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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Bringing You the REAL Story behind the Story!

HOW MUCH DO YOU TRUST THE NEWSPAPERS AND OTHER MEDIA you read to give you the right story, with the right analysis? If you are like me, you are regularly disappointed that the nation's journalists are too quick to report the obvious—while often missing the important nuances that bring out the true dimensions of the story being reported.

In recent months, *The New York Times* did a detailed story about the "failings" of molecular test technology to provide reliable results to guide clinicians at **Dartmouth Hitchcock Medical Center** as they worked to identify a suspected outbreak of *Bordetella pertussis* (whooping cough). As a result, the reported outbreak of *Bordetella pertussis* wasn't an outbreak at all, said *The New York Times*. When we talked to the principals involved at Dartmouth's laboratory, we learned that the problem had nothing to do with placing too much faith in molecular testing. *(See pages 6-8 in this issue.)*

The molecular tests for *pertussis* performed within specifications, a situation understandable to any lab professional. Some test results appeared to be positive, but many more were equivocal. Experts suggest retesting to confirm equivocal results. But since the medical center believed it was dealing with an outbreak, waiting for confirmatory testing was not the right clinical strategy. That didn't stop the newspaper from raising questions about the entire field of molecular testing, a diagnostic technology that has produced significant value for more than a decade.

I offer you this example of how the reporter for *The New York Times* did a story that covered the obvious points, but missed the real story behind the story. THE DARK REPORT'S coverage of this situation, published in this and a previous issue, provides our clients and long-time readers with the analysis of what really happened, and the important laboratory management lessons learned during a suspected outbreak of *pertussis* that saw as many 1,000 healthcare workers tested and more than 4,500 employees of the medical center given the acellular pertussis vaccine. *(See TDR, February 19, 2007.)*

The point is that news and trends are not always what they appear to be. Therefore, pathologists and lab directors need a reliable and trusted source for information. They need one that's willing to go beyond the obvious headline and report the story behind the story. We believe that's why they rely on THE DARK REPORT and consider it to be a reliable source of useful business intelligence. TDR

Lots of IVD Acquisitions As Buyers Spend Money

Slew of deals and the variety of buyers reveal a strong demand for molecular diagnostics firms

CEO SUMMARY: Biggest deal in recent weeks was the $1.55 billion Beckman Coulter paid to acquire BioSite and its Triage BNP test. But the most interesting news may be the entry of 3M Corporation into clinical diagnostics, based on its acquisition of Acolyte Biomedica Ltd., a company which offers a five-hour rapid culture-based MRSA test. Announced in rapid-fire order, these deals demonstrate the hot interest in molecular diagnostics.

CONSOLIDATION CONTINUES among *in vitro* diagnostics (IVD) companies. A growing list of acquisitions was announced over the past few weeks.

A sampling of these deals shows the wide scope of interest. In no particular order, here are some of the more notable acquisitions, with buyer, seller, price to be paid, and date of the announcement.

Beckman Coulter Corporation is to buy **Biosite Incorporated** for $1.55 billion, announced on March 25. **Carl Zeiss MicroImaging** purchased the instrument systems business of **Clarient, Inc.**, including Clarient's ACIS and Trestle product lines, for a price of $11 million with an additional $1.5 million in post-closing contingencies, disclosed on March 8.

Just last Thursday, March 29, **Roche Holdings** disclosed that it will acquire **454 Life Sciences**, a majority-owned subsidiary of **CureGen Corporation**. Purchase price will be $140 million to the shareholders of 454 Life Sciences.

One particularly interesting deal was the purchase, by **3M Corporation**, of **Acolyte Biomedica Ltd.** of Salisbury, United Kingdom. No purchase price was disclosed. Following the February 14 news of the acquisition, 3M announced in March that it had formed a new business division in medical diagnostics.

Access to molecular technology is a key motivator in most of these deals. It shows how the IVD industry's major players are jockeying to bolster their line-up of products and to maintain a strong offering in molecular and other types of advanced diagnostics.

Over the past four years, Beckman Coulter and Biosite have collaborated in several ways. In purchasing Biosite, Beckman

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Coulter says it will improve the company's position in immunoassay testing and cardiac diagnostics. It also plans to expand international sales of Biosite's assays outside the United States. Currently, about 85% of Biosite's $300 million in annual revenue is generated by sales within the United States.

Paid 20 Times Cash Flow

If there was any criticism of the Biosite deal by Wall Street, it centered around the price offered by Beckman Coulter. It paid a 53.5% premium over the market share price prior to announcement of the deal. One analyst noted that Beckman was paying more than 20 times cash flow for Biosite and would take on considerable debt to finance the transaction.

In the past 18 months, Beckman Coulter had done two other acquisitions. One was of **Diagnostic Systems Laboratories Corporation** (DSL) of Webster, Texas. This company, with about $34 million in annual sales, is a provider of specialty immunoassays including proprietary technology for reproductive endocrinology and cardiovascular risk assessment.

Beckman Coulter's other acquisition was of **Lumigen, Inc.**, based in Southfield, Michigan. For $185 million, Beckman acquired Lumigen's "proprietary chemiluminescent chemistry" which Beckman uses in its Access family of immunoassay systems. Lumigen's annual sales were about $33 million, of which 40% were to Beckman.

Clarient's sale of its instrument systems to Carl Zeiss MicroImaging, based in Frankfurt, Germany, is interesting because it gives Zeiss MicroImaging pathology imaging and information management systems. These products can be matched to its laser dissection offerings and microscopes, giving pathologists the ability to capture images, then apply software tools to analyze these images.

Clarient retains access to the intellectual property represented by the ACIS and Trestle systems. Both companies intend to work jointly on developing new assays and other uses for this technology. Carl Zeiss MicroImaging noted that the acquisition advances its capabilities in clinical cancer diagnostics and cancer research.

Ultrafast Genome Sequencing

With its purchase of 454 Life Sciences, Roche is acquiring technology in ultrafast genome sequencing. Roche is familiar with the company and its products because its Roche Diagnostics division is the exclusive worldwide distributor for 454 Life Sciences' instruments and technology. The deal gives Roche access to use the 454 Life Sciences technology for *in vitro* diagnostics applications. 454 Life Sciences is based in Branford, Connecticut.

3M Corporation is using its acquisition of Acolyte Biomedica Ltd. as the backbone of its newly-announced 3M Medical Diagnostics business unit. Based in the United Kingdom, Acolyte produces what it describes as "rapid microbiology products." Early last year, Acolyte launched BacLite Rapid, a culture-based MRSA test that can produce a result from clinical samples in under five hours.

Entering Clinical Diagnostics

Angela Dillow, Ph.D., who is Global Business Manager of the new business unit, noted that, "3M Medical Diagnostics is a natural extension of our infection prevention platform and enables us to offer hospitals a full spectrum of products that detect, prevent and treat infections in the hospital setting."

As these deals show, consolidation is alive and well in the *in vitro* diagnostics industry. Further, the elephant in the room is **Philips Corporation**, the imaging giant which many experts believe may want to buy its way into lab testing, just as its two main competitors, **Siemens** and **General Electric**, have done. TDR

Competitive Bid Update

Implementation Date Passes on Medicare Competitive Bid Project

YESTERDAY, APRIL 1, WAS THE DAY that the **Centers for Medicare & Medicaid** (CMS) was scheduled to implement the first sites for the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project. It was good news for the laboratory industry that the day passed with no action on this issue, says Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA), in Washington, DC.

"Implementation is not happening," stated Mertz. "Since last fall, there has been no movement on the competitive bidding plan. None of the milestones on the implementation timetable announced last year have been achieved.

"CMS has not announced the sites, and the federal **Office of Management and Budget** (OMB) is still reviewing the proposal," he continued. "OMB is working on the design of the demonstration project and will be involved in naming the sites that will participate.

Working For Legislation

"To be honest, we hope that the laboratory services competitive bidding demonstration project never comes together at all," observed Mertz. "We are using this time before implementation to persuade members of Congress to repeal the demonstration project. Getting such legislation introduced and passed can be a lengthy process. It takes time and effort to get a sponsor for the bill and then to educate Congress about this demonstration project.

"Even when CMS announces the sites and releases the final design, we estimate that it will take at least two or three months before they could implement the demonstration project," Mertz explained. "They would need a bidders' conference and laboratories serving the demonstration sites would require time to prepare the bids."

Reducing Medicare Access

The demonstration project is part of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). ACLA argues that lab services are highly complex, professional services. Laboratory medicine is unlike healthcare equipment or supplies, which can be put out for bid easily. "Also, competitive bidding could reduce the number of labs providing services in a region because losing bidders might no longer be able to provide laboratory services to Medicare beneficiaries and could be forced to close," noted Mertz.

THE DARK REPORT observes that it's no surprise that the OMB has yet to develop a viable plan for competitive bidding of laboratory testing services. The questions that still need to be answered are difficult and highly complex. For example, how should the bidding procedure address smaller laboratory providers, as well as hospital and physician office laboratories? Would all 1,100 laboratory test codes be covered or just those test codes ordered most frequently? What will be the effect of competitive bidding on rural or underserved areas with few laboratory providers? With so many unanswered questions, CMS has taken on a significant challenge. TDR

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Newspaper Reports Miss On Molecular Technology

➤Reporting on outbreaks of *Bordetella pertussis*, major newspaper criticizes molecular tests

➤➤CEO SUMMARY: In reporting on a suspected outbreak of whooping cough (Bordetella pertussis), a national newspaper suggested administrators at Dartmouth Hitchcock Medical Center had placed too much faith in molecular testing. In this exclusive interview, Dartmouth's Director of Molecular Pathology comments on how the media misunderstood the story, and why molecular testing remains the preferred method.

MARK TWAIN ONCE SAID, "All in all, the newspapers do a wonderful job, except when I know something about the subject." The great American writer's quote is particularly telling given the circumstances surrounding the reporting of an outbreak of *Bordetella pertussis* at the **Dartmouth Hitchcock Medical Center** in Lebanon, New Hampshire, last year.

The common name for *pertussis* is whooping cough and it is difficult to diagnose in children and even more difficult to diagnose in adults. So, when healthcare workers at the center began coughing last year, administrators were concerned there was an epidemic of whooping cough.

Working with epidemiologists from the federal **Centers for Disease Control and Prevention** (CDC), Dartmouth's pathology department ran molecular tests. The results were typical: Some patients tested positive for pertussis but the results on many more patients were equivocal.

After *The New York Times* published an article questioning the validity of molecular testing, the pathology department found itself in the middle of a controversy that was needlessly started. The issue shows how little healthcare experts know about *pertussis* and how to consistently identify it clinically. *(See TDR, Feb. 19, 2007.)* As a result of the questions raised in the *New York Times* article, Dartmouth's lab is now facing inquiries from several federal agencies.

➤Sensitivity And Specificity

"There was a lot of misinformation out there," explained Gregory J. Tsongalis, Ph.D., Director, Molecular Pathology for the Department of Pathology at the Dartmouth Medical School and Dartmouth Hitchcock Medical Center. "What didn't come across was that only about 40 patients tested positive using the molecular test (with polymerase chain reaction or PCR), meaning less than half were true positives. This was in April 2006. The other 60% were in the equivocal zone of the assay and were called positive as a result of the clinical symptoms they had.

"During the outbreak, we thought it best to treat these people rather than wait for the results of a second PCR test or culture to come back to confirm the positive

When the Media Fails to Understand How Diagnostic Technology Works in the Real World

AN ARTICLE IN *THE NEW YORK TIMES* on January 22 questioned the validity of molecular testing. The article, "Faith in Quick Test Leads to Epidemic That Wasn't," said almost 1,000 workers at the Dartmouth Hitchcock Medical Center were given a preliminary molecular test. It also said 142 people at the center were told they appeared to have the disease.

Later, the article said, "Not a single case of whooping cough was confirmed with the definitive test, growing the bacterium, *Bordetella pertussis*, in the laboratory. Instead, it appears the health care workers probably were afflicted with ordinary respiratory diseases like the common cold."

Still later, the article questioned the value of molecular tests. It said, "Many of the new molecular tests are quick but technically demanding, and each laboratory may do them in its own way. These tests, called 'home brews,' are not commercially available, and there are no good estimates of their error rates. But their very sensitivity makes false positives likely, and when hundreds or thousands of people are tested, as occurred at Dartmouth Hitchcock Medical Center, false positives can make it seem like there is an epidemic."

Compounding the error, **ECRI**, a nonprofit health services research agency in Plymouth Meeting, Pennsylvania (at www.ecri.org), issued a Health Devices Alerts Special Report on February 2. The alert was based on the *Times* article. ECRI said 142 individuals were misdiagnosed with whooping cough based on false-positive molecular assay test results. On February 23, ECRI retracted its earlier statements when it issued another alert.

In the second alert, ECRI said, "According to Dartmouth-Hitchcock, only 41 individuals tested positive by molecular methods that have been widely used for over a decade for diagnosing *pertussis*. The remaining individuals were considered suspect *pertussis* cases based on equivocal molecular test results, *pertussis* symptoms, and concern for patient and employee health. Those with equivocal results were treated as if they had positive results, in accordance with standard protocols."

results a few days later," he noted. "They were given an antibiotic and put on furlough from work. That was the decision and it was the correct one.

"At the time, some people considered it to be a major outbreak rather than just 40 people out of 1,300 who work here and were tested," Tsongalis said. "That's a small outbreak because there were 1,200 people who were true negatives and came back to work the next day. But then, in January of this year, *The New York Times* did an article that made it seem that the PCR-based test was unreliable. As a result, not only did our lab got a bad rap, but molecular testing in general was questioned as well." The article,

"Faith in Quick Test Leads to Epidemic That Wasn't," was published by *The New York Times* on January 22, 2007.

"During the outbreak, federal officials advised us to confirm the positive results by culture, but culture is sensitive in only 30% to 40% of cases," he said. "If it is present and it grows, you can identify it. But it only grows 30% or 40% of the time.

Serologic Assays

"In addition, we were criticized because both a federal and an academic lab did serology testing using an assay that was still in development," added Tsongalis. "Only one lab in the country has a clinically validated serology assay for *pertussis*. All other labs are still developing their serologic assays, and serologic assays may be even more difficult to interpret than a molecular PCR test. Using a non-developed research-based assay to confirm an outbreak is a big mistake.

"Typically, if we weren't in an outbreak situation, we would repeat those tests the next day and report results at that time," he added. "If they came up positive again we would call them positive. If they came up negative, we would call them negative. But we didn't do that because an institutional decision was made to get people back to work quickly or send them home quickly. That's the correct way an organization must respond when there is an outbreak like this. It minimizes the risk of spreading the infection.

Unanswered Questions

"The big question involves all the people who were in the equivocal range and were treated," he continued. "Did they have low level copies of *pertussis* that were accounting for their respiratory symptoms or did they not have it at all? That's the million-dollar question because, in adults, *pertussis* looks similar to a regular cold.

"Most lab professionals around the country are comfortable using molecular tests and believe in the need, as appropriate, to do a second test with a different marker or a different target. But I am not aware of any laboratory moving quickly to change its standard of care in this regard. What I don't want to see happen is to have anyone recommend that we discontinue using this molecular test.

"Pathologists understand the issues involved with molecular testing, but not everyone in healthcare fully appreciates what it means when results are equivocal," Tsongalis explained. "There are nuances with molecular testing, as there are with any diagnostic test. And, there is no gold standard for identifying *pertussis*. So any attempt to compare one test method against another is like comparing apples and bananas. Each one has its own nuances and its own level of sensitivity and specificity.

Standard Of Practice

"Right after *The New York Times* article came out, I surveyed 30 labs across the country and found that each was doing the same targeted molecular test that we perform here," Tsongalis said. "And they are not confirming by culture and are not doing serology. In other words, molecular testing has become the standard of practice. What we now see in testing for *pertussis* are some of the variances in using the test as a screening tool in an adult population for which we would not test routinely.

"The *New York Times* article made it sound as if molecular testing was not worth doing," he added. "That is certainly not the case. We do so much molecular testing now that it would be like taking two giant steps backward to go back to some earlier testing methods that we formerly used in these clinical situations.

"The lesson in all of this is that we don't fully understand *pertussis* infections in adults," Tsongalis said. "With children it's different. They almost always develop the classic symptom, the 'whooping' sound with the cough." TDR

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Compliance Update

Will OIG Reconsider Policy On Discriminatory Pricing?

HEIGHTENED COMPETITION in recent months for exclusive managed care contracts between the two blood brothers may trigger the law of unintended consequences. One such consequence could be renewed interest by Medicare regulators in what they call "discriminatory billing."

"In 2003, the federal **Office of the Inspector General** (OIG) issued a draft statement on discriminatory billing," said Lâle White, Founder and Executive Chairman of **XIFIN, Inc.**, in San Diego, California. "The draft was never finalized, but now that the large national labs are signing national contracts with major health insurers at lower price points, it could be that the OIG will decide it's time to finalize the statement on discriminatory billing.

Draft Language By The OIG

"The basis of that draft language is that federal regulators don't want Medicare to be charged by a provider an amount "substantially in excess" (or 120% above) of its usual charges to the general public," explained White. "As written and published for comment, the draft version of the discriminatory billing policy would include any fee-for-service rates a provider agrees to accept from any third party in the definition of such charges. Sanctions for charging in excess of the usual charge would include exclusion from federal and state healthcare programs. This regulation is not final and third party contract rates were not included in the past.

"But it means that if a laboratory were to contract with a third party provider, such as **Aetna**, **Cigna**, or **United Healthcare**, for a fee-for-service price that is significantly lower than the Medicare fee schedule, then it would be expected that this reduction to the provider's average pricing or "usual charges" would be extended to Medicare," White said. "Now that the two national laboratories have rebid these major exclusive contracts at what are likely to be significantly low fee-for-service rates relative to the Medicare fee schedule, it might motivate Medicare regulators to finalize the draft language that was published in 2003.

Discriminatory Billing Policy

"The larger labs have systems and legal advisers that allow them to stay on top of the discriminatory billing policies, as defined by Medicare guidelines and statutes," continued White. "It is likely that they have negotiated language into their managed care contracts that would allow them to respond to any federal or state changes that would significantly alter how they would bill government or state programs. In other words, they have made sure that their contract language covers them if the draft is finalized. They want to make sure that they're not caught in a problem of this nature."

"Further, given the publicity generated by the managed care contract awards that affect both of the national laboratory companies, it would not be a surprise if OIG officials decided to revisit the subject of discriminatory pricing and evaluate if implementation of the draft language would be financially beneficial to the Medicare program" TDR

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Microwave technology for real time processing

Anatomic Pathology's Coming Revolution: Same Day Diagnoses

CEO Summary: Anatomic pathology has been conducted the same way for 100 years—but no longer at the University of Miami. Pathologists there are using microwave technology to cut processing speed by 90% and improve workflow. By producing faster diagnoses, the lab can report results on 80% of samples the same day that specimens are received. Seeing these improvements, the hospital has added histology labs in other clinical areas to support the goal of point-of-care anatomic pathology.

IF THERE IS TO BE A REVOLUTION in the long-standing operations model of hospital-based anatomic pathology, then one early revolutionary is Azorides Morales, M.D., and his pathology department at the **University of Miami/Jackson Memorial Hospital** in Miami, Florida.

In recent years, Dr. Morales, who is Chairman of the Department of Pathology, and his colleagues have created a "real time" anatomic pathology (AP) service that delivers pathology reports on the same day for more than 80% of the specimens received! This reduction in turnaround time from receipt of specimen to delivery of the pathology report is contributing to a higher level of care. It has also dramatically eliminated the need for the histology laboratory to operate in the early morning hours.

Rapid Processing Approach

Two strategies underpin this revolution in anatomic pathology laboratory operations. One is the use of rapid processing technology (invented by Dr. Morales and his team), which has cut specimen processing time from 12 hours to 75 minutes (a reduction of 90%). The second is to move away from batching large volumes of specimens in favor of single piece and small batch work flow.

There are other benefits from this revolutionary approach to operating a pathology laboratory. Unlike many AP labs today that struggle with long hours and not enough staff, the lab at University of Miami/Jackson Memorial Hospital offers regular hours for the staff and family-friendly scheduling.

The new system has also contributed to a significant increase in productivity in the histology laboratory. This increased productivity has allowed the lab to absorb and process an increased volume of work with fewer histologists than were in the laboratory prior to implementation of microwave processing and the new work flow.

Another innovation that resulted from "real time" delivery of pathology reports is the location of pathology laboratories in other areas of the hospital, including a rapid response pathology laboratory connected to the operating suites by a pass-through window. That's a direct result of clinicians asking for the more accurate and faster diagnoses produced by the University of Miami pathologists.

Recognizing that anatomic pathology histology laboratories have conducted tissue processing the same way for 100 years, Morales, along with co-inventors Drs. Nadji, Nassiri, Vincek, and Harold and Ervin Essenfeld, launched research in 1996 to automate AP with microwave processing. Professor and Chairman of the Department of Pathology at the Miller School of Medicine at the University of Miami, Morales is also the Director of Pathology Services at Jackson Memorial Hospital, Miami. Jackson Memorial has 1,500 beds and each year does 10 million clinical tests, 28,000 surgical cases, 6,000 cancer cases, and 300 autopsies. Other than a few rare exceptions, all tissue specimens go through the microwave tissue processing procedure.

Molecular Testing

Morales has been perfecting his microwave processing techniques for the past 10 years. Not only did he invent a way to reduce the time required to process AP specimens, but his process retains the molecular structure of the tissue samples. This allows processed specimens to be used for follow-on molecular testing.

"All the trends point to increased demand by physicians for faster delivery of laboratory test results," predicted Morales. "This type of specimen processing technology is likely to play a significant role in the future of anatomic pathology. The cornerstone of this process is the **Sakura Finetek** TissueTek Xpress Rapid Tissue Processor, which incorporates the microwave technology developed here.

Morales explained the process, saying, "The tissue is submerged in mineral oil, acetone- and alcohol-based reagents," he noted. "It is then exposed to controlled microwaves at a low level energy, averaging less than 100 watts. By contrast, a home microwave operates at 700 watts and produces uneven levels of energy. While exposed to the microwaves, the tissue is agitated at 51°C.

"Next, the tissue is heated to 65°C in paraffin while subjected to vacuum for infiltration," he continued. "Unlike traditional processing with formalin, this process preserves the DNA, RNA, and proteins in the tissue, thus allowing us to conduct molecular testing on the same block of tissue."

Lack of Cellular Distortion

"During the development stage, we conducted numerous blind studies to compare microwave technology with conventional methods," Morales said. "The histological slides are not completely identical, but when conducting blind studies, a cross section of pathologists (both from our team and other facilities) could not differentiate which method was used to process the specimens.

"Cellular differentiation and stain uptake was not compromised with our new technology for microwave processing," he added. "This is the reason it took a long time to develop: The end result had to show no cellular changes or distortion.

"Our goal was to develop a rapid tissue process that produced an end result that was identical to traditional, formalin-based processing," stated Morales. "A pathologist has years of training and experience in the interpretation of cellular structure. It was imperative to maintain a high level of excellence in processing so that the end product—the processed tissue—contained no cellular changes that might influence interpretation and diagnosis."

After testing and improving the processes, Morales found increased demand for AP services across the hospital. "In the medical center we have three histology labs (HL)," he explained. "Two are at Jackson Memorial. One is the main histology lab. The other lab is next to the operating room (OR) where each day we do 10 to 15 frozen sections and about 100 surgical cases. The proximity of this histology laboratory to surgery has increased our interaction with the surgical teams.

"In fact, the histology laboratory located next to the OR was so successful that we were next asked to establish a histology lab at the cancer center," he recalled. "Although it was more expensive to have another processing instrument on site at the cancer center, it brought point-of-care histology services to the patients, surgeons, and surgical pathology. This improvement is significant for cancer patients because it reduces their anxiety. It also enables physicians to develop and implement treatment plans more expeditiously. For example, we can consistently provide pathology results within two hours of surgery, rather than having the patient waiting anxiously for days."

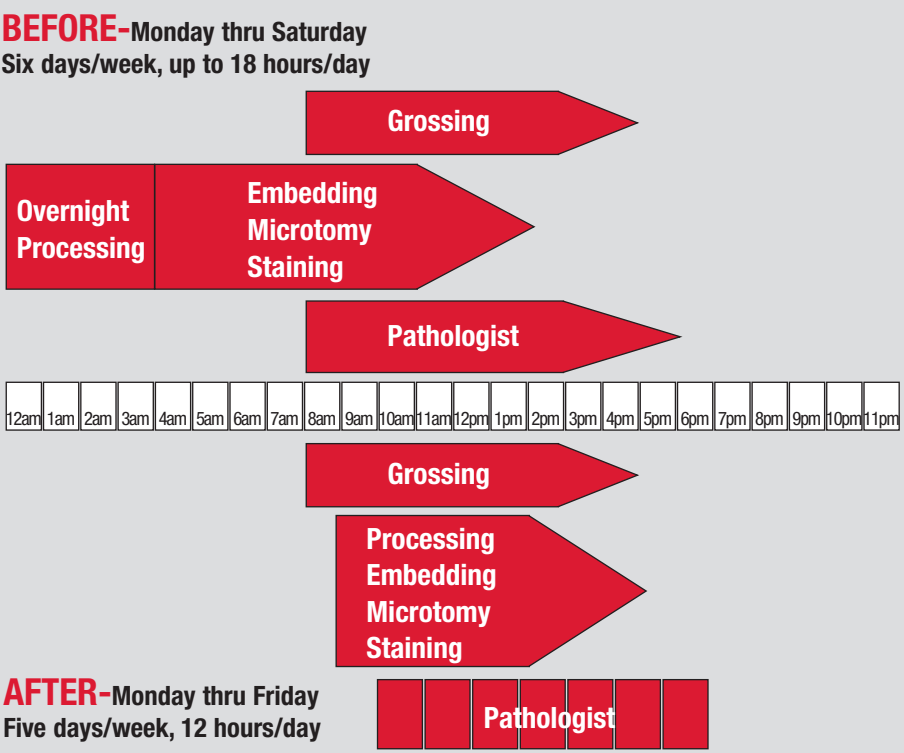
Improved Processes

Using the new rapid microwave technology has been an undeniable hit with clinicians. But it has also delivered important benefits across the entire pathology department. Productivity improved by a substantial amount, with significant benefits in budgets, schedules, grossing, processing, and slide reading.

"These have all been worthwhile and practical benefits," said Carmen Duboue, HLT(ASCP), Supervisor of Microwave Processing. "There is much less stress in the lab. It is much easier for the technical staff. For example, we no longer must deal with large batches of cassettes.

"Instead, we have what we call 'rapid process flow.' Specimens are immediately prepared and put into the processors," she

Changing Histology–Pathology Work Cycle



At the University of Miami/Jackson Memorial Hospital pathology department, histology and pathology operations were radically changed by the adoption of rapid processing technology and small batch work flow. The department now works a five-day week, and primary work in the histology laboratory can be accomplished between 7 a.m. and 7 p.m. each weekday.

explained. "With our multiple processors, about every 15 minutes we have up to 40 cassettes in a basket ready for embedding and cutting.

"That means histologists work at a steady pace throughout the day," observed Duboue. "We've eliminated that big race that would start at 3:00 a.m. in the morning when the overnight processors were unloaded and we would work to finish up all the specimens from the previous day and have those slides ready at the start of the day for our pathologists."

The shift to rapid processing of small batches of tissues throughout the day has also altered the work habits of the pathologists. "Now, instead of starting the day with a big stack of folders containing slides, our pathologists get one or two cases at a time throughout the day," noted Duboue.

"In our histology laboratory, rapid processing has dramatically altered the start and end times for shifts," she continued. "Working hours are now so much better that we call it 'family friendly' and we don't work weekends.

"For example, our staggered shifts start at 5:30 a.m. and finish at 7:30 p.m.," explained Duboue. "Our last specimens go

through processing at 4:00 p.m. Specimens received after 4:00 p.m. are put into molecular processing fixative. They are the first tissues we process the next day and they are generally ready for the pathologists to read by 9 a.m. the next morning.

"For histologists, our rapid processing technology has the advantage that the tissue cuts easier after processing," Duboue continued. "It is not dried out. And, we can get our sections for immunohistochemistry out on the same day that the specimen is received.

"Since instituting rapid processing and small batch work flow, our specimen volumes have increased each year, by an average of 4%," she noted. "Yet, not only have we not added staff since 2003, we perform all the work with fewer people. The productivity increase from the new work flow has been substantial.

> ***"The business advantages are significant," Morales added. "These work flow changes can give labs a competitive edge in the anatomic pathology marketplace."***

Duboue also mentioned that the rapid processing technology has made it easier for the staff to process tissue for molecular testing. "The same tissue block serves as a platform for molecular testing and the microwave process reduces the opportunity for mistakes," she said.

"As a result, it is easier on the technical staff, not the least because there is less stress," added Duboue. "Instead of being confronted with 500 blocks at one time (all of the previous day's specimens batched and processed overnight), they now deal with just 10 or 20 blocks at a time. Also, rapid processing uses less reagents. That reduces the volume of reagents for disposal, which means there is less lifting. We can process 1,000 to 2,000 blocks with one gallon of each solution.

Lower Toxicity

"The rapid microwave process also reduces the volume and toxicity of reagents," Duboue explained. "Because we no longer use formalin or xylene, we work in a safer environment. Since the processor is a closed machine, there are no fumes. It requires only two reagents, which is 80% less reagent volume than the traditional tissue processing machines."

Duboue added that there is minimal maintenance to the machine. "It is very stable and if something goes wrong, it is very easy to troubleshoot," she said. "We have fewer problems than with the traditional processing machines."

When Morales tells pathologists of the remarkable processes in his lab, they are generally stunned. "Typically, most pathologists get their daily share of slides (yesterday's specimens) in one big batch," he said. "They must then work steadily to read them all and finish the reports. But due to the radical change in work flow with this system, our pathologists read slides throughout the day, as specimens come into the laboratory and are processed in real time. This enables the pathologists to have closer interation with the surgeons and to provide faster results to the physicians and patients.

"Because the specimen processing is done sooner, the dictation is completed earlier too," Morales said. "That means reports can be sent electronically or delivered via courier the same day. Getting results out the same day has reduced the number of phone calls we get. Plus, there is another benefit: Getting reports out faster means billing statements go out sooner.

"The business advantages are significant," Morales added. "These work flow changes can give labs a competitive edge in the anatomic pathology marketplace.

Combining processing technology with a small batch work flow can be particularly useful for hospital outreach programs that compete with the big national labs. After all, giving referring clinicians a faster turnaround time to results is a benefit to both physicians and patients."

"In fact, as word gets out about the organization and performance of our pathology department, we now get site visits by people from all over the world," Morales said. "We love to show visitors how the system works and what improvements they can make in their own labs.

Benefits Of A Site Visit

"I encourage anyone thinking about changing to microwave technology to come to our lab and see the process in action," he continued. "Talk with our pathologists and technologists. Gain valuable insight and develop ideas on how to implement changes at your own laboratory. We recommend pathologists and staff spend at least a day with us to see the benefits of our approach, as well as to learn the challenges of evolving to this kind of work flow approach.

"When you see the Tissue Tek Xpress in action, you realize that the most important outcomes of microwave processing are improved patient care," Morales continued. "By improving expediency of surgical reports, the patient waits less time for a diagnosis. It improves patient management for surgeons and other physicians.

"One way to see how successful we've been is to consider that the plans for a new Miami University hospital call for a histology laboratory in the midst of the operating room suites," Morales explained. "It is expected that the new University hospital will be operational in 2010 and, by that time, microwave processing will already be routine, helping pathology to develop even closer relationships with surgeons, and helping to create higher recognition for the contribution that pathology provides to the healthcare team.

Plenty of Advantages To Microwave Technology

AMONG THE MANY ADVANTAGES of microwave technology are the following, according to pathologists at University of Miami/Jackson Memorial Hospital in Miami, Florida:

- Standard grossing technique
- Consistent tissue handling
- Lack of denaturation of tissue sample, leaving DNA, RNA proteins intact
- 80% of specimens resulted within same day
- Molecular testing on same tissue block
- Complete results within 2 hours
- Introduction of Point-Of-Care to surgical pathology
- Improved turnaround time reduces patient anxiety
- No overnight processing
- Family-friendly work schedules and no weekends
- Less stress for technical staff and pathologists
- Improved working conditions
- Overall management of laboratory is easier
- Fumes and toxins eliminated: formalin and xylene no longer used
- Easier disposal of reagents, less volume of reagents used
- Reduction in processing time from 24 hours to 75 minutes
- No overnight processing
- Reduced repetitive manual procedures
- Instrumentation very simple, easy to use, simple to troubleshoot

"This technology means we are poised for the next wave of innovation in molecular pathology: proteomics and genomics at the tissue level," continued Morales. "More will be expected of anatomic pathology to provide diagnostic answers in real time to keep the cost of healthcare down.

"The instruments in histology now come with information technology support, much like the clinical chemistry instruments," he observed. "This will put some labs in a battle with other departments for capital dollars, as AP becomes more capital-intensive. However, automation brings better work conditions for the staff and pathologists, and this is welcome at a time when, in some areas, it is increasingly difficult to recruit skilled laboratory staff."

➤Boosting Pathology Quality

THE DARK REPORT observes that Morales and his colleagues are indeed on the cusp of a revolution. Their work to create a rapid processing technology that preserves the tissue for molecular testing is an impressive accomplishment. But, as Morales notes, the most significant advantage is improved patient care. Because microwave processing speeds workflow and allows labs to get work out the same day with less stress, it is likely that other labs will choose to implement this same approach.

But the most striking insight from these innovations may be how the pathology department at the University of Miami has increased its value as a clinical consulting resource to physicians while at the same time improving its visibility. Putting pathology at the point-of-care is a winning strategy for the entire pathology profession. The integration of pathology services at this medical center demonstrate that fact. **TDR**

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—By June G. Smart, Ph.D.

Gaining Better Quality In Histology Processing

ONE ASPECT OF MICROWAVE TECHNOLOGY that helps improve pathology test results is a different approach to standardizing how specimens are grossed, according to Azorides Morales, the Director of Pathology Services at University of Miami/Jackson Memorial Hospital in Miami, Florida.

"One major change for pathologists using microwave technology comes when grossing specimens," Morales said. "Currently, traditional gross practices do not require uniformity in the grossing process. With microwave processing the thickness of the tissue cannot be more than 2 mm thick. Yet, we can get 300 to 600 sections from the block with this size tissue. We developed specific tools to ensure uniformity in our grossing."

There is another impressive aspect to the microwave processing and AP work flow developed by Morales. "We have an extraordinary level of confidence with microwave processing," he said. "Since October 1996, we have never spoiled a patient's sample. We have processed over 1.5 million samples through December 2006. We could not say the same for the traditional overnight processing, as it can breakdown in the middle of the night and problems occur. Now all our processing is done during the day and someone is always there should anything happen."

Labs Can Be Misguided By Pull-Through Test Myth

Popular wisdom of the 1990s caused a precipitous decline in reimbursement

CEO SUMMARY: For the first time in almost eight years, there are major disruptions to the status quo in managed care contracting for laboratory testing services. As was true in the 1990s, national lab companies are pursuing exclusive national contracts with the nation's largest health insurers. In the 1990s, a similar competitive battle triggered a price war with disastrous consequences for the entire laboratory industry.

By Robert L. Michel

IT WAS DURING THE 1990s that the myth of pull-through business took the laboratory industry down a path of financial disappointment, if not financial disaster.

Now that the two blood brothers have upset the status quo in managed care contracting that existed for almost eight years, some labs have begun to again consider pull-through as part of their managed care strategy. For that reason, it is timely to review the corrosive effects visited upon the laboratory industry by application of the pull-through scheme during the 1990s.

Will Docs Split Specimens?

Pull-through was a business concept based on this simple assumption: We want to be the exclusive laboratory provider for the HMO. Because we are the exclusive provider, physicians won't want to take the time each day to split laboratory specimens between more than one laboratory. Thus, if we hold this HMO contract, we will "pull through" the physicians' non-HMO lab testing business, particularly the private pay and Medicare fee-for-service work.

Circa 1990-1992, as the earliest HMO contracts for lab testing services were negotiated in different regions across the United States—often with a single winning laboratory holding exclusive access—capitated pricing and full-risk utilization were often part of the terms. Capitated pricing was one reason these contracts represented a significant reduction in laboratory reimbursement when compared to typical fee-for-service arrangements.

However, many national and regional laboratory companies exaggerated these reimbursement reductions by bidding the HMO capitated contracts at prices based on the marginal cost (reagents and med tech labor) of high volume routine testing.

Why were they willing to bid a price that was below their fully-loaded cost of performing a test? It was because of the pull-through myth. That myth was simple, and went like this: "If my laboratory is the exclusive provider for this HMO, then the physicians will not want to split specimens between different labs. Thus, by winning this HMO contract, my lab will 'pull through' all the fee-for-service work, including Medicare specimens. The cumulative revenue from

the pull-through, fee-for-service testing will be great enough to offset the money my lab loses on the HMO specimens and generate an overall net profit for physician referrals tied to the HMO contract."

That idea became the popular wisdom in the laboratory industry. For a long time, it was accepted at face value. Plus, if a lab company saw a competitor using marginal cost pricing to win an HMO contract, it was likely to copy that strategy, under that assumption that "they must be doing it because it makes them money."

Popular Wisdom Was Wrong

However, the reality proved much different than the popular wisdom. In many regional markets, physicians proved willing to split specimens in order to continue using their primary laboratory. Thus, the lab holding the HMO contract was often stuck performing tests only for HMO patients at a loss, because the physicians continued to refer non-HMO specimens to their primary laboratory.

More importantly, belief in pull-through as a justification to bid marginal cost pricing for HMO contracts caused laboratory reimbursement to go into a free fall. Two examples illustrate this situation.

Competition for exclusive HMO contracts was probably most intense in California. Not only were there many HMOs, but IPAs (independent physician associations) were also contracting for lab testing services. Capitated rates of 50¢ to 60¢ per member per month (PMPM) were common in the mid-1990s.

Capitated pricing in this range was a huge reduction in reimbursement for lab testing services. In 1993, during my tenure at **Nichols Institute**, an IPA with 5,000 lives in San Diego asked us to renew the lab testing contract with them at the then-prevailing capitated rate of 55¢ PMPM. Because it was a contract renewal, Nichols had utilization data from the previous years. It had been paid $220,000 under its fee-for-service contract the prior 12 months. If it accepted the 55¢ PMPM capitated price for the coming year, it would have received about $33,000 for the same services. That's a reimbursement decline of 85%!

But, among lab executives of that time period, the belief in pull-through business to offset the loss-leader contract pricing was unshakable. Later in 1993, Nichols Institute bid 24¢ PMPM for an integrated delivery system's health plan business. It lost that contract to **Unilab**, which offered a bid of just 19¢ PMPM!

So there was a feeding frenzy of laboratory sharks bidding for HMO business at the front end. The sad lesson was realized on the back end, when victorious labs learned that almost no pull-through business was generated by most HMO contracts. In fact, it was discovered, painfully and over many years, that an exclusive managed care contract could be helpful in obtaining pull-through business—but only if the lab's sales reps conducted an intense sales conversion effort for each individual physician's office account.

Using Up To Five Laboratories

The greatest illustration of the new market reality was Phoenix, Arizona. By 1996, a stroll down the hall of any medical office building would reveal that every physician office had between three and five laboratory collection boxes outside their door. If it meant access to the patients, then doctors in Phoenix were willing to split specimens among many laboratories. In that market, pull-through was virtually non-existent.

The legacy of those years remains with the lab industry today. Pricing for managed care contracts continues to be at rock-bottom levels because of the precedent established when labs rushed to offer payers pricing based on marginal costs. However, one bright spot today seems to be recognition that exclusive provider status on a managed care contract does not guarantee that the lab will enjoy an automatic rise in pull-through specimens. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In the past four weeks, **Genova Diagnostics, Inc.** of Asheville, North Carolina, has acquired two laboratories. First was the purchase of **Individual Well-being Diagnostic Laboratory, Ltd.** (IWDL), located near London, England. The purchase was announced on February 28. IWDL offers tests for "allergy & food intolerance, hormonal balance, digestive analysis, and nutritional assessments." Just 12 days later, on March 12, Genova disclosed that it had acquired **AAL Reference Laboratories** (ARL) in Austin, Texas. ARL has a menu of hormone tests.

MORE ON: Genova

Long known as **Great Smokies Diagnostic Lab** (GSDL), the company changed its name to Genova Diagnostics in March 2006. Its President and CEO is Ted Hull, who formerly held executive positions with **Nichols Institute** and **Quest Diagnostics Incorporated**.

NEW LEGAL BATTLE OVER SELLING HEALTH DATA

Changing consumer and physician expectations over the privacy of medical data is triggering significant changes in long-standing pharma industry practices. Earlier this year, New Hampshire was the first state to ban the collection and sale of prescription data—a common practice for the pharmaceutical industry. Upon passage of the law, **IMS Health** and **Verispan** sued New Hampshire in federal court to overturn the law. Both firms collect prescription data from pharmacies which they sell to drug companies. Drug companies use the data to track prescribing patterns of individual physicians—allowing their sales reps to target doctors for sales calls.

ADD TO: Medical Data

One interesting dimension to this developing trend is that the **American Medical Association** (AMA) makes $30 million per year licensing its physician directory. Drug companies use the directory to cross-reference names with prescriptions. Yet, in a survey of doctors conducted by the AMA, it learned that two-thirds of the physicians surveyed don't like having their names sold and cross-referenced in this fashion. Predictions are that more states will take steps to ban the collection and sale of prescription data. Laboratories should take note of this situation and develop policies that are consistent with changing consumer expectations about privacy of their medical data.

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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...**Delaware Health Information Network** (DHIN), going live as the first statewide system to pass standard format lab data, radiology reports, and discharge data to providers.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, April 23, 2007.

Preview #5

Executive War College

May 10-11, 2007 • Intercontinental Hotel • Miami

Shravan Subramanyam, M.D. on....

Laboratory Services In India: Is the Waking Giant a Threat to the U.S.?

Across the American healthcare system, there is talk of "medical tourism" and the outsourcing of patients to countries with lower costs and skilled physicians. In this national lab industry first, the Executive War College brings a laboratory director to the United States to explain how clinical laboratory and anatomic pathology services are organized in India. Here's your opportunity to get the inside story on the reasons why India could build a business doing laboratory testing for other countries—and when that could become a reality.

Full program agenda and program details, visit darkreport.com

UPCOMING...

- ***More on Middleware: Most Successful Uses of Middleware by Laboratories in Europe.***
- ***Start-up Genetics Laboratory Prepares to Launch National Business.***
- ***Clinical Pathology Professional Compensation Under Siege: Is Pathology Winning the Battles, but Losing the War?***

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