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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

Toronto Labs Stressed in Response To SARS Outbreak

THIS ISSUE OF *THE DARK REPORT* BRINGS SOME OF THE FIRST DETAILS about how the SARS outbreak in the Canadian Province of Ontario is causing widespread, sustained disruption to hospitals, laboratories, and office-based physicians, particularly in the Toronto metropolitan area.

When the earliest SARS patients showed up in Ontario hospitals, international healthcare alerts had yet to be issued. Alarmingly large numbers of healthcare workers were exposed and became infected because they had been around SARS patients with relatively little protection. When public health authorities recognized the emerging pattern of infection, they acted swiftly to control the further spread of SARS and learn more about the disease.

I recommend that laboratory executives and pathologists pay careful attention to the still-unfolding story of SARS in Toronto and its eventual aftermath. SARS is a case study for how both bioterror and contagious diseases can emerge at unexpected moments—threatening the health and economic well-being of major cities overnight. In Ontario, SARS placed healthcare workers in hospitals and other settings at risk.

In March, entire hospitals were closed and their staffs put in quarantine for a minimum of ten days. Hospitals ceased elective surgeries and were allowed to treat only patients in "life-threatening" circumstances. A major international medical meeting of 12,000 attendees was cancelled because of concern about SARS exposure and transmission.

The clinical lab's vulnerability to the unknown aspects of SARS was revealed in an unexpected way. A microbiologist who was director of one hospital's infection control team traveled to another hospital to observe and treat a SARS patient. This microbiologist became infected with SARS and, upon returning to her own hospital, exposed all six members of the infection control team. She and three team members subsequently contracted SARS.

The emergence of a new disease such as SARS fulfills the many predictions of healthcare experts. To help lab directors and pathologists understand this phenomenon and develop appropriate management strategies for their own laboratories, THE DARK REPORT is devoting extensive coverage to the Toronto outbreak. The economic and emotional turmoil unfolding in that town is another timely warning that infectious disease outbreaks can hit any town at any time. **TDR**

Toronto Hospital Labs Cope With SARS Impact

Hospital workers fall ill as health system races to control spread of the new disease

CEO SUMMARY: Canada has become one of the world's hot spots for SARS. Concern about the unexpected number of hospital workers who contracted the disease triggered a halt to all but the most life-threatening patient care needs in many hospitals in Ontario. The manner in which this disease is transmitted is causing lab administrators in Toronto to rethink hospital infection control and microbiology activities.

MODERN AIR TRAVEL is demonstrating how swiftly an emerging disease like SARS (severe acute respiratory syndrome) can spread across the globe and challenge hospital-based laboratories.

Starting in mid-February in Hong Kong, a number of SARS-infected travelers carried the new disease to at least 20 different countries. By mid-March, serious outbreaks were recognized in China, Hong Kong, Vietnam, Singapore, and Canada.

SARS brought an added concern. SARS patients in Hong Kong and Toronto, Canada, once hospitalized, exposed a high number of hospital staff to the disease. Hospital workers were at significant risk if proper precautions were not taken.

In Toronto, health officials were quick to recognize this danger and responded immediately. "Hospitals in Toronto are under extraordinary restrictions," stated Ene Underwood. "For the first two weeks of the outbreak, hospitals did only 'life-threatening' work.

"There's now a gradual ramp-up of urgent work with most elective procedures and new referrals still on hold," she added. "Entry to hospitals is restricted to staff and patients. Visitors are allowed in only if the death of their loved one is judged to be imminent. Almost daily, public health officials issue new guidelines in an effort to control the spread of SARS. "

Underwood is President and CEO of **Toronto Medical Laboratories**, the 50/50 joint venture between **Uni-**

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versity Health Network (which owns three hospitals) and **MDS Inc.** She is actively involved in coordinating how her laboratory responds to the daily changes in hospital procedures required by public health officials.

"We are still in the midst of an unfolding situation which has surprised many of us in the laboratory," declared Underwood. "On one hand, SARS has validated that our laboratories were prepared to deal with a new disease. But the transmission dynamics of SARS presented us with new and unanticipated issues."

Hospital Workers At Risk

One of the first discoveries about SARS was that the highly-transmittable nature of SARS put healthcare workers on the front line of risk. "**Scarborough Grace Hospital** admitted Ontario's first SARS patient on March 7," said Underwood. "Within two weeks, 56 healthcare workers at Scarborough Grace Hospital were diagnosed with SARS and a total of 300 of the hospital's 1,300 workers were exposed to the disease.

"According to statistics from the **World Health Organization** (WHO), the infection rate for people exposed to SARS is believed to be as high as 50%," explained Underwood. "The mortality rate is around 4% to 5%. Exactly how the disease can be transmitted is still unknown and there is no diagnostic test. Because so many healthcare workers became infected in the two Toronto hospitals which treated SARS patients, quick action was required."

Staff Put Under Quarantine

Health officials in the province were justifiably concerned that SARS could spread so rapidly among healthcare workers. The provincial health system took swift steps in response to the threat. "In late March, the entire staffs at Scarborough Grace Hospital and **York Central Hospital** were put under quarantine," Underwood stated. "Also, anyone who visited either of those two facilities since March 16 is to be in quarantine. Quarantine is ten days without symptoms, as ten days is believed to be the incubation period for SARS.

"The changes here at **Toronto General Hospital** [Underwood's base hospital] illustrate the full force of these new restrictions," noted Underwood. "There are only two doors for entry. Patients and visitors go to one door. Hospital staff must enter through the other. At the door, staff is greeted by a staff member in gloves, mask, and goggles. Before entering, staff members must wash their hands with alcohol and complete a form daily which asks about recent travel to Asia, relevant symptoms, and similar questions. The staff member's temperature is taken. Only after completing these steps can a staff member enter the hospital.

Patient Contact Procedures

"Within the hospital, staff has been required to wear masks. If seeing a patient, the staff member must wear gloves, a gown, goggles, and either an N-95 mask or PCM 2000," added Underwood.

"It's much the same story at our hospital," observed Murray Treloar, M.D., Pathologist and Physician Leader of Laboratory and Genetic Services at **Lakeridge Health**, located in the Toronto suburb of Oshawa. "Entry to our hospital is limited and elective procedures are not taking place. We had a SARS patient in our emergency department and several nurses were exposed and were in quarantine at home

"To keep SARS patients out of emergency departments, a SARS evaluation clinic was established at a location away from the hospital," stated Treloar. "It operates from noon to 8 p.m. daily.

SARS patients are not welcome in physicians' offices now. So, if an individual thinks he or she might have SARS, most physicians are doing telephone triage and referring the patient to the SARS evaluation clinic."

Both Treloar and Underwood said that, because elective surgeries and non-urgent procedures were not being done in their hospitals, their laboratories were testing significantly fewer specimens. However, testing on patients suspected of having SARS patients continues. Nasal swabs of such patients are sent to public health laboratories, but other testing continued to be done in the hospital labs.

Cross-Team Exposure

The SARS outbreak in Toronto is posing new questions about certain aspects of the way their laboratories are organized and operated. One example is in the relationship between the hospital infection control department and the microbiology laboratory.

THE DARK REPORT notes that one experience from the Toronto SARS outbreak may cause a rethinking of how infection control teams and microbiology labs interact. News accounts have made a big deal of the fact that microbiologist Allison Geer, M.D., who heads the infection control team at **Mount Sinai Hospital**, contracted SARS after visiting and treating the initial SARS patients before the outbreak was clearly understood. All six members of the Mount Sinai infection control team were quarantined and three members contracted SARS. Because of the close routine interaction between the infection control team and microbiology teams, there were initial concerns that a significant proportion of the microbiology department might be forced into quarantine at a critical time in the hospital's response to the SARS outbreak.

Underwood Lists Lab Management Issues Triggered by SARS

1. **Laboratory safety** with unknown diseases like SARS requires review of universal laboratory precautions and standard operating protocols.
2. **Human resource issues** result from restrictions that limit the number of people in hospitals. Significant numbers of lab staff were asked to stay home because of reduced test volumes and some lab staff are home under quarantine. Pay for those at home creates fairness issues with those in the lab working.
3. **Continuity of business** becomes a challenge. Ways must be developed to get vendors on site to service and repair laboratory equipment, as well as conduct normal lab business.
4. **Transfusion medicine** is affected by SARS. There are questions about the safety of the blood system and no effective screening for blood donors exists.
5. **Microbiology–infection control** relationships require assessment during potential infectious disease outbreaks. Personal interaction between the two groups may need to be restricted.
6. **Legal exposure** and risk of litigation must be recognized and addressed. The need to follow standards of care and fully document decisions is heightened, particularly when existing guidelines do not address the unique circumstances.
7. **Laboratory staff** anxiety and concern about safety requires steps to provide information, education, and protection.

"At this point, the obvious implication is that there needs to be caution in how the microbiology and infection control staff interact," said Underwood. "If the head of microbiology is also part of the infection control team, this may require a 'Chinese wall' to maintain separation."

Impact On Regional Labs

The impact of city-wide restrictions on hospital activities and the quarantine of specific hospitals has revealed unanticipated complexities for regional lab organizations serving multiple sites. "Toronto Medical Laboratories is a regional laboratory and provides services to five acute care hospitals and four smaller specialty hospitals," noted Underwood. "Because none of these facilities have stand-alone labs, restrictions on the movement of laboratory staff presented new challenges.

"For example, through the course of the outbreak, one hospital—a comprehensive cancer center—needed to continue providing relatively high levels of care. Our transfusion medicine service is provided through an on-site satellite lab with staff rotations from the larger consolidated lab located at another hospital site. Staff restrictions caused an increased workload for this satellite lab staff while some staff from the consolidated lab are at home with pay," explained Underwood.

"It is a similar situation with pathology," she added. "At our three teaching hospitals, the pathologists are consolidated at a single site and move to the other two sites to support quick sections. During this outbreak, to avoid moving pathologists among these sites, we've been forced to develop different work flow arrangements. We also had to make a decision about handling lab specimens between sites. Should SARS specimens be handled differently? The infection control team and the laboratory team studied that issue and decided that existing protocols provided adequate protection.

"Outside of the laboratory, the experience from this SARS outbreak has been to demonstrate that hospitals may need to have more negative pressure rooms to handle these types of patients," added Underwood. "Around Toronto, hospital plant operations people have worked miracles to create negative pressure rooms literally overnight!"

THE DARK REPORT observes that the SARS outbreak in Toronto is changing daily. The facts reported here were accurate as of press time. The quarantine periods, which were started late in March, were initially set for ten days. Public health officials are watching to see if the number of new SARS cases declines. They are working to limit the outbreak to the third ring of transmission.

Labs Up To The Challenge

Toronto's experience with severe acute respiratory syndrome (SARS) is revealing that the basic organization of hospital and laboratory services is performing well. But this outbreak has identified gaps in the organization of laboratory services which will need to be addressed by laboratories everywhere.

"Within the microbiology community, there is a strong view by people in the know that SARS is a useful dress rehearsal," stated Underwood. "Just like the big earthquake is considered overdue for California, many infectious disease and microbiology specialists believe the next big influenza epidemic is overdue. SARS has provided compelling evidence of how quickly modern air travel can spread a new disease throughout the world." TDR

Contact Ene Underwood at 416-340-4800 ext. 8833; and Murray Treloar, M.D. at 905-576-8711.

Commercial Labs React To Ontario SARS Outbreak

Canada's largest laboratory company swiftly responds to fast-moving disease

CEO SUMMARY: Ontario's SARS outbreak has affected commercial laboratory companies in the province. Because so many healthcare workers were contracting SARS, laboratory directors at MDS Diagnostic Services took swift action to protect both patients and laboratory staff—to prevent exposure and transmission of SARS as well as to insure that no labs would be lost because of quarantines.

COMMERCIAL LABORATORY FIRMS in the Canadian province of Ontario found themselves on the front lines of the effort to control the province's outbreak of SARS (severe acute respiratory syndrome).

"The SARS challenge facing us has been immense," said Chuck Frosst, Vice President of Operations and General Manager of **MDS Diagnostic Services'** laboratory operations in Ontario and Quebec. "First, we are dealing with a disease about which little is known. Second, the laboratory operations of MDS in Ontario are extensive, so we needed to work quickly to insure that our healthcare team and the patients we serve were protected."

Infecting Healthcare Staff

"Another dimension of the SARS outbreak gave us added concern," declared Frank Thompson, M.D., Medical Director for MDS Diagnostic Services in Ontario. "Unlike the early outbreaks of Legionnaire's disease, which involved only individuals from the community, the Toronto SARS outbreak was infecting healthcare workers first.

"Because our laboratory actively serves healthcare providers throughout the province," he continued, "we needed to protect our staff and patients from the disease. We also needed confidence that our laboratory activities did not, unintentionally, expose anyone to SARS."

Frosst and Thompson do not understate the challenge of meeting these objectives. About one-third of the population of Ontario is served by some part of MDS Diagnostic Services' laboratory infrastructure.

Within the province, MDS provides direct testing services to physicians' offices, manages a number of hospital laboratories, performs send-out testing for many hospital laboratories, and has hospitals perform tests for it. MDS maintains an extensive network of patient service centers (PSC), and provides phlebotomy services for home healthcare.

"Province-wide, we collect, transport, test, and transfer laboratory data to all segments of the healthcare system," noted Frosst. "Because we go everywhere and interact regularly with hospitals, physicians, and patients, it is imperative that our response to SARS be effective. Any lapse or flaw in our performance might expose someone to SARS."

Threat To Public Health

"SARS is a public health threat," said Thompson. "When the outbreak in Toronto was first recognized last month, we immediately organized what we called the 'business continuity team.' Meeting daily, it has representatives from each area of laboratory operations.

"This team recognized the need to take three distinct actions. Each was effected in rapid-fire sequence," noted Frosst. "Remember, our management strategy was protection—protect patients and protect our staff."

"Our first priority was to communicate to physicians. It was critical that any patient showing symptoms common with SARS *not* come to our patient service centers," explained Thompson. "We used our electronic links, courier system, and direct phone calls to educate physicians about SARS and notify them that, if they had a patient fitting this definition, to contact us by telephone. We respond to that patient's needs in a setting that protects both the patient and the phlebotomist.

Prevent Exposure

"Effectively, we were going upstream to turn off the tap to prevent possible SARS patients from going into our PSCS, sitting in a waiting room, and exposing other patients and lab staff," noted Frosst. "We took these steps even before the public health sector had turned their attention away from hospitals and toward physicians' offices.

"Our next priority was to ensure that patients were handled in a manner that protected them from exposure and protected our laboratory staff from exposure," said Frosst. "This was essential, because it preserved our ability to respond to the community's needs. If any lab worker is exposed, we lose their services for the ten days of their quarantine. We did this in several phases.

"In the first phase, we made sure they had the right protection," he explained. "Anyone seeing a patient suspected of having SARS, at a minimum, wears gloves and an N-95 mask.

"Our next phase was to secure adequate supplies to maintain protection for our staff," noted Frosst. "We contacted suppliers in Canada, the United States, and Europe. We secured enough supplies to guarantee that all our PSCs would be fully protected through the course of this outbreak."

Reassure Laboratory Staff

The third phase of this project was to educate and reassure the laboratory staff. "With a disease like SARS around, laboratory staff has valid questions. 'Do I come to work?' 'Am I safe at work?' 'Can I be exposed to SARS at work?' Remember, newspapers and TV news were full of stories about healthcare workers contracting SARS," Frosst observed.

"We conducted employee education and meetings," he said. "We did a video, established a telephone hotline, provided Web-access to information, and gave updates at the same time every day.

"We also helped our staff understand how to conduct business while minimizing the risk of exposure," stated Thompson. "These were little things, like having smaller meetings, meeting off site, restricting access to facilities, and increased use of telecon-

ferencing. Because many people chose to work in the laboratory to provide healthcare services to others, our laboratory staff was very responsive to these efforts. They understood the importance of maintaining work flow, while reducing the chance that disease might be transmitted."

"There is also the need to test specimens from diagnosed SARS patients," stated Thompson. "Although SARS testing is done by public health laboratories, routine testing work on these patients must continue. We reinforced the need to follow existing protocols, which should already be in place in a well-run laboratory."

Restricted Access To Lab

"We also instituted restricted access into the laboratory, similar to what hospitals are doing at entry," added Frosst. "Our staff signs in daily, has their temperature taken, and, if they have traveled to areas of known SARS outbreaks, they don't come into the laboratory for ten days.

"Our couriers have the same protection as is required in hospitals, including gloves and N-95 masks," continued Frosst. "They go through each hospital's screening process and are screened again at our lab. They may be screened as often as 12 times each day."

Effective Response

To date, MDS's management response to the SARS outbreak has been effective. "We know several instances where our staff have been in contact with SARS patients," stated Thompson. "In each case, these were protected sessions and infection did not result. In fact, public health authorities state that no healthcare worker who was properly protected has contracted SARS. That gives us and our laboratory a high degree of confidence as we go about our work."

Lab directors and pathologists at MDS plan a post-outbreak review to identify changes that would improve their laboratories' protection. "One insight is that the design of our laboratories may need changing," stated Frosst. "We intend to rethink high ceilings, open lab spaces, and other aspects of our facilities' designs."

Overall, Frosst and Thompson give their laboratory staff high marks for an effective response to SARS. "Neither we nor our healthcare system can afford to lose any of our laboratories to quarantine," noted Thompson. "It's why we describe our protection process as 'shrink wrapping' our labs. Laboratories are a front-line defense and must always be ready to continously provide diagnostic services." **TDR**

Contact Chuck Frosst and Frank Thompson, M.D. at 416-675-6777.

Update to Ontario's SARS Outbreak

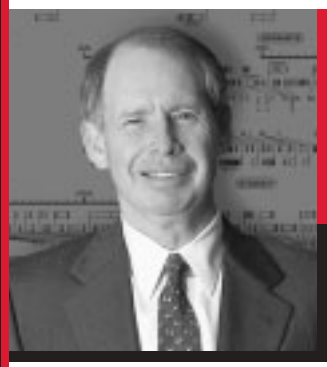
PUBLIC HEALTH AUTHORITIES in Ontario are watching closely to see if they have the SARS outbreak under control.

As of as last Friday, the **Ministry of Health** reported the total number of suspected or probable cases of SARS in the province was 217. This was an increase of 11 over the previous day. Ten deaths have been attributed to SARS in Ontario. For all of Canada, suspected and probable cases total 266.

Public health officials were closely watching the number of new cases daily. They are hoping to contain the outbreak in its "third ring." The main containment strategy emphasizes control of potential exposure of staff and patients in hospitals, believed to be the primary source of "second ring" infections.

News reports in Toronto indicate that health officials believe that SARS is likely to permanently change how hospitals in the province treat certain types of patients.

NEWSMAKER INTERVIEW



"Molecular pathology has the opportunity to be the cutting edge of medicine as we move forward."
—Thomas Mac Mahon

LabCorp's Mac Mahon Provides Insights About Lab Marketplace

LabCorp positions itself to offer more anatomic pathology services

CEO SUMMARY: Pathologists will be particularly interested in what Thomas Mac Mahon has to say about the evolution of laboratory medicine. As Chairman, President, and CEO of Laboratory Corporation of America Holdings, he has continuous access to some of the best strategic analysis about the laboratory testing marketplace and its evolution. Mac Mahon has several surprising predictions to make about the future of laboratory medicine. In this exclusive interview, conducted by **THE DARK REPORT'S** Editor-In-Chief, Robert L. Michel, Mac Mahon talks about the impact of 2002's laboratory acquisitions, specialty esoteric testing, and why more hospital laboratories are entering the laboratory outreach business.

EDITOR: **Laboratory Corporation of America Holdings** is a different company today than it was one year ago. During the past 12 months, it paid $1.3 billion to acquire **Dynacare, Inc.** and **DIANON Systems, Inc.** These companies had annual net revenues of $238 million (U.S. revenues) and $190 million, respectively. Why was LabCorp willing to make such a big investment?

MAC MAHON: Each acquisition supports a core strategic objective within LabCorp. Although Dynacare and DIANON Systems were very different types of laboratories, we viewed their component pieces as good complements to our existing laboratory system.

EDITOR: It may help, then, for you to describe the attributes of LabCorp which you believe makes it unique. What differentiates it from other laboratory companies in the marketplace?

MAC MAHON: LabCorp is a large reference laboratory with 47 major laboratory facilities across the United States. Essentially, LabCorp is a series of regional laboratory business units. Over the past five years, we've worked to standardize our billing systems. To accomplish this goal, we had to also standardize operations and testing services across these regional laboratories. As a result, today we can move specimens throughout our national system.

EDITOR: How does this standardized network of 40+ regional laboratories help LabCorp differentiate itself from other lab companies?

MAC MAHON: I think what separates LabCorp from other competitors is that we have a focused regional effort supported by the consistent quality standards of a national laboratory with standardized billing and lab systems. In the United States, healthcare remains highly regionalized. Most of us recognize, for example, that the needs of physicians and patients in Seattle, Washington may differ from the needs of physicians and patients in Miami, Florida. LabCorp considers it important to have a base in each region of the United States and to understand what is required to best meet the unique healthcare needs of different regions around the country.

EDITOR: What business advantage do you realize from this strategy?

MAC MAHON: We think it gets to the crux of the competitive issue. LabCorp is capable of serving the nation's largest managed care organizations (MCOs) in a consistent manner, while meeting the specific lab testing needs that differ from region to region. By holding these important managed care contracts, it gives us an anchor in physicians' offices. This anchor provides us the opportunity to convince the physician to refer his other lab testing business to us.

EDITOR: But using managed care contracts to provide access to office-based physicians is only one competitive objective. Could you speak to how LabCorp wants to develop its business relationships with physicians?

MAC MAHON: Our over-arching goal is to offer as many testing capabilities to a physician as we can. Whether it's an ob-gyn, family practitioner, or internist, we want to convince physicians to use LabCorp and its testing services in a manner that may be unavailable to them from other laboratories in the region.

EDITOR: To sum up this point, one key attribute that differentiates LabCorp is its national system of 47 regional laboratories, which helps it be a "local provider" in nearby communities. This complements LabCorp's ability to win and hold national managed care contracts, which provide it with a foothold in physicians' offices for upselling more lab testing.

MAC MAHON: Yes. But this attribute must be seen in context of how the laboratory industry has changed during the past five years.

EDITOR: Because LabCorp is responding on several other levels?

MAC MAHON: Definitely. Another factor which has changed our laboratory industry over the past five years is the clinical value of new information that can be gleaned from the human body. Whether that information is about an infectious disease or a genetic disorder, laboratories can now provide physicians with diagnostic information that was unavailable just a few years ago.

EDITOR: How has this affected the laboratory industry?

MAC MAHON: Within the market for laboratory testing services, we believe two business industries are emerging and must be addressed by every laboratory. The first business industry is the routine testing done by all laboratories to support office-based physicians. Just as it has during the 1970s, 1980s, and 1990s, this will continue into the future. However, new science is contributing to the creation of a second business industry that I will describe as "sophisticated esoteric

testing." Examples are enhanced Pap tests, HPV tests, the cystic fibrosis test for family planning, phenotyping and genotyping. I see progression in this business as different from that of the regionalized, routine testing business.

EDITOR: In what ways?

MAC MAHON: Today specialty esoteric testing is a relatively small part of the lab testing pie, but is evolving rapidly. There are only a handful of established companies offering these types of tests, such as LabCorp, **Quest Diagnostics**, **ARUP Laboratories**, **Mayo Medical Laboratories**, and **Specialty Laboratories**. At LabCorp, we want to be unique and bring lab customers tests from both of these business segments. There are not many laboratory companies which can compete in both the routine and the esoteric segments. For example, we don't see much competition in the areas of phenotyping and genotyping from non-profit hospital laboratories.

EDITOR: Tom, that comment indicates you have distinct views about the evolution of routine lab testing compared to sophisticated esoteric testing. What roles might hospitals and hospital-based laboratories play in this evolution?

MAC MAHON: That question strikes to the heart of our profession's competitive evolution. In both the short term and long term, chronic disease will be treated in outpatient settings. More of the testing, whether for cancer, for infectious disease, and for other illnesses, will be done in support of outpatient treatment.

EDITOR: This has major ramifications for hospitals.

MAC MAHON: Certainly. The growth of outpatient activity has been well-documented since the early 1980s. To me, here is the interesting dilemma for laboratories that you write about all the time and about which I am constantly asked. What will be the relationship of the hospital laboratory and the independent laboratory like LabCorp?

EDITOR: It sounds like you expect more hospitals will develop laboratory outreach programs. Explain the dynamics behind this trend.

MAC MAHON: Actually, I don't. My premise is that existing hospital laboratories which are already vigorous competitors against commercial laboratories have done so because they recognize this fundamental shift away from inpatient treatment in favor of outpatient treatment.

EDITOR: It's a case of following the patients.

MAC MAHON: Look at how healthcare has changed the way the important diseases are treated, such as cancer, infectious disease, and cardiovascular disease. In the 1970s, it was common for a patient to be admitted to the hospital for between one and four weeks. Because of advances in medicine, better technologies, and new drugs, it is now unnecessary for a patient to spend weeks in a hospital undergoing treatment. Today, most patients stay only a few days in the hospital as a result of efforts to minimize inpatient stays as a way to control costs. These developments are steadily transforming hospitals into short-term healthcare facilities.

EDITOR: That is certainly true.

MAC MAHON: Take infectious diseases such as HIV, hepatitis B and C, chlamydia, and others. Fifteen years ago, we couldn't think about treating these infectious diseases. Today there are outpatient treatments that minimize hospitalizations. Collectively, these factors bode well for continued growth in non-hospital sources of healthcare. It also bodes well for the laboratory industry, because almost all of these medical advances require laboratory testing to support diagnosis, therapy, and patient monitoring.

EDITOR: Is that why you see growing numbers of hospital laboratory outreach programs that are viable and professionally-managed?

MAC MAHON: Yes—and that shouldn't surprise anyone! These hospital outreach programs know how to identify business opportunities in laboratory testing and capture specmen volume.

To me, the greatest opportunity for a pathologist, moving forward, is to get control of molecular diagnostics.

EDITOR: Moving past the impact of the shift toward outpatient services, is there another strategic market driver that you believe will have great influence on laboratories?

MAC MAHON: If any company wants to be in the testing business, it's my strong belief that tissue-based diagnostics is the place to be. I read each issue of THE DARK REPORT and you seem to be strongly convinced that tissue will play the major role in reshaping diagnostics as we know it today. I concur with equal conviction. I believe any laboratory seeking to be a leader in laboratory medicine must be a leader in cancer diagnostics. And if a lab is to be a leader in cancer diagnostics, it must have a tissue business and work closely with pathologists to evaluate those tissue specimens.

EDITOR: That certainly mirrors my thinking. It's an opportunity that few pathology group practices recognize, and even fewer have decided to pursue.

MAC MAHON: To diagnose cancer requires tissue. To me, the greatest opportunity for a pathologist, moving forward, is to get control of molecular diagnostics. Pathologists should be expanding both their skill base and their business base, not only to read tissue, but to read tissue as it relates to molecular biology. Molecular pathology is expected to be the cutting edge of medicine as we move forward. Ongoing scientific advances in genomics and proteomics guarantee this will be true.

EDITOR: That's an unqualified recommendation to the pathology profession. We both read the tea leaves the same way.

MAC MAHON: Absolutely. Those who predict that tissue will not be important as we go forward are shortsighted. In our strategic planning efforts at LabCorp, we consistently recognize that we must develop and maintain a significant tissue business.

EDITOR: That is certainly a change! In past years, commercial laboratories invariably farmed out anatomic pathology (AP) services to local pathologists.

MAC MAHON: This is different from ten years ago. At that time, it seemed commercial labs wanted to run away from anatomic pathology. That's reversed at LabCorp. We want to be a leading company in tissue-based diagnostics and recognize the need to develop our capabilities in anatomic pathology.

EDITOR: Tom, you've just provided me a great segue into our next topic. Let's talk about the acquisitions of Dynacare, DIANON, and the Northern California lab assets during 2002. How are these transactions changing LabCorp? In particular, let's start with DIANON, because of its emphasis on anatomic pathology.

MAC MAHON: DIANON Systems boosted our capabilities in anatomic pathology. This fits our second core strategy, of providing sophisticated esoteric tests. DIANON stood apart from the other anatomic pathology companies that were out there.

EDITOR: In what ways was DIANON different?

MAC MAHON: First, it is organized to provide AP services to office-based physicians throughout the United States and has an established base of clients. Second, it has a proven ability and corporate system already providing uniform anatomic pathology services. Third, DIANON has an effective in-house anatomic pathology system along with its CarePath system for reporting to physicians, patients, and payers.

EDITOR: What "holes" did you hope DIANON would fill for LabCorp?

MAC MAHON: Go back to our national system of regional laboratories. Anatomic pathology services in LabCorp were always provided at the regional level. For example, AP services in Texas were done as the pathologists in Texas wanted and that might be different from how pathologists in North Carolina handled similar cases. LabCorp never had a national system to handle anatomic pathology. Nor did it have a national strategy to develop anatomic pathology. Although we will always have relationships with many pathology groups and pathologists, DIANON gives us the framework to support our molecular diagnostic testing. We hope the pathologists who work with us see the DIANON model as an opportunity to enhance their relationship with us.

EDITOR: In lacking both, LabCorp would not be best positioned to develop opportunities in molecular diagnostics.

MAC MAHON: True. What LabCorp actually had was a variety of regional AP capabilities that supported a range of regional anatomic pathology strategies. That's why we seized on DIANON to be the focus of a consistent national strategy in AP, as well as a standardized program of anatomic pathology services within our regional laboratory facilities.

EDITOR: So DIANON forms the backbone of your developing national strategy in anatomic pathology, plus it supports your second strategy of providing sophisticated esoteric testing services.

MAC MAHON: That's right. We intend to funnel many of our cancer-based products to customers through the DIANON channel. It is also a way to funnel services from our relationships with companies like **Myriad Genetics**, **Correlogics**, **Celera Diagnostics**, and **Exact Sciences** as we launch those esoteric testing products to customers.

EDITOR: Let's now look at the Dynacare and Northern California acquisitions. How do these support LabCorp's strategic plans?

DIANON Systems boosted our capabilities in anatomic pathology. This fits our second core strategy, of providing sophisticated esoteric tests.

MAC MAHON: This returns us back to the first core strategy I discussed with you. That was to have coverage across the United States. To be a national resource with regionalized lab services, we can't have geographical gaps. As an acquisition, Dynacare brought us a system of routine testing laboratories located in some of the fastest-growing areas of the United States. It had a strong lab in the Northwest. In the South, it filled in areas where we weren't as strong as we wanted to be.

EDITOR: How does the acquisition of **Immunodiagnostics Laboratory** and the Quest/**Unilab** assets in Northern California help fill in gaps?

MAC MAHON: We've always wanted to be a major factor in California, but on business terms which meet our criteria for market share and profitability. LabCorp has infrastructure in Southern California. These Northern California acquisitions now give us a business foundation from which to grow in that part of the state.

EDITOR: What are your plans for Northern California?

MAC MAHON: We've expanded our routine business in the Bay area with these acquisitions. In particular, the IPA (independent physician association) contracts compliment our strategy of having a contract anchor with office-based physicians. We can now use that anchor to convince physicians to refer us more of their laboratory testing business.

EDITOR: That also supports your strategy of using this access to sell more esoteric testing, correct?

MAC MAHON: Yes. The San Francisco Bay Area generates a lot of esoteric testing, particularly in diseases like HIV and hepatitis. We now have access to physicians in this regional market. For example, by year's end we will have 60 patient service centers in this area. We expect Northern California to be a big source of esoteric testing for us.

EDITOR: Can we talk more about esoteric testing? Patent-protected, branded diagnostic tests are growing in number. LabCorp is doing partnerships with a number of companies that have developed these tests. How does this fit your strategic vision?

MAC MAHON: At LabCorp, our fundamental business is to create information from laboratory tests and deliver that information to our physician-clients. In that sense, we are a distribution and information company. We are not in research and development.

EDITOR: Thus, you want to align yourself with companies that develop tests to provide them a channel to the clinical marketplace.

MAC MAHON: Yes. Once a diagnostic test is developed, these companies recognize they can get their test to market much more rapidly through companies like LabCorp without having to spend enormous amounts of money to educate physicians and do their own marketing. This change has come about during the past three years.

EDITOR: But what about reimbursement for these high-priced assays. That is always a hurdle.

MAC MAHON: LabCorp has sophisticated expertise in reimbursement issues along with extensive working relationships among payers. Part of our value-added to diagnostic test developers is our ability to persuade payers to provide adequate reimbursement to launch diagnostic tests that are supported by good science.

EDITOR: That describes a symbiotic relationship.

MAC MAHON: We need their technology. They need our distribution channel and reimbursement expertise. It's a natural complement, which is why LabCorp gets the opportunity to see lots of promising technology while it's still in the development phase.

EDITOR: I'd like to shift gears now to another topic. During the past few years, the two blood brothers have posted strong profit gains. Public laboratory companies have sold at impressive multiples of earnings. There is plenty of optimism about opportunities in laboratory testing. Why don't we see existing lab companies building new laboratory facilities from scratch to open up "new" regional markets and compete for physician's office testing? Why don't we see lab entrepreneurs building a new laboratory from scratch to enter that business and compete for market share?

MAC MAHON: I have two answers to that question. First, there continues to be a feeling among the investment

community that the laboratory industry still has exposure to low profitability and risk. It can be called a fear factor among investors. That makes it tough to get the necessary start-up capital.

EDITOR: And your second reason?

MAC MAHON: It requires uniquely experienced people to successfully construct a clinical laboratory and launch the business from a standing start. Creating a new laboratory company to service office-based physicians requires a deep roster of talent: from the CEO through the executives required to support operations, testing, sales and marketing, logistics, and billing. There's not a lot of those types of individuals available. And because of the difficulty of running such laboratory companies, many shy away from the challenge.

EDITOR: That's an interesting response. Over the last ten years, there have been only a handful of attempts to launch, from a cold start, a laboratory company organized to provide lab test services to office-based physicians. Let's finish with your thoughts about laboratory information and LabCorp's response to changes in this field.

MAC MAHON: In simplest terms, LabCorp is an information company. What we do is take human specimens and develop information that we report to clinicians. We are electronically linked to more than 100,000 physicians' offices. Our information capabilities are a critical success factor for LabCorp. That is why one of my biggest disappointments during my six years at this company is that the information technology which is available to us every day has not been converted into useful tools that help clinicians manage their practices.

EDITOR: Please explain.

MAC MAHON: For example, physicians still do not use the Internet to the degree that we expected. In the area of disease management, which links together information on therapeutics with information on laboratory testing and patient demographics, greater use by clinicians has been hampered by many factors.

EDITOR: You sound a bit frustrated.

MAC MAHON: That's because we know the value of laboratory medicine to help clinicians achieve better outcomes.

EDITOR: Do you have examples of payers using enriched laboratory test data sets from LabCorp to drive changes in clinical practices?

MAC MAHON: That's a tough question. Few of the nation's health insurance companies have devoted resources to assemble information from a variety of sources, including laboratory test data, and then use it with physicians to improve clinical outcomes. However, physicians are beginning to demand better information sets that will help their practice of medicine.

EDITOR: Then you do see growing interest among physicians, but no instances where this is happening?

MAC MAHON: In general, yes. However, the clinical laboratory profession has yet to do an adequate job of converting diagnostic information into useful outcome data, then use this outcome data to demonstrate the cost-benefit of diagnostic tests to the clinical community. The pharmaceutical industry does this.

EDITOR: That's true.

MAC MAHON: It's an obvious opportunity for our leaders in this industry. As we do a better job of demonstrating the cost effectiveness of our laboratory testing services, not only will laboratories get more recognition for their contribution, but it will make it easier to get fair reimbursement for laboratory testing services. TDR

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SARS Challenges Met With New Technology

Clinical labs gain important insights about dealing with new infectious disease

CEO SUMMARY: When SARS began to spread around the globe, the United States was fortunate to escape the type of outbreak which still dogs Hong Kong and Toronto. Had SARS cases appeared in the U.S. a week earlier, the first affected cities would have experienced widespread concern, reduced tourism and economic activity, as well as severe disruption of normal hospital and laboratory activities.

HOSPITALS AND LABORATORIES in the United States should consider themselves lucky. By the time the first SARS patients began to show up in U.S. hospitals, the healthcare system was on the alert.

As a result, few healthcare workers in U.S. hospitals were infected and the normal operation of hospitals continued. It was the exact opposite in Toronto. As described by THE DARK REPORT on pages 2-8, in recent weeks hospitals throughout Greater Toronto ceased all elective surgery and non-urgent care as part of the effort to control SARS.

Imagine A Similar Scenario

Move 100 miles from Toronto across the Canadian border to Detroit. Imagine the impact on healthcare if Detroit's hospitals were banned from doing normal surgeries and non-urgent care for at least two weeks. The financial consequences would be disastrous, not to mention the sizeable backlog of patient care that would result.

The laboratory profession is paying close attention to the battle against SARS. SARS follows on the heels of 9/11 (a shutdown of the air transport system for several days, interrupting blood supplies and reagent deliveries to labs) and the anthrax terror attacks (putting emergency departments [ED] and hospital labs on alert that any patient appearing in the ED may be sick with some of the nastiest bugs known to mankind).

Laboratories survived both those challenges with a high degree of proficiency. So far, SARS can be considered a similar success story. To date, it has demonstrated that healthcare officials across the globe can collaborate to share information and work effectively to limit the spread of the disease.

Not widely reported is the exceptional cooperation that took place among research laboratories and public health laboratories worldwide. Without regard to protecting potential patent claims, researchers and investigators shared findings.

For the laboratory profession, the technology used to identify the SARS virus and connect it with an existing family of viruses demonstrates how swiftly genetic-based technology is transforming laboratory practices. It was Joseph DeRisi, Assistant Professor of Biochemistry and Biophysics at the **University of California at San Francisco**, who first identified the SARS virus as being a probable member of the coronavirus family, reporting that fact to the **Centers for Disease Control and Prevention** (CDC) on March 23.

Virus Hunting Microarray

Two years ago, DeRisi created a microarray chip to help virus hunters. His microarray contains a "huge library of genetic sequences of all known human and animal viruses that have ever been sequenced, and which possesses the capability of detecting previously unknown viruses as well." To better use this microarray, DeRisi and his partner in the project, David Wang, a postdoctoral student at **Massachusetts Institute of Technology** (MIT), created a software program to help evaluate the microarray.

After receiving SARS samples from the CDC, DeRisi used a laser microscope to compare the SARS genetic samples against his microarray, which contains the genetic sequence of 1,000 different viruses. In just a few minutes, he had established the relationship between SARS and other viruses in the coronavirus family.

Because most microarray projects have targeted human genes, DeRisi's successful identification of an unknown virus using microarray technology has attracted lots of attention. It is a powerful demonstration of how genetic knowledge will revolutionize healthcare.

Laboratory medicine is making another important contribution in the fight against SARS. Using a variety of new technologies, efforts are underway to create at least three different types of diagnostic tests for SARS. They are expected to be available within a few weeks. Two of the assays will test for antibodies. The other will detect the presence of viral DNA in blood.

SARS Is Unusual Event

In other developments, physicians from Hong Kong's **Prince of Wales Hospital** authored a report published in the online edition of the *Journal of New England Medicine* about an enzyme test that may help predict which SARS patients are most likely to die of the disease. According to the report, high levels of the enzyme lactate dehydrogenase indicate lung damage and may be an important clue to why some SARS patients die while others recover.

As a contagious new disease, SARS must be considered an unusual and important event. In speaking with laboratory administrators and pathologists in Toronto, THE DARK REPORT constantly heard statements such as "In my healthcare career, I've never seen anything like this."

Attracted Lots Of Attention

At a minimum, the SARS lessons learned by laboratories in Toronto will change certain aspects of hospital laboratory management, particularly in the relationship between the infection control team and microbiology. There will also be informed changes made in how regional laboratory networks are operated.

Probably the most far-reaching impact of SARS was identified by Donald Low, M.D., Microbiologist In Chief at **Toronto General Hospital**. He observed that "what Hepatitis B and HIV did for body-fluid precautions, we hope this [SARS] will do for respiratory precautions." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Lab executives and pathologists concerned about closed-panel HMOs should closely study a recent Supreme Court decision. On April 2, the court issued a ruling that supports a state's right to enact "any willing provider" laws. Kentucky had passed two laws requiring health plans to accept all out-of-network physicians, hospitals, laboratories, and other healthcare providers, so long as they agree to abide by the plan's contract terms. The case was titled "**Kentucky Association of Health Plans** v. Miller."

On March 31, **IMPATH, Inc.** announced that its quarterly financial report would be delayed. IMPATH has decided to report revenue from non-contracted payers net of an estimated allowance. This is how most labs report revenue from contracted payers and Medicare. The accounting change will affect IMPATH's net revenue and bad debt and comes in response to criticisms about the company's accounting and billing practices.

CONSUMER-DRIVEN HEALTH PLANS ARE GROWING IN NUMBER

To control double-digit increases in healthcare costs, employers are turning to consumer-driven health plans. **Deloitte & Touche** released a survey of 287 companies earlier this month. By a significant percentage, respondents expect to make consumer-driven health plans, where employees take greater responsibility for their health care, part of their benefit packages. Currently 11% of the surveyed companies offer consumer-directed options. An additional 8% expect to offer such plans within two years while another 35% of the companies are reviewing these types of plans.

ADD TO: Consumer-Driven Health Plans

Results of Deloitte & Touche's survey support THE DARK REPORT's long-standing prediction that consumers will assume a greater role in their healthcare in coming years. That means clinical laboratories and pathology group practices should actively develop business strategies designed to meet the changing expectations of their patients. The Deloitte & Touche survey indicates that employers are heading in the same direction as their workers—benefit options that provide more healthcare choices. This supports the growing numbers of workers who, on their own, want broader access to physicians, hospitals, and health providers of their choosing.

ANOTHER ISO LAB

Beaumont Reference Laboratories (BRL) is the first clinical laboratory in Michigan to become certified as ISO-9001:2000 compliant. The audit took place in December 2002. As a result of the ISO certification effort, BRL has reassessed operational practices in all areas of its organization. Moreover, BRL expects its ISO certification to be a marketing plus for its laboratory outreach program. That's because Michigan employers, particularly the auto manufacturers and their vendors, consider ISO-9000 to be a respected hallmark for a company's quality.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 5, 2003

PREVIEW #5

EXECUTIVE WAR COLLEGE

May 6-7, 2003 • Astor Crowne Plaza Hotel • New Orleans

"Turbocharge Your Laboratory's Performance!"

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UPCOMING...

- ***Nine Information Technologies Now Driving Change in Hospitals and Physicians' Offices.***
- ***More on the Unfolding SARS Story: Why Experts Believe New Cases Will Continue to Spread into New Regions.***
- ***Have GPOs Failed Hospital Laboratories? Like-Minded Lab Directors Seek Different Ways to Gain Contracting Leverage.***

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