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LABORATORY INDUSTRY REPORT®

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Sisters Of St. Francis And Provena To Merge Lab Systems

Sisters of St. Francis Health Services (SSFHS-Mishawaka, IN) and Provena Health (Mokena, IL) have announced plans to merge their laboratory services. The top objective of the integration is to create the economies of scale necessary to bring in-house more than 80 esoteric tests, especially in the area of molecular diagnostics, according to Jim Sparks, Ph.D., who will serve as executive vice president of the new organization.

The combined lab system will include approximately 1,300 employees, or 1,000 FTEs, at 22 lab facilities throughout northern and central Illinois and Indiana. The operation, which has not yet been given a name, will perform more than 10 million billable tests per year, making it one of the largest hospital lab systems in the nation.

Alverno Clinical Laboratories (Hammond, IN), an independent lab owned by SSFHS, will serve as the primary reference lab for the combined lab system. The announcement of the SSFHS/Provena lab merger follows a growing list of health systems combining lab operations to reduce send outs, gain negotiating leverage with managed care plans, and build outreach. More details, pp. 5-7. 

Medicare Cuts Sting Flow Cytometry Labs

New CPT codes and reimbursement rates that became effective on January 1 will lead to a severe reduction in the revenues generated by flow cytometry labs, according to coding expert Charles Root, Ph.D., president of CodeMap (Barrington, IL). Root estimates that the changes to the 2005 physician fee schedule will result in an average 40% to 50% reduction in the annual Medicare revenue (including technical and professional charges) earned at the typical flow cytometry lab.

Despite letters of protest to CMS from several laboratory and diagnostic trade groups, Root says, "It's a final rule on the physician fee schedule. I see no chance of any change."

Furthermore, he expects managed care plans to follow suit and begin cutting their flow cytometry rates by a similar, if not greater, amount than the new Medicare fees over the course of the next year. "Flow cytometry is still a good business, but it will take a few years for labs and pathologists to regain their revenue levels," observes Root. ➤ p. 2



■ MEDICARE CUTS STING, from page 1

In the 2005 physician fee schedule, five new CPT codes have replaced CPT 88180 (flow cytometry; each cell surface, cytoplasmic or nuclear marker), which has been deleted. The change means that flow cytometry work performed by laboratories and pathologists will now be reimbursed on a per-interpretation basis, rather than a per-marker basis.

Root believes CMS made the change to counter the growing number of markers that are now being tested per specimen, which has resulted in an explosion in flow cytometry reimbursement. "Ten years ago, an average of four or five markers were tested per specimen, now it's common for twenty, thirty, or even one hundred markers to be tested," he notes.

As an example of the impact the reimbursement change will have on laboratories and pathologists, Root cites a common flow cytometry procedure: leukemia/lymphoma bone marrow evaluation of Total T-cell and NK cell counts plus 10 markers (see table below). Lab reimbursement for this procedure now totals \$371.40, compared with \$595.40 in 2004—a 38% reduction. Pathologist reimbursement now totals \$86, compared with \$200 in 2004—a 57% reduction. Total payment has decreased from \$795.40 to \$457.40—a 42% reduction.

Flow cytometry had been one of the fastest-growing and most profitable areas of the lab testing business, and the reimbursement cut must be particularly painful to several of the national reference labs that have made substantial investments in this area.

For example, **LabCorp** (Burlington, NC) just announced plans to acquire **US Labs** (Irvine, CA), a national provider of flow cytometry services, for \$155 million (see *LIR*, January 2005, p. 3). This follows LabCorp's \$605 million acquisition of the anatomic pathology firm **Dianon** (Stratford, CT) in January 2003. In addition, **Genzyme Genetics** (Westborough, MA) made a major commitment to the cancer-testing market by spending more than \$250 million last year to purchase **Impath** (New York City) and **Alfigen** (Pasadena, CA).

Medicare Reimbursement for a Typical Flow Cytometry Procedure

	2004	2005	Change
Laboratory/Technical Charges			
86359 (absolute T cell count)	\$ 52.70	\$ 52.70	
86379 (natural killer cell count)	52.70	52.70	
88180-TC x 10	490.00		
88184 (first marker)	50.00		
88185 x 9 (each additional marker)	216.00		
Total	595.40	371.40	-224.00
Pathologist/Professional Charges			
88180-26 x 10	200.00		
88189 (9-15 markers)	86.00		
Total	200.00	86.00	-114.00
Grand Total Reimbursement	\$795.40	\$457.40	-\$338.00
Source: CodeMap			

So far, the only major lab to publicly announce how the Medicare cuts might impact their business has been **Bio-Reference Labs** (Elmwood Park, NJ). Bio-Reference says that if the changes had been in effect during 2004, the company's revenue of \$136.2 million would have been reduced by about 2% (\$2.6 million), while its pretax income of \$12.2 million would have been lowered by nearly 20% (\$2.3 million). The damage will be even more severe if managed care companies initiate similar cuts, observes *LIR*.



Update: Memorial Hermann Launches Outreach Program

Memorial Hermann Healthcare System (MHHS—Houston, TX) is back in the outreach business, Jim Faucett, vice president of lab services at MHHS, tells *LIR*. He says the program became operational in July 2004—about two months later than initially planned (see *LIR*, February 2004, pp. 3-4).

Despite the delay, Faucett says the program, which is based at Memorial Hermann Hospital's main laboratory, is running ahead of projections. The progress includes the opening of two new patient services centers in the Houston area and the hiring of two sales people. He says MHHS will open another nine or 10 PSCs over the next three years. Billing for the new outreach business is flowing through the hospital's billing system, but several people have been dedicated to specifically monitor the outreach claims and review denials.

Faucett says the outreach program is targeting the 6,000 physicians that have admitting privileges to the nine hospitals that are part of MHHS, including Memorial Hermann Health Network Providers, a 3,000-physician independent physician association (IPA).

His biggest competitor in Houston is LabCorp/Dynacare. Memorial Hermann Hospital had a long-term lab management contract with Dynacare (which LabCorp acquired in July 2002), but chose to terminate the agreement and in source management of its lab effective October 2001. After a two-year non-compete contract ended, MHHS chose to get back into the outreach business.

In addition to LabCorp/Dynacare, Faucett notes that Quest Diagnostics and Clinical Pathology Laboratories (Austin, TX) each have a presence in Houston. "Getting market share is a challenge. . . There's a certain level of inertia at physician offices. They get used to their routine of sending tests to a particular lab," he says. Another challenge has been pricing competition. "The test prices are quite a bit lower than the Medicare fee schedule," he observes.

Note: Jim Faucett will be a featured speaker at Washington G-2's upcoming conference: "*Building Profitability in a Competitive Outreach Market*" March 31 to April 1, 2005, at the Renaissance Concourse Hotel (Atlanta, GA). For more info go to www.g2reports.com. 

MDS, Duke End Lab Management Agreement

MDS Inc. (Toronto, Canada) says that it has discontinued its lab management contract with Duke University Health System (Durham, NC) effective Oct. 31, 2004. The agreement had initially been announced in December 2001 and had called for MDS to integrate and manage the Duke labs, including those at the Duke University Hospital, the Raleigh Community Hospital, and the Durham Regional Hospital. Duke and MDS had also signed a letter of understanding to form a joint venture to provide outreach laboratory services for the region, although this initiative never got off the ground.

The move nearly completes MDS's exit from its money-losing lab business in the United States. In March 2004, MDS sold its New York and Georgia labs to LabCorp. And, in November 2004, it sold its interest in Memphis Pathology Laboratory to American Esoteric Laboratory (Brentwood, TN).

MDS's remaining operations in the U.S. laboratory market now consist of a 50% interest in a south Florida lab partnership with HCA Inc. called Integrated Regional Laboratories. The management services agreement for this joint venture expired on Dec. 31, 2004, and MDS says it's in discussions with HCA to terminate its involvement with these operations by June 30. 

IBT Reference Laboratory Raises \$5 Million

IBT Reference Laboratory (Lenexa, KS), a specialty lab focused on allergy, clinical immunology, and molecular biology, has raised \$5 million from the venture capital firm Ampersand Ventures (San Diego, CA). Ampersand now has a 55% stake in IBT, while John Halsey, Ph.D., founder and president of IBT, owns 45%. Ampersand general partners David Parker and Herb Hooper, Ph.D., are also joining Halsey to form a three-member board of directors for IBT, with Parker as chairman.

IBT is profitable and currently generates annual revenue of approximately \$5 million, including 78% from reference lab testing and 22% from clinical trials testing for drug companies, according to Halsey. He says the funds will be used to expand IBT's clinical trials testing business by making acquisitions.

He says IBT has been growing by roughly 15% per year for the past five years, with the highest growth coming from its clinical trials testing business. "Several factors are driving this demand, including the emergence of innate immunity as

a major area of research interest, recent FDA guidance regarding immunotoxicity and immunogenicity testing for new drugs, and an increased interest in establishing and monitoring biomarkers related to immune system response during clinical trials," explains Halsey.

In addition, he says IBT is seeking to expand its reference lab business by adding new tests, particularly in the areas of immunogenomics (i.e., polymorphisms, or

SNPs, in genes that regulate patient immune responses), cellular immune function tests, and immunotoxicology panels.

Halsey believes IBT has the potential to grow its annual revenue to \$20 million to \$50 million over the next two to four years. He notes that IBT doubled its lab capacity when it moved into a new 26,500-square-foot facility in August 2004.

Halsey founded IBT in 1983 after leaving his job as a professor at the University of Kansas School of Medicine. Halsey is also founder of Personal Diagnostic Center (Lenexa, KS), a direct-access testing business that was sold to Quest Diagnostics in November 2000. 

IBT Reference Lab at a Glance

Chairman:	David Parker
Founder and president:	John Halsey, Ph.D.
Headquarters/lab:	Lenexa, KS (26,500 sq. feet)
Employees:	46 FTEs
Annual revenue:	\$5 million
Inception:	1983
Source:	IBT	

INSIDE THE LAB INDUSTRY

Two Catholic Hospital Systems Join to Reduce Sendouts

Cheryl Vance, who will be president of the merged SSFHS and Provena lab system, tells *LIR* that the biggest challenge of combining the two lab systems will be execution. The key is first having a complete integration plan that covers the integration timeline, quality indicators, information system connectivity, etc., and then moving through the implementation process quickly.



Cheryl Vance, 57, currently president of MedCentre Labs, will be president of the merged lab system. Prior to joining MedCentre in September 2002, Vance had served as vice president of Illinois operations at ACL Laboratories (Chicago, IL and Milwaukee, WI), where she was involved with the integration of the labs at Advocate Health Care and Aurora Health Care.

Vance expects the testing integration of SSFHS and Provena labs to begin in July. The merged system is expected to reduce overall lab costs by approximately 5%, primarily from reducing send outs to reference labs and renegotiating vendor contracts. Vance would not disclose the budget for the two lab systems, but *LIR* estimates it's somewhere around \$100 million per year. So

a 5% cost reduction would result in roughly \$5 million of annual savings.

Sparks says the idea to merge the lab operations of Sisters of St. Francis Health System (SSFHS) and Provena was initiated by the hospital CEOs. SSFHS and Provena are both Catholic health systems, and Kevin Leahy, chief executive of SSFHS, and William Foley, chief executive of Provena, knew of one another through this connection, according to Sparks.



Jim Sparks, Ph.D., 60, will be executive vice president and will manage the core lab that will serve the merged lab system. For the past six years, Sparks has served as president of Alverno Clinical Labs, the core lab for SSFHS. Prior to that, he worked at a consulting practice in North Carolina that focused on pathologist needs. Sparks has also held executive positions at Specialty Laboratories and Genetic Design Inc. (Greensboro, NC), an identity testing lab that was acquired by LabCorp in 1996.

He says the consulting firm Sprick, Stegall & Associates (New Orleans, LA, and Charlotte, NC) was hired in mid-2003 to perform a feasibility study. The consultants came back with an initial report in November 2003 that indicated that combining the two lab systems could expand their breadth of services

and reduce costs. A more in-depth plan was completed in April 2004, and both health system boards gave the green light in December. The final contracts for the merger are in the process of being drawn up. Sparks notes that Sprick, Stegall will not be involved with the implementation of the plan.

Under the plan, a 501e nonprofit corporation will be formed to manage the hospital labs and a taxable limited liability corporation will run Alverno Clinical Laboratories, which currently serves as the core lab and outreach operation for SSFHS's 12 hospitals. Sparks says Alverno will now serve these same functions for Provena's six hospitals as well.



Provena currently operates a core lab and outreach business named MedCentre Laboratories that is located across the street from Provena St. Mary's Hospital (Kankakee, IL), which is 60 miles south of Chicago. MedCentre has approximately 200 FTEs and performs about 700,000 billable tests per year. Non-time sensitive tests from MedCentre and the Provena hospitals will now be sent to Alverno, which is located about 50 miles northeast of MedCentre. Existing courier systems at Alverno and MedCentre will be expanded to cover all hospitals at the combined system. The MedCentre facility will then be refocused on inpatient testing for Provena St. Mary's Hospital.

Sparks says that only 2% of the combined 1,000 lab FTEs at SSFHS and Provena will be cut—either through attrition or retraining to new positions at the health systems.

Alverno currently performs about three million billable tests per year, including 1.2 million at the core lab and 1.8 million at six

inpatient labs it manages for SSFHS. As a result of the merger with Provena plus the expanded test menu, Sparks anticipates that Alverno's core lab test volume will triple to three to four million billable tests per year. With 50,000 square feet plus a Roche automation system that brings tubes to analyzers, he says that Alverno has the capacity for the added volume.

Because of the added volume, Sparks says that Alverno will be able to bring inhouse more than 80 esoteric tests that are now being sent to the national reference labs. Tests that have already been added include DNA-based HPV testing, EGFR (epidermal growth factor receptor), Free T3, homocysteine, and an expanded flow cytometry menu. Other tests that Alverno will add include genotyping for hepatitis and HIV, Factor V Leiden, and a number of tumor markers (e.g., CA 19-9, CA 27-29, etc.).

The combined lab systems currently send out roughly 2.5% of their total test volume. The expanded menu will help cut this

percentage to between 1% and 1.25%, according to Sparks. Doing more testing locally will also reduce turnaround times, he notes.

The primary reference lab for both SSFHS and Provena is currently Quest Diagnostics. However, Vance says that the merged lab system will send out a request for proposals for reference lab services with the

SSFHS and Provena at a Glance

	<i>Sisters of St. Francis Health System</i>	<i>Provena</i>
Hospitals	12	6
Inpatients admissions*	92,309	78,276
Lab employees (FTEs)	650	350
Annual billable test volume	6.5M	3.5M
LIS system	SCC Soft Computer	Meditech
Primary reference lab	Quest Diagnostics	Quest Diagnostics

Core laboratory

	<i>Alverno Clinical Labs</i>	<i>MedCentre Labs</i>
President	Jim Sparks, Ph.D.	Cheryl Vance
Location	Hammond, IN	Kankakee, IL
Employees (FTEs)	400	200
Web-based connectivity	CareEvolve	none
Annual billable test volume**	3.0M	700,000
Annual net revenue (est'd by LIR)	\$35-40M	\$12M

*Inpatient admissions are for 2003; all other data is current

**Test volume for Alverno includes 1.2 million billable tests performed at the core lab plus 2.8 million tests managed at six SSFHS hospitals

Source: LIR from SSFHS, Provena, Alverno, and MedCentre



expectation of receiving pricing reductions. Other factors, including service, quality, and market alignment, will also be considered. More savings are expected to come from standardizing instruments and reagents and renegotiating vendor contracts, she adds.

Less than 10% of the combined annual billable tests from the new lab system will be from outreach and there are no current plans to aggressively expand this business, according to Vance. "We certainly want to use outreach growth to fill the capacity of our central lab and provide a continuum of care for the physicians who use our system's hospitals, but in our current project phase, expanding outreach is less important," she says.

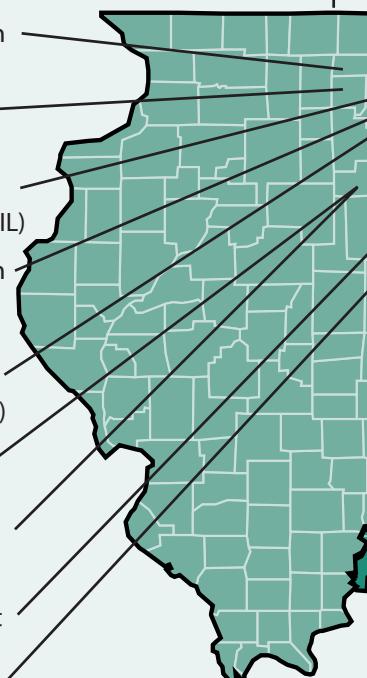
Pathology Consultants Inc. and Pathology Associates of Chicago are the two practices that currently serve Alverno, and there are several other pathology groups that serve

the SSFHS and Provena hospitals. The amount of work that each pathology group will get as a result of consolidation will largely depend on the preferences of the physician clients served by the new lab system, says Sparks. And all pathology practices that will support the new organization will continue to contract with our hospitals, not with the laboratory. In general, pathologist professional component activities will fall outside the purview of the new lab organization to control or specify, he adds.

The SSFHS labs and Alverno all currently use an LIS system from SCC Soft Computer, while the Provena labs and MedCentre use Meditech. Sparks says that these two LIS systems will be connected using SeeBeyond's Datagate/eGate interface engine. Web-based order entry and results reporting to outreach clients will be provided through the CareEvolve system. ■

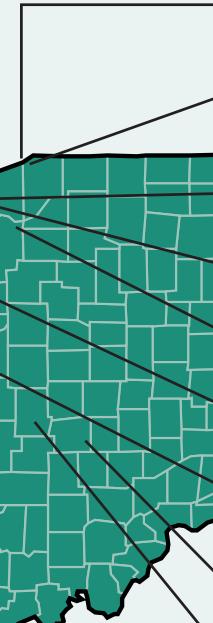
Illinois

- Provena St. Joseph Hospital (Elgin, IL)
- Provena Mercy Center (Aurora, IL)
- St. James Hospital (Chicago Heights, IL)
- Provena St. Joseph Medical Center (Joliet, IL)
- St. James Hospital (Olympia Fields, IL)
- MedCentre Labs (Kankakee, IL)
- Provena St. Mary's (Kankakee, IL)
- Provena Covenant (Urbana, IL)
- Provena United Samaritans (Danville, IL)



Indiana

- St. Anthony Memorial Health Centers (Michigan City, IN)
- Alverno Clinical Labs (Hammond, IN)
- St. Margaret Mercy North (Hammond, IN)
- St. Anthony Medical Center (Crown Point, IN)
- St. Margaret Mercy South (Dyer, IN)
- St. Clare Medical Center (Crawfordsville, IN)
- St. Francis Hospital (Beech Grove, IN)
- St. Francis Hospital (Mooresville, IN)



Spectrum Wins Contract With Cigna

Spectrum Laboratory (Greensboro, NC) has signed a new contract with Cigna Healthcare to be a network provider of lab services in Georgia, North Carolina, South Carolina, Tennessee, and Virginia effective Jan. 1, 2005. The contract covers all Cigna managed care and indemnity health plan members in the five states. Nate Headley, chief executive of Spectrum, says Spectrum had been working to win a contract with Cigna for the past four years. 

Specialty Labs In, LabCorp Out At Premier

Premier Inc. (San Diego, CA) has dropped LabCorp (Burlington, NC) from its list of contracted reference labs. Priscilla Cherry, laboratory consultant director at Premier, says pricing was not the determining factor in the negotiations. "It was terms and conditions that they [LabCorp] chose not to agree to. We have performance guarantees that are crucial to our contracts that we now insist on having," she says.

Specialty Laboratories (Santa Monica, CA) has filled the space left by LabCorp and is now a contracted reference lab with Premier (see *LIR*, December 2004, pp. 1-2). In addition, ARUP Laboratories (Salt Lake City, UT) and Quest Diagnostics have renewed existing contracts with Premier.

Specialty, ARUP, and Quest will compete to provide reference lab services to Premier's 1,450 hospital members. Participating Premier members order approximately \$200 million of reference lab testing per year through its group purchasing agreements. 

New York Hospital Labs Eye Statewide Contracts

A group of 27 hospital labs in the Buffalo, New York area is in the final stages of creating a corporation to manage a lab network to go after statewide managed care contracts, according to Francisco Velazquez, M.D., pathologist in chief at the health system Kaleida Health (Buffalo, NY).

Velazquez is heading up the effort and says the network is being patterned after Joint Venture Hospital Laboratories (Detroit, MI), a lab network with more than 100 hospitals in Michigan and managed care contracts covering roughly one million members. "There's no reason we can't do the same thing in New York," he says.

The proposed name of the network is The Hospital Laboratory Network and it will be owned by four health systems in western New York: Kaleida Health, Catholic Health System, Erie County Medical Center, and Roswell Park Cancer Institute.

Velazquez says these health systems and other local hospitals have already had success in coming together to negotiate a uniform contract (effective Sept. 1, 2004) to provide anatomic pathology and cytology services on a fee-for-service

basis to 525,000 members of Community Blue, the HMO plan of BlueCross BlueShield of Western New York. Quest Diagnostics had previously been the exclusive lab provider to Community Blue.

Velazquez says that he has had informal discussions with executives at Centrex Clinical Labs (New Hartford, NY) and Laboratory Alliance of Central New York (Liverpool, NY) about the potential to cooperate to go after statewide contracts. ☀

FDA Approves Roche's AmpliChip Microarray

The FDA has approved Roche's AmpliChip CYP450 test making it the first microarray ever to gain clearance for kit sale to the clinical market. The test analyzes variations in two genes (CYP2D6 and CYP2C19) that play a major role in how individuals metabolize many widely prescribed drugs.

The FDA cleared analysis of the CYP2D6 variation in late December, but the test is only complete with the inclusion of the second gene, which was cleared on January 11. Both gene variations as well as the instrument system that runs the test were cleared under the FDA's "de novo" classification, which was established in 1997 for lower-risk diagnostic products for which there is no predicate device.

Steven Gutman, M.D., director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, tells *LIR* that the FDA has not made a final decision on exactly how it might handle all future clearance decisions for multi-gene tests. "I suspect that with increasing review experience our perspective may change but cannot predict an exact path for all future submissions," he says.

A Roche spokesman says the test will be ready for sale in the United States in late February/early March. Quest Diagnostics is expected to be among the first U.S. labs to market the test, but pricing information is not yet available. However, the test has been on the market in Europe since September, and European labs are charging about 400 euros (US \$525) per test. ☀

ViroLogic Completes Acquisition of Aclara BioSciences

ViroLogic (South San Francisco), an esoteric lab that specializes in HIV testing, completed its acquisition of Aclara BioSciences (Mountain View, CA) on Dec. 10, 2004. Aclara has developed an instrument system called eTag for testing biopsy-sized samples of patient tumors. ViroLogic hopes to use its existing sales and marketing infrastructure, which includes 23 sales reps, to commercial homebrew cancer tests utilizing the eTag system.

Under the deal, each share Aclara was exchanged for 1.7 shares of ViroLogic with a total value of \$137 million. Aclara shareholders now own approximately 54% of the total 116 million shares outstanding at the merged company. Aclara shareholders may get an additional cash or stock payment of up to 88 cents per share, or \$32 million, depending on ViroLogic's stock price 18 months from the date of the transaction.

ViroLogic & Aclara in Brief

(for 9 months ended Sept. 30, 2004)

	ViroLogic	Aclara
Revenue	\$26.9M	\$1.3M
Net loss	-4.4	-12.7
Cash holdings	8.1	78.6
Accumulated deficit	-110.5	-175.7

Source: LIR from company reports

Aclara's Mountain View, California operations are being relocated to ViroLogic's headquarters in South San Francisco. ViroLogic is keeping 35 of Aclara's 55 employees and now has a total of 240 employees. William Young, chairman and chief executive of ViroLogic, will continue those roles at the combined company.

In the nine months ended Sept. 30, 2004, ViroLogic recorded a net loss of \$4.4 million on revenue of \$26.9 million; Aclara lost \$12.7 million on revenue of \$1.3

million. Combined, the two companies have lost a total of \$286 million since being formed. ■

New Study Highlights Weakness Of Traditional FOBT

The American Cancer Society estimates that there will be about 104,950 new cases of colon cancer and 40,340 new cases of rectal cancer in 2005 in the United States. Combined, they will cause about 56,290 deaths.

A study published in the January 18 issue of Annals of Internal Medicine says that performing a single fecal occult blood test (FOBT) in a doctor's office to screen from cancerous growths in the colon is wrong 95% of the time.

In the study, titled "A National Survey of Primary Care Physicians' Methods for Screening for Fecal Occult Blood," Beckman Coulter's Hemoccult II was given to 2,665 healthy men, age 50 to 75, for a single blood test in their doctor's office and as a six-sample at-home test, followed later by a colonoscopy. Of the 284 people with colorectal cancer or large polyps that probably would become cancer, the single office test spotted 4.9% of the cases and the six-sample home test was positive 23.9% of the time.

The U.S. Department of Veterans Affairs financed the study, led by Judith Collins, M.D., section chief, gastroenterology, at the Veterans Affairs Medical Center (Portland, OR).

Separate surveys of 1,147 primary-care doctors and 11,365 adults 50 and older found about 30% of colon cancer screening was done using only the test performed in the doctor's office. Ninety percent of doctors said they use the office test at least once a month, according to the study led by Marion Nadel, Ph.D., an epidemiologist from the U.S. Centers for Disease Control and Prevention.

Publication of the studies could lead to faster adoption of some of the newer immunochemical FOBTs, which are more sensitive and patient friendly. The immunochemical FOBTs are also reimbursed at a higher level. Medicare reimbursement is set at a national limit of \$22.22 per immunochemical FOBT vs. \$4.54 per traditional FOBT.

Quest Diagnostics markets the InSure immunochemical FOBT through a distribution agreement with its maker Enterix (Falmouth, ME). And Beckman Coulter is in the process of rolling out an immunochemical FOBT named Hemoccult ICT.

In addition, LabCorp markets Pre-Gen Plus, a DNA-based stool test developed by Exact Sciences (Marlborough, MA) that has a list price of \$795 per test. ■



Lab Stocks Rose 29% In 2004 Led By Medtox

Ten laboratory stocks rose an unweighted average of 21% last year versus a 9% gain for both the S&P 500 Index and the Nasdaq.

Medtox (St. Paul, MN) led all lab stocks last year with a stock price gain of 127% to \$9 per share for a market value of \$71 million. The company has benefited from a rebound in drugs-of-abuse testing. For the nine month period ended Sept.

30, 2004, revenues increased 10% to \$43.1 million; net income increased to \$1.7 million, compared to a net loss of \$70,000 for the same period a year earlier.

Psychemedics (Cambridge, MA), which specializes in drugs-of-abuse hair testing, also performed well, with a gain of 38% to \$12.95 per share for a market cap of \$67 million. Revenue for the nine months ended Sept. 30, 2004 increased 19% to \$14.4 million; net income increased to \$2.2 million from \$853,611.

Myriad Genetics (Salt Lake City, UT) rose 75% to \$22.51 per share for a market value of \$680 million. Late last year, the company announced that it had submitted separate investigational new drug (IND) applications to the FDA to begin Phase I human clinical trial on two drug candidates (MPC-2130 and MPI-176716) for treating cancers that have progressed despite

previous chemotherapy. To help fund its drug development program, Myriad operates a clinical lab that performs proprietary genetic tests sold by a 100-person direct sales force. In the three months ended Sept. 30, 2004, Myriad's lab revenue increased 79% to \$14.4 million.

Meanwhile, over the five years ended Dec. 31, 2004, the best-performing lab stocks have been Quest, up an average of 44% per year, LabCorp, 40%; and Bio-Reference and LabOne, each up 36% per year. ■

Lab Stock Review for 2004

Company (ticker)	12/31/03 Price	12/31/04 Price	52-Week % Chg	P/E Ratio	Dividend Yield
Medtox (TOX)	3.97	9.00	127%	49
Myriad Genetics (MYGN)	12.86	22.51	75%	NA
Psychemedics (PMD)	9.37	12.95	38%	26	2.5%
LabCorp (LH)	36.95	49.82	35%	20
Bio-Reference (BRLI)	13.06	17.40	33%	26
Quest Diagnostics (DGX)	73.11	95.55	31%	21	0.6%
Enzo Biochem (ENZ)	17.06	19.47	14%	NA
LabOne (LABS)	32.47	32.04	-1%	23
ViroLogic (VLGX)	3.76	2.79	-26%	NA
Specialty Labs (SP)	16.79	11.04	-34%	NA
Unweighted average			29%		

NA=The company has reported a loss in the most recent four quarters or the P/E is 100 or more.

Source: LIR



South Carolina has become the seventh state to enact a direct billing law. Under the new law (H-3891), bills for anatomic pathology services must directly go to patients, health insurance plans or other third-party payers, and hospitals. The law prohibits "client billing," which often involves a physician mark-up of charges to the patient. The law applies only to anatomic pathology; client billing for clinical lab work is still allowed. South Carolina Governor Mark Sanford had tried to veto the measure, but was overridden by the state's Senate and House in January.

The College of American Pathologists says it worked closely with the South Carolina Society of Pathologists to win initial passage of the direct billing law and to win support for an override of Sanford's veto.

Mick Raich, president of the consulting firm Vachette Pathology (Palmyra, MI), says the law will reduce the ability of the national reference labs to compete for anatomic pathology business at cut throat prices. Raich says it's not uncommon for the national reference labs to charge a global fee of \$65 for client billings of CPT 88305. "Smaller pathology groups have trouble competing at that level," notes Raich. The Medicare physician fee schedule reimburses CPT88305 at a global rate about \$100.

Other states with direct billing requirements include California, Louisiana, Nevada, New Jersey, New York, and Rhode Island. A spokesman from CAP anticipates that more states will enact direct billing law within the next year. ■

References in this issue

Alverno Clinical Labs
219-989-3700

CodeMap 847-381-5465

IBT Reference Lab 800-637-0370

MedCentre Labs 815-937-2198

Roche Diagnostics 317-849-9350

Spectrum Laboratory Network
336-664-6100

Vachette Pathology
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