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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

MemorialCare Health System Ponders Future For Outreach Labs in Challenging Market

When should a hospital laboratory commit all out to its outreach services?

That was the question posed by Hugo Folli, vice president of ancillary services at Saddleback Memorial Medical Center in Laguna Hills, Calif., during G2 Intelligence's recent Volume to Value conference in Fort Lauderdale, Fla.

The answer: When competitive pressures dictate it.

Saddleback is not a standalone facility; it is part of MemorialCare based in Fountain Valley, a six-hospital system that is the primary acute health care player in southern Los Angeles and northern Orange Counties. "The area is not very consolidated" compared to other parts of the Southern California market, Folli observed. Nevertheless, it still has formidable competitors such as Kaiser Permanente's system of both hospitals and medical groups. This prompted MemorialCare to recently purchase a medical group that is now rapidly growing.

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Quest's Athena Division Releases New Panel of Tests for Neurological Disorders

Athena Diagnostics (Worcester, Mass.), a subsidiary firm of Quest Diagnostics, has introduced a panel of genetic tests to detect a wide array of difficult-to-diagnose neurological disorders in order to speed up their treatment.

The lab-developed tests are for hereditary neuropathy, neuromuscular disease, epilepsy, and certain movement disorders such as hypokalemic periodic paralysis and limb girdle muscular dystrophy, among others.

Although many of the diseases are relatively rare, they have been extremely difficult to diagnose using traditional testing. Moreover, the symptoms of these disorders often overlap, creating even more diagnostic issues for clinicians.

An example is a disease known as Charcot-Marie-Tooth Disease, a form of hereditary motor sensory neuropathy that affects about one

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■ **Quest's Athena Division Releases New Panel**, *from page 1*

in 2,500 people. Its symptoms are similar to many other disorders, but an early diagnosis is considered important in order to avoid treatments that involve contraindicated medications.

"The genetic causes of neurological disorders are sometimes difficult to diagnose without reliable tests that are guided by specific clinical phenotypes," said Joseph J. Higgins, M.D., medical director for Athena and Quest Diagnostics Neurology. "In addition, overlapping clinical signs and symptoms in certain rare, neurogenetic disorders present a different challenge for physicians. The new test services for evaluating epilepsy and neuromuscular disorders will aid physicians in diagnosing these diseases, some of which may be amenable to treatment, and assist in the diagnosis of other potentially affected family members. The results will also better prepare patients and their families to make informed life decisions based on their health risks."

According to Quest spokesperson Wendy Bost, the complicated process of properly diagnosing some of the disorders is often more harrowing than the treatment itself. Some of the disorders that can be identified via the Athena assays can be controlled easily with moderate doses of anti-convulsant medications or even keeping a patient's potassium levels in check.

"Patients seeking to identify the source and nature of their rare disorder may also be inclined to submit to ongoing evaluations—and additional tests—adding to their frustration and heartbreak while also contributing to waste," Bost said. "A reliable early diagnosis may help minimize the likelihood of such an unfortunate series of events."

Quest acquired Athena in April 2011 primarily because the company leadership believes "neurology is an important and promising diagnostic market. Athena complements Quest's broad menu in biological and molecular diagnostic information services, and significantly extends Quest's expertise and capabilities in neurology," Bost said. Athena was the first lab to offer a genetic test to identify sporadic amyotrophic lateral sclerosis, also known as Lou Gehrig's disease or ALS.

Bost declined to disclose current or projected sales volumes for the assays. G2

ARUP Develops Molecular-Based Colon Cancer Test

ARUP Laboratories has introduced a molecular test that it says can serve as a potential replacement for a colonoscopy when searching for suspected cases of colon cancer.

The Septin 9 methylated DNA test, also known as Sept9, can detect even a minute amount of colon cancer cells in the bloodstream, ARUP officials said. The method has a 90 percent overall sensitivity and 88 percent specificity in detecting colorectal cancer at all stages—significantly higher than current fecal occult blood testing.

Although ARUP currently performs the test only in house, a kit is currently being developed for Food and Drug Administration approval. It would likely drive significant sales—particularly if the assay is incorporated into clinical guidelines—said Karen Heichman, vice president in charge of ARUP's oncology product development.

A typical colonoscopy involves the insertion of a long tube into the digestive tract equipped with a miniature camera. The procedure usually requires general anesthesia and can cost $1,500 or more. Nevertheless, as many as 15 million of the procedures are performed in the United States every year, according to the National Comprehensive Cancer Network, with about 100,000 new cases of colon cancer diagnosed annually.

Although medical guidelines recommend regular colon cancer screenings be undertaken by individuals over the age of 50, ARUP officials noted that because of the price and invasiveness of the procedure, about 40 million Americans at risk of developing the disease are left unscreened every year.

"This test ensures that everyone, even our special populations, has an option for colorectal cancer screening," said Edward Ashwood, M.D., ARUP's chief executive officer.

However, the test does have its limitations. Heichman noted that the test is "not very sensitive" for detecting precancerous lesions that can be pinpointed during a colonoscopy and removed. And if the Sept9 results in a positive test, the patient would likely undergo a colonoscopy anyway.

ARUP does not set the pricing for the test, instead deferring to its client hospitals and clinics. The CPT code for the test is 81401, a tier 2 molecular pathology procedure, which may be billed to Medicare using the interim HCPCS add-on code G0452 introduced in late 2012.

Interleukin Genetics Narrows Losses in 2012

Interleukin Genetics, the Massachusetts-based molecular diagnostic startup offering tests through some unique retail channels, narrowed its losses slightly for 2012, but its revenue took a steep plunge in the last quarter of the year.

The company reported revenues of $2.2 million for 2012 and a loss from continuing operations of $5.1 million. That compares to a 2011 loss of $5.2 million on revenues of $2.9 million.

For the fourth quarter of 2012, Interleukin reported a loss of $1.2 million on revenue of $300,000. That's a 50 percent drop compared to the year-ago quarter, when revenue was $600,000.

The company provides a variety of molecular tests, most aimed for a direct consumer audience rather than for medical necessity. They include tests for an individual's genetic propensity toward periodontal disease, determining which diet would be the best fit for someone attempting to lose weight, their propensity toward developing heart disease, and for their risk of developing osteoporosis. The nondental tests have been sold through Amway Global since 2009, with Interleukin performing the tests in its laboratory in Waltham. Interleukin also offers testing directly to consumers via Inherent Health subsidiary.

Company officials indicated that weak Amway sales had impacted its revenue, particularly in the fourth quarter, but that attempts were being made to better integrate the test into Amway's weight loss programs.

Zacks analyst Brian Marckx has rated Interleukin as an outperform, noting strong sales in its dental line of tests and a recent multimillion-dollar investment in the company by San Francisco-based Delta Dental.

Inside The Lab Industry

The Value of Laboratories in Controlling Hospital-Acquired Infections

Frederick Kiechle, M.D.

Denise L. Uettwiller-Geiger, Ph.D.

Hospital-acquired infections (HAIs) are becoming the greatest threat to health care safety in the United States.

According to the Centers for Disease Control and Prevention (CDC), about 2 million incidents of HAIs are reported every year—a number private entities such as the Committee to Reduce Infection Deaths believe is underreported. HAIs also lead to about 100,000 patients dying each year. Each infection costs on average about $20,000 to treat regardless of outcome, and about 70 percent of HAIs are resistant to at least one form of antibiotic.

Moreover, cases of a hospital-acquired intestinal infection known *Clostridium difficile*, or *C. diff.*, are rapidly growing in the hospital setting. Forms of the bacteria cannot be checked with hand washing and often attack patients after they have been treated with antibiotics for another infection (which reduces the levels of intestinal bacteria that keep *C. diff* in check). The CDC estimates that as many as 165,000 cases of *C. diff.* are occuring in hospitals annually, killing 9,000 patients.

With G2 Intelligence's recent Volume to Value conference in Fort Lauderdale, Fla., exploring ways laboratories can contribute to the productivity of providers, their role in infection control was a natural topic for discussion.

Frederick Kiechle, M.D., medical director of clinical pathology at Pathology Consultants of South Broward in Hollywood, Fla., and Denise L. Uettwiller-Geiger, Ph.D., director of laboratory services at John T. Mather Memorial Hospital in Port Jefferson, N.Y., both spoke of their experiences using laboratory services to battle HAIs.

Molecular Testing for MRSA

Kiechle works closely with the five-hospital Memorial Healthcare System in the Fort Lauderdale area. In late 2008, Memorial rolled out a system to detect and combat methicillin-resistant Staphylococcus aureus, an HAI better known as MRSA. It represents about 60 percent of all HAIs, and is usually spread via the hands of hospital employees involved in health care delivery. The health system performs testing on high-risk patients—those admitted to or transferred from the intensive care unit, all orthopedic and neurological implant cases, all patients undergoing open heart surgery, and all patients with a prior history of having a MRSA infection.

"It's not everybody," Kiechle said, noting that not every patient needs to be tested for the infection.

Memorial uses molecular testing from swabs in a patient's nasal cavity to

Excess Cost of MRSA HAI at Memorial Healthcare System

- The following graph shows the excess cost of MRSA healthcare acquired infection. ($9,449 per case @ MHS)
- An analysis of cases with and without MRSA HAI was done in order to determine an average cost of our MRSA infections.
- Literature based excess cost of MRSA healthcare acquired infection ($27,000-$35,000)*

Year	# of Infections at MHS
2008	184
2009	140
2010	85
2011	72
2012	24

Number of infections documented by ICPs. (Numbers for MHM were extrapolated based on Infection Rates)

* Infect Cont Hosp Epid 2010 31:365
Emerg Infect Dis 2007; 13:1840
Amer J Infect Cont 2006 E40
Infect Cont Hosp Epid 1999 20:408

Source: Frederick Kiechle, M.D.

detect the presence of MRSA DNA—a detection process that's far faster than traditional culturing processes. The focus is not whether a patient is infected, but the colonization status of the MRSA bacteria. According to Kiechle, about one-third of patients who have colonized MRSA on their person will develop an infection after they undergo surgery. Treatments include a twice daily application of bactroban in the nasal passages, a daily bath or wipedown using chlorhexidine, and delays in undergoing invasive procedures. The process lasts for seven days.

Memorial uses Roche's MRSA Advanced Assay test, with lab work for all hospitals undertaken at Memorial Regional Hospital South in Hollywood. Positive rates have held fairly steady, from 16.95 percent in October 2008 when the screening program began to just over 15 percent through most of 2012. But the number of MRSA infections plunged. Memorial reported 184 cases systemwide in 2008. In 2012 it reported 24—not only a huge drop from four years prior, but a 67 percent drop from 2011, when there were 72 cases. When the testing program began, the MRSA infection rate within the Memorial system was 14.8 per 1,000 discharges. By 2011, it averaged 1.1 infections per 1,000 patients.

"It's an initiative that engaged everyone from the board of directors to the people who clean the rooms."
—Denise Uettwiller-Geiger, Ph.D.

It costs Memorial $25 to perform a single MRSA lab test and $10.49 to perform a decolonization. That compares to Memorial's average cost of more than $9,400 to treat a MRSA infection. As a result, Memorial's MRSA prevention program saved more than $362,000 in 2010 alone and an estimated $1.39 million since it was introduced.

The cost-avoidance of preventing MRSA infections since the program was implemented in 2008 ranges from almost $4 million (using $9,449 per infection as reported by Memorial Healthcare System) to $11 million (using $27,000 per MRSA infection as reported in literature).

'The Bug Stops Here'

John T. Mather Hospital is not an urban multihospital system like Memorial but instead a community hospital of less than 250 beds on Long Island's North Shore. Nevertheless, it launched an HAI containment program in 2008 that was no less ambitious than Memorial's. Titled "The Bug Stops Here," the program's goal is to reduce the HAI rate to zero.

"It's an initiative that engaged everyone from the board of directors to the people who clean the rooms," said Uettwiller-Geiger. Infection control crews make rounds of the hospital floors daily, and hospital management does not hesitate to isolate patients who are at risk for spreading infections—even though Mather only employs semiprivate rooms.

Like Memorial, Mather embraced molecular testing specifically because of the rapid turnaround time, and it chose to bring testing for HAIs in-house. The traditional culturing process requires two days and sometimes up to four days to yield results—more than enough time for an infection to spread among patients. Like Memorial, Mather tests patients via nasal swabs.

"It allows us to return to the physician actionable information in less than an hour," Uettwiller-Geiger said—a 96 percent faster response time than the traditional testing methods. Moreover, testing for HAIs takes place around the clock, using the Cepheid GeneXpert testing system.

Testing patients suspected of carrying MRSA is pricey compared to Memorial, running about $50 a test, Uettwiller-Geiger said. By 2012, Mather was spending just under $100,000 a year on MRSA testing alone. It has spent about $450,000 in total since the initiative launched.

However, the MRSA infection rate went from 0.9 infections per 1,000 patient days prior to the launch of the initiative to as low as 0.17 per 1,000 in 2011 (it crept back up to 0.23 last year). According to Uettwiller-Geiger, the rise last year represented five additional infections and could be a statistical anomaly.

"We'd like to get to zero, but it may not be realistic," she conceded.

Nonethless, Uettwiller-Geiger concluded that the testing avoided at least 56 MRSA infections, saving about $35,000 in treatment per case. Altogether, that resulted in avoiding $1.96 million in additional costs, meaning the investment in the additional lab work has saved the hospital $1.51 million to date, or an average of $300,000 per year.

Cost-Benefit Analysis of MRSA Surveillance at John T. Mather Hospital

Costs

- Screened high risk patients
  - 2008: 88/mo = 1,050/yr
  - 2009: 139/mo = 1,663/yr
  - 2010: 176/mo = 2,107/yr
  - 2011: 182/mo = 2,181/yr
  - 2012: 164/mo = 1,967/yr
- PCR Assay ~ $50 per test
- Total Screening Cost $448,400
- NO ADDITIONAL FTE' S
- MRSA testing performed 24/7

Savings

248 bed hospital

82,373 patient days/91% occupancy

- 0.90/1,000 = 74.0 infections (2007)
- 0.59/1,000 = 48.0 infections (2008)
- 0.29/1,000 = 23.0 infections (2009)
- 0.25/1,000 = 19.0 infections (2010)
- 0.17/1,000 = 13.0 infections (2011)
- 0.23/1,000 = 18.0 infections (2012)

(2007 vs 2012)

Difference = 56.0 fewer infections @ $35,000

Decrease in 2008 hospital costs = $910,000
Decrease in 2009 hospital costs = $875,000
Decrease in 2010 hospital costs = $140,000
Decrease in 2011 hospital costs = $210,000
Increase in 2012 hospital costs = $175,000

$1,960,000 cost avoidance

Net Savings Due to Prevention
$1,511,600

Source: Denise Uettwiller-Geiger, Ph.D.

The results were equally impressive in treating *C. diff.* Mather's lab used two different tests to determine not only the presence of *C. diff.* but also whether it is generating life-threatening toxins. The combined cost for the two tests is $52.

Between 2010 and 2012, Mather spent $86,460 testing for *C. diff.* Its infection rate dropped from 0.95 per 1,000 patient days in 2009 to 0.34 per 1,000 in 2012. Altogether, 44 infections were prevented, resulting in a cost avoidance of $1.54 million and total savings of $1.45 million.

Additionally, the average length of stay in the intensive care and critical care units dropped from 4.4 days in 2007 to 3.3 days in 2012, saving Mather another $491,000 a year.

Nevertheless, Mather remains under the financial pressure faced by many community hospitals these days, prompting it to recently discontinue its defined contribution pension plans and offer buyouts to some employees.

But when Uettwiller-Geiger recently encountered Mather's chief financial officer in the hospital coffee shop, she learned that she would not be among those tendered a buyout offer.

"I was told that I killed more than I eat," she said.

■ **MemorialCare Health System Ponders Future**, *from page 1*

"Our market is changing quickly," Folli said. Offering outreach laboratory services is the way to accomplish market differentiation, he added.

Both Saddleback and Long Beach Memorial Hospital, MemorialCare's flagship facility, operate labs that provide outreach services, with both under different management. Although they are less than 35 miles from one another and the Long Beach lab is nearly five times larger than Saddleback's, neither has a lot of territorial overlap. Combined they cover a 25-mile-wide by 70-mile-long band from about Los Angeles International Airport to the boundaries of San Diego County. They perform about 2.2 million outreach tests annually and realize annual revenue of about $45 million. Altogether, the labs have a 22 percent market share for outreach—a number that offers a lot of growth potential, particularly given they have the capacity to double their volume.

But whether or not the labs can compete against the region's two big players—LabCorp and Quest Diagnostics—remains a question mark. Provider surveys undertaken by an outside consultant placed MemorialCare's outreach services near the two national labs', but they still fell short. And even though the parent system had acquired a medical group, Folli said those newly affiliated providers see lab services as a commodity to be chosen primarily based on cost—a focus being redoubled by the region's payers.

Moreover, Long Beach's outreach volume began to stagnate about 18 months ago. Folli said MemorialCare was approached by an unnamed national lab with offers to upgrade its IT system, and Citi to monetize its lab operations. The latter would yield about $30 million—money MemorialCare did not need, and a sale would likely require the hospital lab operations to perform more sendouts and see its turnaround time increase.

Maintaining the status quo would mean a likely loss of 10 percent to 15 percent of outreach volume annually in the coming years, explained Folli. However, making investments in outreach would likely lead to higher prices on inpatient lab services.

"We can't stay where we are," Folli said. "In five years, we'll be out of business or just a 'mom and pop' operation."

Three Options

That leaves MemorialCare with three options: Divest its outreach business, joint venture, or pursue a growth strategy on its own.

A joint venture seems unlikely due to lack of interest. The system is considering beefing up its laboratory IT, consolidating operations and switching its outreach billing from hospital rates to a more competitive independent lab fee schedule. It is also communicating with other unnamed parties for a potential deal.

"The story is not done," Folli said.

INDUSTRY BUZZ

Marijuana Driving More Positive Screening Tests

Possessing marijuana has morphed from being a felony to being legal in some states for medical and recreational use and as a result is flying high into the radars of laboratories that test for drug usage.

Quest Diagnostics' annual Drug Testing Index concluded that the rate of positive tests for pre-employment urine drug screening in the United States rose 5.7 percent during the first half of 2012 compared to the first half of 2011.

"These findings align with recent news reports citing some employers facing increasing drug positives when recruiting," said Barry Sample, M.D., director of science and technology for Quest Diagnostics' employer solutions division.

The report is based on an analysis of more than 3.4 million urine and 340,000 oral fluid drug tests performed at Quest Diagnostics laboratories between January and June 2012.

But how comparatively illicit are the drugs leading to positive tests nowadays?

According to Quest, marijuana is the drug that most commonly leads to a positive test—a 2 percent overall positive rate, more than twice as much as the second-leading drug, methamphetamine. The oral fluid testing positive rate during the first half of 2012 is up 15.7 percent compared to the 4.4 percent positive rate.

This uptick in positive drug tests has been confirmed by another lab that performs drug screenings. According to Philip Radford, chief executive officer of AvuTox in Rocky Mount, N.C., the number of inconsistent results—indicating the presence or absence of a drug in a patient's system—has risen to 43 percent from about 36 percent over the past six months. Marijuana is the number-one driver, according to Radford.

Marijuana is now legal for recreational use in two states and legal for medicinal use in 13 others and the District of Columbia.

"Many of our doctors don't know what to do with it," Radford said of a positive marijuana test. "They don't know whether they should even be testing for it, or even be concerned about . . . it."

Quest spokesperson Wendy Bost noted that it remains illegal under federal law, and the company performs most of its drug testing for the "safety-sensitive workforce."

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ARUP Laboratories
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