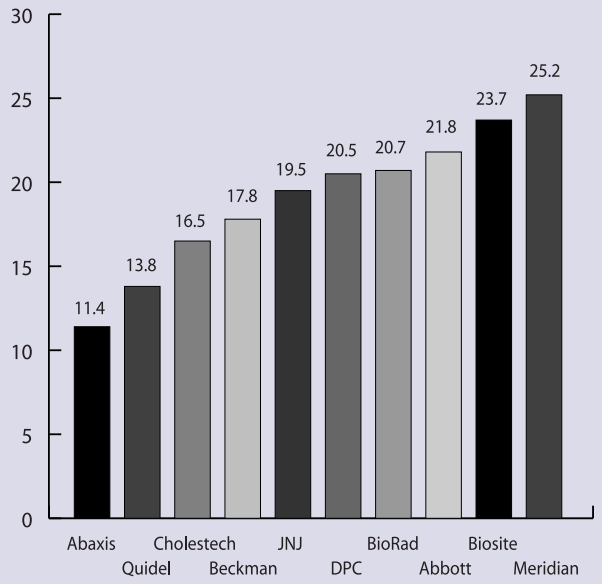
IVD Stocks Rise 4%; POCT Stocks The Cheapest

Five of the 10 cheapest IVD stocks are point-of-care test makers: Abaxis, Quidel, Cholestech, Biosite, and Meridian.

The 20 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 4% in the month of October, with 13 stocks up in price, six down, and one unchanged. Year to date, the G-2 Index is up 20%, while the S&P 500 Index is up 3% and the Nasdaq is unchanged.

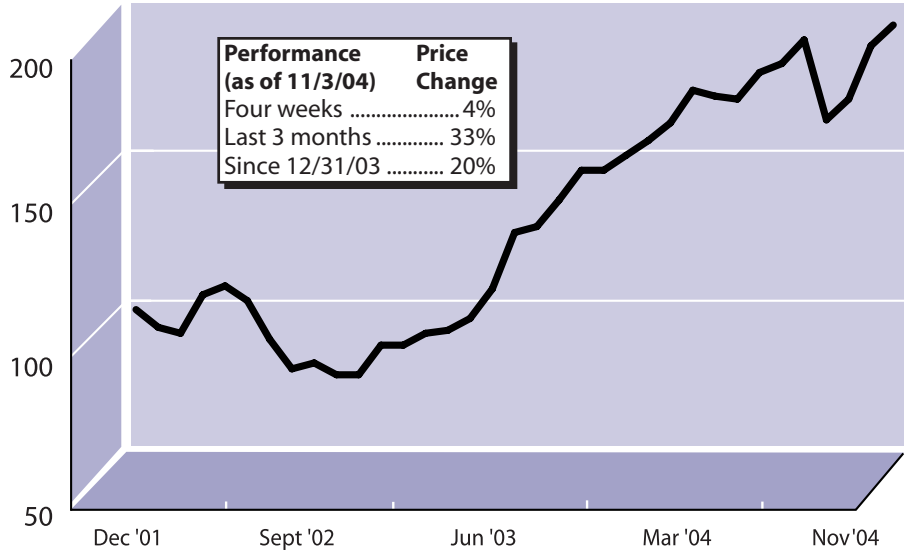
Which IVD stocks are the cheapest on a price-to-earnings basis (i.e., share price/trailing 12 months earnings per share)? The answer is Abaxis, which has a P/E ratio of 11.4. Next lowest is Quidel, which has a P/E of 13.8 largely because its stock price has been beaten down over the past few months due to a benign flu season (the company sells rapid flu tests). Next is Cholestech at 16.5. Among the largest IVD companies, Beckman Coulter had the lowest P/E ratio at 17.8, followed by Johnson & Johnson at 19.5, and Diagnostic Products Corp. at 20.5.

The 10 Cheapest IVD Stocks By P/E



Source: *Reuters* as of November 3

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 20 IVD companies.

% Price Change, Four weeks ended 11/3/04

UP	Price	% Chg
Abaxis	12.88	15%
Abbott Labs	43.61	3%
Beckman Coulter	59.85	5%
Cholestech	8.01	21%
Cytyc	25.55	5%
Diagnostic Products	45.65	9%
Inverness Medical	21.01	3%
Johnson & Johnson	59.45	4%
Meridian	13.40	2%
OraSure	7.33	19%
Quidel	5.60	24%
Third Wave	7.82	2%
Ventana	54.23	6%
UNCHANGED		
Bio Rad	53.50	0%
DOWN		
Becton Dickinson	51.70	-2%
Biosite	48.75	-5%
Dade Behring	52.14	-7%
Digene	26.20	-3%
Gen-Probe	31.95	-22%
Immucor	25.67	-2%

G-2 Insider

The American Red Cross (ARC) says its closing four of its regional blood-testing labs with the aim of streamlining its business in the face of growing competition. The labs will be closed in March 2005 and include facilities in Boston, MA, Atlanta, GA, southern California, and St. Paul, MN. The Red Cross says blood testing will be consolidated at its five remaining labs.

In recent years, hospitals have become dissatisfied with the Red Cross's high prices and inflexibility, and many have turned to independent blood centers or started their own blood collection operations (see *DTTR*, October 2003, page 1). Blood expenses make up 13% of the average hospital labs budget and have been rising by more than 10% in each of the past several years, according to data from Park City Solutions/ Laboratory Services Group.

"Over the last several months, we did an evaluation of our operations and that indicated that changes were necessary," said Stephanie Millian, Red Cross spokeswoman. "The main objective is to streamline operations, save money and take advantage of excess lab capacity," she said. Other recent changes made by the Red Cross have included giving hospitals the choice of buying less-expensive non-leukocyte-reduced blood.

But it may all be a little too late in the eyes of some Red Cross customers. After years of frustration, some hospitals around the country have already made the decision to seek alternatives to the Red Cross. For example, Harton Regional Medical Center (Tullahoma, TN) recently announced plans to make Blood Assurance Inc. (Chattanooga, TN) its sole provider of blood and blood products, citing savings of up to $100 per unit versus Red Cross.

Company References

ACL Laboratories
800-877-7016

Beckman Coulter
714-871-4848

Cytyc Corp. 978-263-8000

Dartmouth Hitchcock
603-650-5000

Mercy Integrated Laboratories
419-251-8383

MeritCare Laboratory
701-234-2401

Southcoast Health System
800-497-1727

St. Luke's Health System
816-932-3377

TriCore Reference Labs
505-224-7999

VCU Molecular Diagnostics
800-363-9234

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