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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Dodging the A/H1N1 Influenza Bullet

DID THE UNITED STATES AND THE WORLD DODGE A BULLET because the first outbreak of A/H1N1 influenza was neither as lethal nor as virulent as long-predicted by public health officials? That might be true today. But wait until the next flu season.

No one knows if the A/H1N1 virus will mutate in ways that make it more virulent and more lethal. Only time will provide the answer. Meanwhile, this spring's relatively short-lived A/H1N1 influenza outbreak has lessons for the laboratory testing industry—and many are described in this issue of THE DARK REPORT. Three separate intelligence briefings detail some rather remarkable stories of how laboratories and lab industry vendors met the unexpected challenges presented by the A/H1N1 outbreak.

First is an analysis of how clinical laboratories and public health laboratories coped with the surge of influenza specimens. Influenza assays currently available to clinical laboratories are less than ideal when a new influenza strain like A/H1N1 appears. Also, the supply chain can be quickly overwhelmed, as laboratories increase their orders and vendors struggle to keep enough lab supplies in the distribution pipeline. *(See pages 3-5.)*

Second is a fascinating story about how the testing capacity and capabilities of many public health labs were increased literally overnight! A unique collaboration involving the **Centers for Disease Control and Prevention** (CDC), the **Association of Public Health Laboratories** (APHL), and **Applied Biosystems**, a division of **Life Technologies Corporation**, led to the installation and validation of 40 new molecular test systems in public health labs in this country because of a 24/7 crash program. *(See pages 6-8.)*

Third, THE DARK REPORT interviews two laboratory professionals about how their organizations stepped up to meet the increased volume of flu specimens that needed testing during the peak of the A/H1N1 outbreak. Both lab companies are gearing up for a busy flu season this fall and have useful advice to share with other pathologists and lab directors. *(See pages 17-18.)*

In my view, the United States and the laboratory medicine profession got a lucky break with this outbreak of A/H1N1. Similar to the SARS outbreak in 2003, this country avoided a serious epidemic for reasons unrelated to preparedness. However, the good news is that the public health establishment has greatly enhanced its ability to respond to similar outbreaks in the future. TDR

Influenza A/H1N1 Outbreak Offers Lessons for Labs

Lack of influenza test capacity at peak demand is warning to private labs and public health labs

CEO SUMMARY: As influenza A/H1N1 spread, clinical labs nationwide learned that they did not have the capacity to test for an outbreak of flu that generated a 10-fold increase in sample volume. To move the samples through the system, many clinical labs ran extra shifts and ran short of supplies. It was a similar situation at public health laboratories, which were inundated with influenza specimens and sometimes a week behind in reporting results. In turn, that meant health officials were often days behind tracking the flu outbreak.

EVERY PANDEMIC OFFERS LESSONS for health professionals seeking to prevent or limit the next event. The current A/H1N1 influenza pandemic has been no exception.

In the United States, the recent A/H1N1 flu outbreak revealed at least four major lessons for lab directors and pathologists. First, the nation's capacity for running confirmatory tests on a new strain of disease, such as A/H1N1, was severely limited. Second, clinical laboratories didn't have the supplies they needed to meet a sudden, 10-fold increase in testing volume for a new infectious disease.

Third, public health labs also lacked the supplies and the capacity to meet this same surge in specimens requiring confirmatory testing. Fourth, the A/H1N1 outbreak demonstrated that molecular testing is now an effective and relatively fast way to detect and identify a specific strain of virus. Rapid molecular assays give public health officials useful new tools to identify and characterize the spread of a virus like A/H1N1.

Experts point out that one important fact about the recent A/H1N1 outbreak is that it began in April, at the very end of the normal flu season in the Northern Hemisphere. Thus, public health agencies in the United States and around the world faced a much reduced incidence of flu cases compared to what would be expected during the height of the normal flu season, which usually peaks in January or February.

These experts also predict that A/H1N1 will be around next flu season. Jeremy Bridge-Cook, Ph.D., Vice President of **Luminex Molecular Diagnostics**, in Toronto, Canada, said current testing

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shows poor immunity worldwide for A/H1N1. Luminex developed the xTAG Respiratory Viral Panel, which tests for 12 different respiratory viruses including influenza A and the normal season flu subtypes H1 and H3.

Poor Immunity in Population

"It's impossible to predict what we will see during next winter's flu season," observed Bridge-Cook. "However, in the United States now, of the samples that test positive for influenza A, roughly 50% are actually the new H1N1 strain. It suggests that the population has poor immunity. In turn, that does not bode well for the coming flu season. This recent H1N1 pandemic hit during a relatively quiet part of the influenza season."

Steven B. Kleiboeker, DVM, Ph.D., is Chief Scientific Officer and a Vice-President of **ViraCor Laboratories** in Lee's Summit, Missouri. He agreed, saying, "Laboratories in the United States experienced a phenomenal surge in specimen volume during the first few weeks of the outbreak of A/H1N1. This event shows that the capacity in our nation's public health system for large amounts of testing is inadequate.

"For example, case volume for the primary assay we run for influenza increased 10-fold," continued Kleiboeker. "That increase lasted only about two weeks. But to accommodate that volume, we extended our normal testing operations by about five or six hours each day. We generally run our lab at about 60% or 70% capacity on any given day. The resources of our laboratory were definitely strained when case volume for one assay in our test menu surged by a factor of 10.

"At ViraCor, we specialize in testing for immuno-compromised patients, which are usually transplant patients," Kleiboeker said. "Most of our clients are hospital laboratories. Only one client sent us a lot of specimens. This client is located in the Southwest, in the border region where the earliest and most rapid spread of the virus was expected to occur. If two, three, or four clients had sent us comparable volumes of flu specimens, our lab would have been challenged to accommodate this testing and sustain normal turnaround times."

Stories of public health labs being inundated with influenza specimens were common, said Kleiboeker. "One thing we learned about A/H1N1 was that the ability of the public health community and public health laboratories to step in and accept such a surge in testing volume was woefully inadequate," he observed.

"We heard stories that, given the heavy demand, some state public health labs were 4,000 to 6,000 samples behind per day," said Kleiboeker. "In the early stages of an epidemic, the pathogen is often spreading rapidly and if laboratory testing can't keep up with demand, then health officials don't know where the virus has spread until two or three days later. In these situations, having an accurate and confirmatory diagnosis of the case from a timely lab test is critical."

Delay In Test Confirmations

In Houston, Texas, by May 12, its public health laboratory had received 6,387 specimens from 17 counties in Texas and only 2,334 had been tested. That left a backlog of 4,053 untested influenza specimens, according to television station **KPRC** in Houston. KPRC also reported that the public health lab had confirmed 52 specimens as positive for A/H1N1. One pathologist interviewed by the television station said that his hospital was waiting for results on flu specimens his laboratory had referred to the city's public health lab more than 10 days earlier.

On the following pages, THE DARK REPORT provides additional intelligence briefings about the influenza outbreak and how both clinical labs and public health laboratories coped with the surge in demand for influenza testing.

Expectations are that A/H1N1 will reappear during the next influenza season.

Labs Report 10-Fold Surge in Test Volume As Lab Supply Chain Overwhelmed by Demand

Testing volume for A/H1N1 influenza cases rose so sharply since April that some labs saw increases of two- to 10-fold in testing volume for the novel strain and ran short of supplies.

The virology department at **PAML**, a medical reference laboratory in Spokane, Washington, reported a 260% increase in testing in the two weeks from April 26 through May 10 compared with H1N1 testing levels for the same period in 2008, said Mona Veltri, Director, Supply Chain Management and Administration. PAML has five joint ventures with 182 patient service centers in nine states.

Sunrise Medical Laboratories in Hauppauge, New York, reported a 10-fold increase over normal levels of H1N1 testing for April and May, said Larry Siedlick, president and CEO. On Thursday, May 14, when New York City Mayor Michael Bloomberg announced the closing of three city schools, Siedlick saw the number of flu cases rise again.

The H1N1 flu strain was detected in April in Mexico. On June 1, the federal **Centers for Disease Control and Prevention** (CDC) in Atlanta reported 10,053 cases in 50 states and the District of Columbia and 17 deaths. Recently, the **World Health Organization** (WHO) said 62 countries reported 17,410 cases of A/H1N1 and 115 deaths.

"We had problems just trying to keep supplies in stock and getting stock on a timely basis," said Veltri. "We would put in an order and be told it would arrive on a particular day and then it wouldn't show because our suppliers didn't have the product. But it wasn't just the distributors; it was the manufacturers as well. Following our disaster preparedness plan, we had conference calls to make sure we updated all the warehouses of our joint venture partners on a daily basis. When product didn't arrive as scheduled, we filled orders short to ensure customer service to all.

"In particular, we had shortages of flocked swabs," she said. "When we couldn't obtain enough product for the kits, we had to use substitutions. Back up plans are critical.

"Even though there were challenges obtaining the volume of supplies we wanted, our patients were not impacted," Veltri said. "We wanted to make sure that every client received some product. Right now, we're fine and the testing volume seems to have slowed down.

"But what we learned was that our plan could use some modifications," she added. "You have your contingency plan A and your contingency plan B for back up— but when the manufacturers can't meet the demand, you know it's a serious problem. Moreover, we all need to be on high alert. This episode shows why it's necessary to plan and prepare for a pandemic.

"Using this experience, we are discussing ways that we can revise disaster preparedness plans," Veltri commented. "We will meet with our distributors and field staff because we hope to be more prepared for the next influenza season for the event that may arise this fall."

That means every clinical laboratory should be developing a strategy and contingency plans to deal with different scenarios. To date, the A/H1N1 influenza has not been as lethal as initially feared by public health officials. However, because knowledge about this new strain of influenza is limited, experts remain concerned that, during the next flu season, A/H1N1 might turn out to be more virulent than expected. That is why THE DARK REPORT advises that lab managers take steps now to prepare for the coming influenza season. **TDR**

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CDC, Public Health Labs Added Flu Test Capacity

➤Crash program beefs up capacity & capabilities of public health laboratories in U.S and abroad

➤➤CEO SUMMARY: Discovery of the A/H1N1 strain of influenza made it imperative that public health laboratories in the United States, Mexico, Canada, and other countries have more molecular testing capacity and capabilities in support of efforts to track and control the outbreak. Applied Biosystems, a division of Life Technologies Corporation, stepped into the breach, upgrading existing public health lab instrument systems while installing 40 more instruments in the United States and 60 additional instruments in countries across the globe.

WITH AN URGENT NEED TO IDENTIFY the A/H1N1 influenza virus quickly and accurately, officials from the federal **Centers for Disease Control and Prevention** (CDC) placed a call to Brian Plew, Director of Biosecurity Solutions for **Applied Biosystems**, a division of **Life Technologies Corporation** of Carlsbad, California.

It was Thursday, April 23. The world was not yet familiar with the novel A/H1N1 strain of influenza virus that was already spreading from Mexico to the United States, to Canada, and to other countries worldwide.

At the time, Plew and a team of Applied Biosystems professionals were already collaborating with the CDC to roll out the company's 7500 Fast Dx Real-Time PCR Instrument for use by public health labs in the United States. The 7500 Fast Dx is the only machine cleared by the FDA for molecular testing of influenza.

Prior to the A/H1N1 flu outbreak in April, Applied Biosystems had already installed about 105 of these systems across the country. Following an FDA 510(k) clearance issued to Applied Biosystems on September 30, 2008, the firm started to recalibrate these systems in the field from research-use only to diagnostic capability.

➤Installing New Systems

The upgrade process had proceeded at a measured pace. But that changed immediately after the outbreak of A/H1N1 flu in Mexico in late April. The need for additional instruments meant that Plew and more than 100 of Applied Biosystems' lab professionals and consultants would work almost nonstop to install 40 of the 7500 Fast Dx machines in the United States and another 60 systems in public health labs worldwide. The pace of installations was—and continues to be—frenetic.

"From the moment when the CDC called us on April 23, any step we took with respect to public health labs in the United States was coordinated among us, The CDC, and the **Association of Public Health Laboratories** (APHL)," Plew said last week in an interview with THE DARK REPORT. "Absolutely, the CDC helped set the priorities in the United States. Following that ini-

tial call on April 23, we set up a task force the next day, which was Friday, April 24. Then calls starting coming in from around the world. By Sunday, we had a global task force up and running.

"On Monday, April 27, Mexico was the absolute top priority for us," recalled Plew. "That country had very little testing capability. A CDC team was traveling there and asked us to support health authorities in Mexico as well.

"In recent years, we have worked with the CDC on influenza, but at a measured pace," recounted Plew. "Applied Biosystems was upgrading certain instruments in the field to give them the diagnostic capability for influenza. As part of its plan for influenza surveillance, the CDC was also training state health laboratories in how to operate the instrument as a diagnostic tool. However, that measured pace changed overnight into a crash program to help boost molecular testing capability and capacity for the CDC, for public health labs in the United States, and for public health programs in countries across the globe.

Fastest Detection Methods

"The reason the CDC wanted the 7500 Fast Dx is that it has two capabilities," observed Plew. "First, it can detect H1N1. Second, it is a 96-well instrument, providing public health laboratories with the throughput required to support outbreaks.

"Epidemiologists know the limitations of many flu tests," he continued. "Antibody tests can identify that the virus is influenza A or B. But these tests can't tell you if it's swine influenza A/H1N1. Nor can they confirm any influenza subtype.

"Also, antibody tests might offer a faster turnaround time to result—but antibody assays deliver less specificity and less sensitivity," Plew stated. "Studies show some of those assays typically run at about 50% to 60% sensitivity, which is close to the odds on a coin toss."

To cope with the flood of influenza specimens generated by the outbreak, public health laboratories needed the higher capabilities provided by more sophisticated molecular technologies. Thus, Applied Biosystems worked nonstop to meet the urgent demand for instrument systems. "In New York City, for example, we upgraded five instruments over a single weekend by shipping the machines overnight and having multiple technicians running each upgrade in parallel," he said. "The same was true for machines we installed in many states, such as Texas, which was hit hard by H1N1.

Instrument Runs 24 Specimens With Three-Hour Time to Result

IT'S NOT A BIG INSTRUMENT SYSTEM. The 7500 Fast Dx Real-Time PCR Instrument manufactured by Applied Biosystems "looks like two desktop computers side by side with a cover on them, and it's connected to a laptop," said Brian Plew, Director of Biosecurity Solutions at Applied Biosystems, a division of Life Technologies Corporation.

"The instrument processes 96 reactions in a single run, which takes about an hour for the detection component," explained Plew. "This comes after the steps to extract the nucleic acid and prepare the sample for analysis on our instrument.

"The entire process takes about three hours, from specimen prep to result," he added. "Running 96 tests in three hours is considered high throughput for this particular molecular technology.

"These 96 tests represent 24 samples because each sample receives the four tests that are part of the CDC's swine flu panel," noted Plew. "The CDC's Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel) has:

a) a matrix test for influenza A;
b) an updated matrix for the new novel strain of influenza A (meaning A/H1N1);
c) a subtype for H1; and,
d) a control (which is a human gene)."

"The CDC also had us working in Mexico, where we probably had our greatest positive impact," Plew said. "Since the beginning of the flu outbreak, we have installed about 30 instruments in Mexico, and helped establish perhaps 10 new laboratories.

"We continue to maintain technicians in Mexico to support those labs and the CDC's team in that country," he stated. "Around the world, Applied Biosystems had an installed base of 100 instruments in public health laboratories. About 60 more instruments have been delivered and made operational globally since the beginning of the flu outbreak."

"Now that we have these systems in place in U.S. public health labs, all states have the capability to identify the spread of the H1N1 virus, which is something many states didn't have at the beginning of the outbreak," noted Plew. "Currently state health officials can evaluate flu specimens with specificity using the CDC's influenza test panel and our instrument.

Used Only For Epidemiology

"Of course, this system is currently used for epidemiology only, and not for patient care," Plew added. "It speeds up the identification of the virus at the state public health level, but it does not improve conditions at the clinical level. Doctors treating patients do not have access to this science and technology.

"Someday it may be available for clinical laboratories, but the challenge with an influenza virus like H1N1 is that it is highly susceptible to mutation," he explained. "Thus, the more specific you make the assay, the more likely the mutation will drift off your design. This in turn requires closer monitoring of performance and the ability to rapidly implement subtyping assays."

Plew points out that molecular diagnostics is a game changer in public health. "This latest influenza outbreak demonstrate the immense value of molecular testing. Twenty years ago, there was no way for public health officials to recognize this type of disease outbreak as it happened. The off-season flu cases would be recorded as a flu outbreak. Then, later in the fall, the same flu strain might come back and be a big killer.

Ready For Next Flu Season

"In fact, that is now the big question: will the U.S. public health system be ready for influenza season in the fall?" he asked. "Absolutely! The public health establishment now has the capability to monitor an outbreak from an epidemiological standpoint and to manage surveillance.

"What worries some is the fact that this molecular flu testing capability doesn't yet translate into patient care," observed Plew. "If H1N1 turns more deadly, and people start demanding a flu test to know if they have H1N1, those demands could overwhelm the public health system—in locations where the doors might be opened to permit that type of testing. After all, demand for access to more accurate influenza testing by a worried public would be difficult for health officials to ignore."

THE DARK REPORT observes that the A/H1N1 outbreak is probably the first major global disease outbreak where molecular testing played a front line role. Further, ongoing improvements in molecular technologies and laboratory testing systems guarantee that a growing number of public health laboratories and clinical laboratories will have more sophisticated assays for influenza and other types of infectious disease.

100+ Instruments Installed

This speed of technology change and its introduction into use is well-illustrated by Applied Biosystems' response to the A/H1N1 flu outbreak. In only a few weeks, it was able to manufacture, install, and bring up more than 100 new, sophisticated testing systems. That's an impressive reaction to a national and global need. **TDR**

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FDA Enforcement Update

35 Firms Get FDA Warning Letters Regarding Various Swine Flu Claims

THREE COMPANIES ADVERTISING laboratory tests for swine flu A/H1N1 were among those firms targeted for warning letters by the **Food and Drug Administration** (FDA) last month.

Between May 4 and May 29, the FDA sent warning letters to 35 companies. The warning letter typically noted that the FDA had reviewed each company's Website and had determined that the site offered a product for sale that is intended to diagnose, mitigate, prevent, treat, or cure the A/H1N1 flu virus in people. "This product has not been approved, cleared, or otherwise authorized by FDA for use in the diagnosis, mitigation, prevention, treatment, or cure of the 2009 H1N1 Flu Virus," the FDA said in the 35 warning letters.

Web Claims Examined

In the letters, the FDA stated that the marketing of these products violates federal law. The FDA further requested that the companies cease marketing these unapproved, uncleared, or unauthorized products for the diagnosis, mitigation, prevention, treatment, or cure of the A/H1N1 flu virus "immediately."

Three lab testing companies were among the 35 firms that received the FDA warning letters. They are: **Becton Dickinson & Company** for its BD Directigen EZ Flu Test; **Luminex Corporation** for its xTAG Respiratory Viral Panel; and, **Prodesse, Inc.**, for its Prodesse ProFlu+ Assay.

It is not known if the FDA has taken further enforcement action against any of the 35 companies that received these warning letters. But the collective list of 35 products shows why regulators face a difficult time. Other types of products targeted for warning letters run the gamut from nutritional supplements and drugs that claimed to be effective against swine flu, to medical devices and protective products, such as masks and gloves.

For example, the **Skilling Institute** offers the "Proton Genie," which claims, among other things, to "stimulate and strengthen the entire immune system."

Another company which received an FDA warning letter is **LifeSecure**. Among its swine flu product offerings is the "On-The-Go Swine Flu Personal Infection Protection Kit." Offered at $19.95, the product description says, "The kit is designed to accommodate one person for up to two days and includes such items as N95 respirators, eye protection, vinyl gloves, disposable thermometers, tissues, hand sanitizer, and biohazard bags."

In these 35 warning letters, the FDA advised each company that, "You should take immediate action to ensure that your firm is not marketing, and does not market in the future, products intended to diagnose, mitigate, prevent, treat or cure the 2009 H1N1 Flu Virus that have not been approved, cleared, or authorized by the FDA."

Some publications that closely watch the FDA have interpreted the warning letters to BD, Luminex, and Prodesse as a sign that the FDA is using this opportunity to more tightly regulate molecular testing. But, given that these three warning letters were sent during the same May 4-29 period as the other 33, it is likely that regulators wanted to establish a public record that they were actively monitoring for any and all products advertised as effective for swine flu without proper regulatory review of those claims. TDR

Earns Dual Medicare and ISO 9001 Accreditation

Accreditation with DNV Helps Hospital Raise Inpatient Volume

CEO SUMMARY: In Utica, New York, 201-bed St. Elizabeth Medical Center was the first hospital in New York State and one of the first five hospitals nationwide to meet the new accreditation standard from DNV Healthcare, of Cincinnati, Ohio. St. Elizabeth administrators credit use of this new accreditation process in helping the hospital improve efficiency, patient satisfaction, and employee retention. Meeting the DNV accreditation standards was relatively easy because the facility was already accredited for ISO 9001 and ISO 14001 from the International Organization for Standardization (ISO).

FOR HOSPITAL ACCREDITATION, there's a new player in town. Last fall, **DNV Healthcare, Inc.** (DNV), of Cincinnati, Ohio, was approved by the **Centers for Medicare and Medicaid Services** (CMS) as a hospital accreditation program in the United States.

This changes the accreditation landscape in two ways. One, DNV Healthcare, a division of Norway-based **Det Norske Veritas**, becomes the first new hospital accreditation competitor for **The Joint Commission** in 40 years. Two, DNV's accreditation program allows hospitals and other healthcare organizations to meet Medicare accreditation criteria while at the same time achieving ISO 9001 accreditation.

For hospital laboratories and pathology group practices, this development is likely to have long-term consequences. That is because, in one stroke, CMS increased competition for hospital accreditation while giving hospitals an option that allows them to pursue ISO 9001 accreditation.

Accreditation Through DNV

To learn more about DNV's hospital accreditation process and the different ways it may involve laboratories and pathology groups, THE DARK REPORT contacted **St. Elizabeth Medical Center** in Utica, New York. This 201-bed medical center is the first hospital in New York State and one of the first five hospitals nationwide to meet the new accreditation standard from DNV Healthcare.

Currently, DNV has accredited 20 hospitals in the United States. The accreditation confirms that St. Elizabeth is meeting Medicare and Medicaid's standards to provide healthcare services and is meeting the **National Integrated Accreditation for Healthcare Organizations** (NIAHO) standards for ISO 9001 from the **International Organization for Standardization** (ISO).

St. Elizabeth is a first-mover in these achievements. It was the 12th hospital to be accredited to ISO 9001 in the United States. In 2005, it became the first hospital to hold dual certifications in ISO 9001 and ISO 14001:Environmental Management, said David Briggs, St. Elizabeth's Quality Director. Now that it works with DNV, St. Elizabeth is no longer accredited by The Joint Commission, the longtime leader in hospital accreditation in the United States.

According to Briggs, accreditation is about more than meeting standards. "By learning how to be more efficient, St. Elizabeth has increased the number of patients it treats without adding to capacity," observed Briggs. "Our medical center also increased its patient satisfaction ratings and its employee retention numbers. We attribute both of these improvements to pursuing ISO accreditation."

Accreditation Decision

Last October, the federal Centers for Medicare & Medicaid Services (CMS) announced that it would allow DNV to accredit hospitals. Two months later, St. Elizabeth's dropped its longstanding affiliation with The Joint Commission in favor of DNV.

"It was both a practical and a philosophical issue for us," Albert D'Accurzio, M.D., the medical center's Vice President of Medical Affairs, told *HealthLeaders* magazine. "If we wanted to maintain ISO certification and use The Joint Commission for our CMS accreditation, we would have undergone two different surveys by two different organizations. This is a simpler process."

St. Elizabeth's President and CEO, Sister M. Johanna, believes DNV is more than a new accreditation program. "It's a catalyst for our ongoing commitment to patient safety and clinical quality," she said. "With NIAHO, we can achieve full ISO compliance and satisfy our annual accreditation requirements at the same time, for no additional cost. Quite literally, it is a win-win for us, our patients, and our community."

What sets St. Elizabeth apart from many other hospitals is that the ISO standards are the foundation of the medical center's quality management system, which ensures that the medical center is taking all necessary steps to deliver safe and effective healthcare services to patients.

In the clinical laboratory, there is another benefit. The lab is accredited by the **College of American Pathology** (CAP) and the New York State Department of Health. "Since both of these entities have accreditation standards similar to those of ISO, the lab was more prepared than any other hospital department when it was time to make the transition to DNV accreditation," stated Briggs.

"As our hospital went through this process, the clinical lab was one of the most supportive departments," Briggs commented. "That is because the laboratory is CAP-certified and there are similarities to DNV in terms of accreditation standards.

DNV Accreditation Standards

"It meant our lab was functioning somewhat ahead of our organization in this regard," he explained. "While there were minor formalities relative to structure, it was not as difficult for our clinical laboratory to comply with the DNV accreditation standards as it was for other departments in the hospital.

"And now CAP is pursuing ISO 15189 as a standard for clinical laboratory accreditation," Briggs continued. "Recognizing the value of ISO 15189, we are working on a project now to be certified for ISO 15189 and we would like to get that done in the next two years."

While using DNV for Medicare accreditation requirements only became possible late last year, the hospital has worked with ISO accreditation for seven years. "We started the journey to ISO in 2002, and we have been ISO 9001 accredited since 2005," Briggs explained. "In that sense, it was a natural evolution to pursue Medicare accreditation through DNV.

"That's because the NIAHO standards for the DNV accreditation are integrated and blend the requirement to comply with the conditions of participation from CMS with compliance with ISO 9001 standards," stated Briggs. "What is new to healthcare in the United States is to be compliant with the ISO 9001 standard.

Already ISO 9001 Accredited

"Given that we were already compliant with the ISO 9001 standard, it was natural that we would seek DNV accreditation to meet Medicare program requirements," he said. "We believe our ISO accreditation distinguishes us from most other facilities. For us, ISO accreditation has been a good business decision."

St. Elizabeth Medical Center adopted quality management methods during the 1980s and 1990s. ISO accreditation was a logical next step in transforming its management culture. "We decided to pursue ISO accreditation for several reasons," recalled Briggs. "At that time, we believed we had taken total quality management (TQM) about far as it could go.

"Next, we recognized that many quality management systems are built on a reactive approach to situations," he continued. "Thus, it often takes some external stimulus, such as a failure of some kind, to trigger the quality system review. At St. Elizabeth, we wanted to be more proactive and manage quality from the 'system of prevention' mind set.

Structured Quality System

"So, as we considered moving from TQM to a Six Sigma quality management system, we quickly recognized that we would need to deploy Six Sigma as a structured system hospital wide," Briggs added. "That was necessary to realize sustained benefits from other quality improvement methods.

CAP, ISO Processes Put St. E's Laboratory Ahead of the Curve for DNV Accreditation

LAB DIRECTORS AND PATHOLOGISTS may wonder what it's like to go from being accredited by the Joint Commission to being accredited by DNV Healthcare. After all, the Joint Commission in Oakbrook Terrace, Illinois, is the long-time market leader in hospital accreditation. DNV in Cincinnati is the new rival upstart. DNV earned deeming status from the federal Centers for Medicare & Medicaid Services last fall.

St. Elizabeth Medical Center in Utica, New York, earned Medicare accreditation last December using DNV. It was one of the first hospitals in the United States to use DNV for a dual Medicare and ISO 9001 designation. For St. Elizabeth's clinical laboratory, the transition was relatively painless.

"In terms of the ISO accreditation, we were a bit ahead of the curve and that's because we were already extensively regulated by the Joint Commission, the College of American Pathologists, and the New State Department of Health," said Lab Manager Kathy Inglis, MS, MT/ASCP.

"Our lab was already using control charts and statistics for managing processes," she added. "Therefore, the DNV accreditation steps were not new to us."

Billable Tests Per Year

The laboratory performs about 850,000 billable tests per year. Outreach testing makes up about 30% to 40% of total volume. In addition to serving the 201-bed facility, the laboratory serves five nursing homes and 14 clinics. The lab has 74 employees and two contracted pathologists.

"CAP and the New York State Department of Health follow many of the ISO and CLSI standards," Inglis noted. "So our laboratory found it a natural transition to meet the ISO standard. Even though our lab is not certified to ISO 15189:Medical Laboratories, we will look at starting that process in the next year or two.

"ISO requires your laboratory to focus on key quality indicators," she continued. "Among other things, it encourages you to listen to the voice of the customer to develop those indicators, then use outcomes to guide improvement efforts," Inglis stated. "Your customers will include anyone interacting with your laboratory. That ranges from physicians and nursing staff, to patients and your laboratory staff.

ISO 9001 Standards In Lab

"Once our lab met the ISO 9001 standards, we've seen many positive outcomes, including reduced turnaround time," Inglis said. "For morning lab tests, we consistently report results by 7 a.m. for intensive care patients and by 9 a.m. for regular inpatients. Before starting our ISO accreditation process several years ago, the lab met morning turnaround times only about 50% of the time.

"Each area in the lab that we have attacked with an improvement project has produced worthwhile gains, including patient satisfaction with phlebotomy and our error rate," she added. "For example, the rate of hemolyzed specimens from the emergency room has improved—in part because of improved communication between departments.

"In the past, the ER staff often drew blood using an IV catheter," Inglis observed. "About 50% of those samples were hemolyzed. As part of a joint improvement project, we asked the ER staff to use straight sticks and venipunctures. That has sharply reduced the rate of hemolyzed specimens to a level that is now at the national average. As a result of working together more effectively with the ER staff, line draws have been almost eliminated."

"Thus, our natural evolution in quality management was to build a system that would be used in every department of the hospital," he said. "The ISO 9000 standard met our specification for a quality management system because we could hardwire the effort in every department and it would be sustainable.

A Natural, Logical Addition

"We achieved ISO 9001 accreditation in 2005," Briggs commented. "The same year, we also achieved the ISO 14001 accreditation, which is a standard for environmental management systems designed to decrease the pollution and waste a business produces.

"When it became possible to use DNV for our Medicare accreditation, that was a natural step," he stated. "Now we have accreditation under DNV (for Medicare), ISO 9001, and ISO 14001. Because all three are built on the same quality management platform, it simplifies the process for us and puts us all under one house for accreditation."

Briggs discussed some of the key changes required to pursue these accreditations. "For example, control of documents and documentation management was a major project," he observed. "Implementing systems to manage documents was a fairly significant task. We implemented formal corrective action and internal audit programs.

"Another big change in working environment was to teach staff how to work with continual improvement as a defined process.

Accreditation Advantages

"Since becoming accredited to ISO 9001, it's possible to see the advantages to our hospital over time," commented Briggs. "We know that we are accomplishing continuous improvement. In turn, that is moving our patient and customer satisfaction numbers in a positive direction.

"In addition, we believe these accreditations give us a competitive advantage," he added. "It helps us produce a better product and we know that from our own internal staff surveys, our outside patient satisfaction surveys, our patient volume, and our employee retention rate.

"Last year, for example, we discharged roughly 800 more patients in 2008 than we did in 2007," he said. "That healthy growth came from increases in efficiency because we had the same number of beds: 201. Increasing efficiency allows us to increase throughput," noted Briggs.

"Another way to qualify our results is to consider how our competitors view us in the Utica market," he added. "We have another hospital across town that is a bit larger than we are. There are hospitals in Rome, Oneida, and Hamilton, and each of these four hospitals is in a primary or secondary market for us. I have fielded inquiries from some of these facilities, asking questions about the ISO/NIAHO process offered by DNV Healthcare.

Achieving 6-Sigma Quality

"In fact, for the past 40 years, the healthcare system has had one way of operating, yet it continues to struggle to maintain a 2-Sigma or 3-Sigma level of quality. Outside of healthcare, many industries are reaching 5-Sigma and 6-Sigma quality levels. Healthcare must change to achieve similar quality levels. This is one reason why I supported the introduction of the ISO philosophy here at our medical center."

THE DARK REPORT observes that St. Elizabeth Medical Center is a first mover in the American hospital industry because of its use of DNV's dual Medicare and ISO 9001 accreditation service. It is significant that hospital administration is enthusiastic about the benefits which result from this dual accreditation service.

From a patient care and revenue perspective, St. Elizabeth was able to discharge 800 more patients in 2008 compared to 2009, without any increase in its 201-bed facility. It attributes this improvement to better work flow within

New Accreditation Processes From DNV Put the Focus on Non-Punitive Environment

HOSPITAL LABORATORY DIRECTORS may be interested to know that there are sharp differences between a typical Joint Commission accreditation audit and a DNV Healthcare accreditation survey.

"From a staff perspective, one difference we noticed was that the DNV accreditation reinforced a significant change in attitude," said David Briggs, Quality Manager for St. Elizabeth Medical Center. "DNV focuses on the 'just culture' philosophy, which holds that human beings will make errors and when they do, processes are often at fault.

"We continue to deploy that idea by developing a non-punitive environment," he explained. "When an error occurs, we look first at the processes involved. Then, if human error is involved, we determine whether that human error was intentional or not.

"Because this approach removes the fear, it helps us get more out of our performance improvement activities," Briggs continued. "Previously, it wouldn't be uncommon that, when external surveyors were on site, staff would be advised to provide a simple answer to surveyors' questions and not offer additional information.

"But DNV's accreditation process is highly collaborative. In turn, that encourages our staff to be open and work closely with the surveyors," he said. "In fact, we ask staff to be open because we know that the accrediting surveyors are here as an integral part of our quality improvement activities.

"Essentially, the entire accreditation survey process is now viewed by most as a benefit to our organization," added Briggs. "At the same time, the staff members also consider that they have a voice and can contribute to improving processes and outcomes.

"One example of this positive difference during the accreditation process is that, when the surveyors are scheduled, we do absolutely nothing to get ready," Briggs said. "In fact, the surveys are unannounced. We know roughly when they're coming and so we may identify who will be around when the surveyors are here. But that's it. Then, when surveyors arrive at our hospital, it tends to go smoothly."

the hospital because of how it uses quality management methods to improve individual work processes and outcomes.

Another benefit results because many of the biggest employers in the region understand how ISO 9001 accreditation contributes to higher quality and better customer service. As an ISO 9001-accreditated hospital, this achievement gives St. Elizabeth additional competitive advantage in its marketplace.

Perceptive pathologists and laboratory administrators probably also noticed the comments about the "non-punitive" nature of the accreditation process followed by DNV Healthcare. This is consistent with effective use of quality management systems, where the objective is continuous improvement by recognizing sources of errors and fixing them.

It is also obvious that adminstrators at St. Elizabeth Medical Center are quite satisfied with the DNV Healthcare approach to hospital accreditation. This may be a sign of an impending competitive shift in the hospital marketplace as other hospitals decide to use the dual DNV and ISO 9001 option for accreditation. **TDR**

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Lab Marketing Update

Mickey Mouse to Educate Kids About Allergy Lab Test Options

THIS MAY BE A FIRST IN LABORATORY TEST SALES AND MARKETING! Mickey Mouse will star in a new children's book designed to educate children and parents about diagnosis and management of allergies.

This unique marketing campaign is the brainchild of **Siemens Healthcare** and **Walt Disney Corporation**. The book is called *Mickey and the Giant Kachoo!* It features Disney character Mickey Mouse and explains how blood testing can help identify allergies.

Here is the front cover of the new children's book produced by Disney in collaboration Siemens Healthcare. It is designed to educate children about allergy testing and treatment.

Disney and Siemens plan to distribute the book to physicians and pathologists. In turn, they would make it available to parents and children.

Siemens Healthcare is using the Mickey Mouse book as part of a larger marketing campaign to promote wider use of its 3gAllergy tests. These assays were introduced in 2002 and can be run on the company's IMMULITE immunoassay systems.

Mickey and the Giant Kachoo! is intended to show how the use of blood tests can be used to detect allergies without the child having to undergo the unpleasant scratch or skin prick allergy testing process. From this perspective, the book is aimed at informing parents that they have other options for allergy testing which don't involve the unpleasant scratch/skin prick testing procedure.

This project is one aspect of a "12-year strategic technology and marketing alliance" initiated in 2005 by Siemens and Disney. This includes Siemens' sponsorships of certain attractions at Walt Disney Resort World in Orlando, Florida.

Mickey and the Giant Kachoo! is another aspect of the Siemens–Disney alliance. It involves the use of Disney characters to educate children about health issues.

For pathologists and lab executives, this new laboratory test marketing campaign shows how consumer-directed advertising will play an important role in helping *in vitro* diagnostics (IVD) companies expand the market demand for their laboratory test products.

It also is an early and innovative demonstration of how collaborative marketing can benefit both IVD manufacturers and clinical laboratories. This campaign is based on the assumption that educating parents about another allergy testing option besides the scratch/skin prick test panel will increase demand for a lab test that is less painful for the child without sacrificing diagnostic accuracy. **TDR**

Influenza A Test Is a Help When Screening for H1N1

In anticipation of the next flu season, some labs are expanding flu test capacity and capabilities

CEO SUMMARY: Viracor Laboratories is preparing to handle expanded volumes of influenza testing prior to the start of the next flu season. It will use added instrumentation and expanded working hours to expand capacity. Another strategy is to use influenza A testing as a way to reduce the overall number of influenza specimens that might need to be referred for additional testing. New molecular tests offering better sensitivity for influenza are also entering the clinical marketplace.

So far, influenza A/H1N1 has not been the public health threat long predicted by experts. It arrived at the very end of the flu season and has not proved to be as lethal as originally feared. But this is only the first chapter in the A/H1N1 story.

"Fortunately, this influenza virus has not been highly lethal or highly virulent and standard flu treatments work well," stated Steven B. Kleiboeker, DVM, Ph.D., Vice-President and Chief Scientific Officer at **ViraCor Laboratories** in Lee's Summit, Missouri. "It did spread rapidly, spanning the globe in a short period of time. But the number of deaths has been moderate. That can all change because flu viruses often pick up virulence. Thus, we are not yet finished with this virus.

"So, will clinical laboratories heed the lesson and develop the requisite testing capacity?" Kleiboeker asked. "As a company, we are planning to expand our capacity to handle a surge, by this fall, of around 2,000 flu samples a day. We can get to that level by having our staff work up to 70 hours per week and by operating double shifts of 10 or 11 full capacity hours per day. That would require us to operate the lab for 20 to 22 hours per day.

"It's my belief that all labs should consider ways that they can get more capacity," Kleiboeker continued. "But having the laboratory capacity is only the first step. The second step is to have a validated assay ready to go. Here in Missouri, our public health lab didn't have such an assay in hand until the second full week of the outbreak. That's very late.

Reagent Licensing Issues

"Another issue is that the CDC and the state health laboratories have been unwilling to supply private laboratories with reagents," he said. "Even though the assay is in the public domain, licensing issues create difficulties in making these reagents available.

"It is now recognized that a general influenza A assay is useful," he added. "At a minimum, it allows the laboratory to identify the 5% or 10% of the flu samples that are positive for this factor. These influenza A tests have great sensitivity and reasonably good throughput. Thus, for labs lacking a true definitive assay, those specimens could be reflexed to another lab.

"That arrangement alone would reduce reflexive testing by 90%," said Kleiboeker. "Public health labs need to have a certain number of flu strains that we can identify today and be ready to run them in case of a future similar epidemic."

Another laboratory professional who agrees with the value of using an influenza A test is Jeremy Bridge-Cook, Ph.D., Vice President of **Luminex Molecular Diagnostics**, based in Toronto, Ontario. "It was the ability of the Luminex test to quickly and accurately recognize and subtype influenza A that helped our customers during this outbreak," observed Bridge-Cook.

"Because the Luminex test identifies subtypes, the lab does not have to send out every flu A sample," he explained. "It only needs to refer the specimens which are negative for a subtype result because that indicates that the sample may contain a novel flu A that should be investigated by a public health lab. This benefits hospital labs and public health labs because it greatly reduces the number of flu samples that require follow up testing.

➤Labs Asked To Report Flu A

"Currently the CDC and the FDA are requesting that labs report all flu A samples that are unsubtyped and provide those samples to a public health lab," noted Bridge-Cook. "Thus, labs using a rapid EIA (enzyme immunoassay), DFA (direct immunofluorescent antibody), culture, or any method that does not subtype, must send every positive flu A result to a public health lab to be analyzed.

"Currently, that volume of referral specimens is manageable because it is not peak flu season," he stated. "But, were we to be in the middle of the flu season, it is likely that public health labs would be inundated with flu A-positive specimens that need subtyping." TDR

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Molecular Analysis of H1N1 Proved Fast and Accurate

WITH THE EMERGENCE of the influenza A/H1N1 strain, new molecular testing technologies faced a major public health challenge and played new roles in helping health officials understand and react to the outbreak.

"To my knowledge, this is the first time where large scale molecular testing was helpful and necessary to understanding the spread of the A/H1N1 influenza," said Steven B. Kleiboeker, DVM, Ph.D., the Chief Scientific Officer and a Vice-President of ViraCor Laboratories.

"The rapid flu tests in common use by most clinical labs don't have great sensitivity or specificity and were not designed to distinguish between the different strains of the influenza virus," he noted. "Rapid flu tests are useful for screening. However, when public health considerations become important, a more accurate screening test is needed to identify the genealogy of a virus strain like A/H1N1.

"That's where PCR (polymerase chain reaction) testing has a role," Kleiboeker continued. "PCR testing runs on a robust platform and one scientist with the appropriate instrumentation should be able to process 100 samples every three to four hours."

"This is still a relatively new technology. Many labs that have molecular testing have a narrow spectrum of capability," he added. "The laboratory also needs an assay that has been developed and validated."

"This new H1N1 strain returns a negative resolution H1 assay and a flu A positive," said Kleiboeker. "The H1 component turns out to be significantly different than the seasonal swine A/H1N1. That makes it easy to distinguish from other strains of the influenza virus. It also shows how molecular testing has been an effective tool to help labs identify the new A/H1N1 strain of influenza."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Earlier this spring, **El Camino Hospital** of Mountain View, California, announced the launch of what it calls the "Genetic Medicine Institute (GMI)." It claims it is the first hospital in the United States to "integrate genomic medicine into healthcare delivery." El Camino will use the institute to deliver information and counseling services to physicians and patients so they can "make informed decisions about genetic tests and genomic therapies that can lead to earlier intervention, more effective prevention, and improved care." This moves the hospital forward as a pioneer in offering genetic testing and genetic medicine services.

MORE ON: El Camino

Of particular interest to pathologists and lab managers is the fact that 371-bed El Camino Hospital has contracted with **DNA Direct** to provide "guidance and decision support" that will enable "community physicians to properly use counseling, tests and targeted therapy." El Camino has identified nine genetic tests that it will emphasize in the earliest stages of this program.

GE ANNOUNCES $6 BILLION TO FUND HEALTH INITIATIVES

Another confirmation of the revenue potential of serving the American healthcare market came from a major corporation. Last month, **General Electric** (GE) made a big splash by announcing that it would spend $3 billion during the next six years on research and development to produce innovations that would "lower cost, increase access, and improve quality by 15%" in healthcare. It pledged another $3 billion of financing and technology projects "to drive information technology and health in rural and underserved areas." GE is using the term "Healthymagination" to describe this effort.

ADD TO: GE Initiative

GE sees healthcare technology as a major engine of growth. Of the $17 billion in revenue generated by its GE Healthcare business unit, only 10% is derived from information technology. According to John Dineen, CEO of GE Healthcare, that will change. "We're going to approach this with scale," he said last fall. "How do we double these types of businesses?"

GENETIX ACQUIRES SLIDEPATH LTD

It's an interesting acquisition in the digital pathology sector. Ireland-based **SlidePath Ltd.** was acquired last month by **Genetix Group, plc** of New Milton, United Kingdom. Both companies have marketed their digital imaging products in the United States.

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