

### SAME SERVICE, NEW OWNER

Diagnostic Services is now officially owned by Borealis Infrastructure, an investment arm of OMERS. The sale of Diagnostics by MDS Inc. was finalized February 26, 2007.

While we finalize our trademark procedures on a new business name, we will continue to operate under the MDS Diagnostic Services brand. During this time, our legal name will be BPC Ontario Labs LP. Other than an eventual change in our business name, there are no significant changes planned for our business.

We appreciate the support you offered our employees during our sale process and look forward to continuing to serve you. ■

### SPECIMEN IDENTIFICATION AND SPECIMEN REJECTION:

#### Prevention Is Better than Cure

Like the patients from whom they originate, samples for laboratory analysis must be confidently and uniquely identified. The correct interpretation or analytical result on a sample attributed to the wrong individual may be most difficult to detect and investigate. Moreover, it can cause real harm by triggering unnecessary investigation or treatment of one individual and the delay or failure to take action for the patient from whom the sample actually originated.

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Pre-analytical errors are more common than actual analytical errors although the latter have frequently gained more attention possibly because they are viewed as "someone else's mistake" from the perspective of the clinician or procurer of specimens. In general, pre-analytical errors are easy to prevent.

Good administrative practices and attention to detail in the clinic, medical office, home (for homecare) and patient service centre are essential to prevent

misidentification of samples. In the office, this includes the principle of "single patient processing" whereby requisitions are carefully and legibly completed one at a time and specimen containers are immediately labeled with two identifiers in the presence of the patient. When labeled, requisitions and samples are moved to the "safe area" before the next patient is served. Batch processing, lack of attention to detail and failure to properly train and educate staff will invite the possibility of mistakes that may have serious consequences.

When a definite link between a sample and an individual is unclear, in most cases, the specimen must be rejected and a new sample obtained. This is the best way to promote patient safety. The Ontario Association of Medical Laboratories (OAML) has recently released revised "Procedures for the Processing of Specimens by Medical Office Staff" and "Guidelines for the Rejection of Specimens" (available at [www.oaml.com](http://www.oaml.com)). These documents are worth reading and bringing to the attention of your staff.

You will see in the above documents, specimens which are defined as irreplaceable, may be exceptions to the usual rejection guidelines. This is so when the risk to the patient(s) of outright rejection is potentially unacceptable because it is greater than the risk of proceeding with analysis. When clinical decisions are based on the analysis of specimens which would have been rejected had they not been regarded as irreplaceable, it is essential the clinician understands the risk involved. Community Laboratory Directors are available for consultation in these circumstances and this is frequently required to determine the best course of action.

Pre-analytical "patient safety" is a real focus of quality improvement in our laboratory and you and your staff are significant contributors to this initiative. Every year we receive specimens in which there is a significant abnormality that cannot be attributed to an individual patient. After much work the problem is solved in some cases, but in a few it is not. The potential consequences are easy to imagine. ■

## D DIMER (FIBRIN DEGRADATION PRODUCTS)

MDS Laboratories has decided to discontinue D Dimer (Fibrin Degradation Products) testing effective March 1, 2007.

There are two reasons for this decision which we feel are important to explain to clients who have used MDS as a reference laboratory for this test.

A sensitive semi-quantitative latex agglutination assay for D Dimer, which has been the method we have employed, is best performed close to the patient in the emergency room or local laboratory, particularly when used in conjunction with clinical assessment to determine whether ultrasound is required in the exclusion of deep vein thrombosis (DVT)<sup>1</sup>. When used in conjunction with compression ultrasound or other studies, the negative predictive value of the test is clinically most valuable when available soon after the clinical encounter.

It follows that MDS has performed the latex agglutination test which is best used close to patient in our reference laboratory environment and secondly cannot deliver a turn around time required clinically for the exclusion of DVT. Therefore, we believe we should cease testing.

A sensitive quantitative assay is available, but requires special handling of samples including freezing prior to transportation. Failure to comply with these strict handling requirements will lead to falsely elevated D Dimer values. We are prepared to make this assay available via an external reference laboratory. The turn around time will be several days which in most acute situations means there will be no clinical utility. The test has also been used as an aid in identifying patients who can cease anticoagulant therapy initiated for treatment of DVT<sup>2</sup>. ■

### REFERENCES

1. Evaluation of D-Dimer in the Diagnosis of Suspected Deep Vein Thrombosis Philip Wells *et al.* NEJM 349:13 September 25 2003.
2. D-Dimer testing to Determine the Duration of Anticoagulation Therapy Gualtiero Palaretti *et al.* NEJM 355:17 October 26 2006.

## CLINICAL MANAGEMENT SYSTEMS (CMS) AND LABORATORY TEST RESULTS

Laboratory test results are an important component of the medical record. Electronic integration of these into a Clinical Management Systems (CMS) presents a number of obvious advantages including elimination of manual transcription and improved patient care through enhanced information management.

When an electronic record of laboratory results replaces the paper record it is essential to establish that data transmitted to the CMS is received and reliably integrated into the correct patient record along with the applicable reference ranges and interpretive comments. This should be established during initial certification of the software.

Clinicians are responsible for the accuracy of their medical records, so it is advisable for clinics to perform and document a periodic audit by verifying the receipt and integration of a sample of reports into the electronic record. MDS Diagnostics can assist in this by providing printed reports to clinics that normally receive data electronically.

On occasion, we have been made aware of failures of results being integrated within electronic records and feel that a high level of vigilance is required to maintain patient safety. The effort required need not be great.

MDS must monitor successful transmission to and receipt of results by a CMS, but the ongoing responsibility for integration into the patient record lies with the clinician.

The Health Level 7 (HL7) standard is widely accepted as the standard for health specific data exchange. An interface between the laboratory and a CMS, conforming to this standard permits us to verify transmission and receipt of data to the level of the individual patient accession. We believe this is required and that laboratory/CMS interfaces should be HL7 compliant. Not all systems currently use HL7, whereas others have not upgraded their system to the available HL7 interface.

MDS strongly advises users of CMS software to consider the HL7 standard when choosing a system and for current users to upgrade their interface to HL7. ■

## THROAT CULTURES FOR GROUP A STREPTOCOCCUS (GAS)

Group A Streptococcus (*Streptococcus pyogenes*) is the most common bacterial cause of acute pharyngitis. Antibiotic therapy is indicated for laboratory confirmed streptococcal pharyngitis to prevent major sequelae such as acute rheumatic fever and can be initiated for up to 9 days after the onset of symptoms. Symptoms of streptococcal pharyngitis are usually self-limited to a few days from onset and can be decreased with the early initiation of antibiotics. Susceptibility testing is not performed routinely as there is no documented resistance to penicillin or cephalosporins. However, erythromycin resistance is well documented with up to 8-15% of GAS isolates reported to be resistant. In patients who are allergic to penicillin, susceptibility testing for erythromycin and clindamycin may be requested.

Several factors improve the sensitivity of detection of GAS from throat cultures. Swabbing both tonsils and the posterior pharynx wall improves detection. The duration culture plates are incubated in the laboratory also impacts the detection rate. Internal studies have confirmed that increasing the incubation time increases the positivity rate. **As of March 19, 2007 MDS Laboratories will be extending the incubation time for all throat cultures.** This will result in an increase in the turn around time for reports by an average of 12 hours compared to our previous standard, but that still falls well within the timeline for initiation of therapy.

If required, quick delivery of results (preferably by autofax) may be requested. ■

## REFERENCES

1. Practice Guidelines for the Diagnosis and Management of Group A Streptococcal Pharyngitis. *Clinical Infectious Diseases* 2002; 35:113-125.
2. M. Desjardins et al. Prevalence and Mechanisms of Erythromycin Resistance in Group A and Group B Streptococcus: Implications for Reporting Susceptibility Results.
3. McGeer A. How the Emergence of Antimicrobial Resistance Should be Changing our Practices. *TIBDN* 2006; 4(2)

## HPV VACCINE AND CERVICAL SCREENING: KEEP IT UP!

A quadrivalent vaccine against Human Papilloma Virus (HPV) types 16, 18, 6, 11 was approved for use in Canada in July 2006. Types 16 and 18 are responsible for 70% of cervical cancer and types 6 and 11 for 90% of genital warts. A bivalent vaccine against types 16 and 18 has been submitted for licensure.

Knowledge of HPV and HPV vaccines in the prevention of cervical cancer is in an important phase of evolution, but vaccines are not considered to have therapeutic effect in women already infected with one of the HPV types in the vaccine. Conversely, there may be protection against types not encountered prior to vaccination.

The purpose of this note is not to address the use of HPV vaccine in younger women as a tool to prevent cervical cancer, but to emphasize Cervical Cytology Screening should continue as before whether or not the vaccine has been administered. There is concern that even women who have not been immunized will believe regular screening has become unnecessary. ■

## REFERENCES

1. HPV and HPV Vaccine, Information for Healthcare Providers, Centers for Disease Control and Prevention. <http://www.cdc.gov/std/HPV/STDFact-HPV-vaccine.htm>
2. Human Papillomavirus (HPV) Prevention and HPV Vaccine, Questions and Answers, Public Health Agency of Canada. [http://www.phac-aspc.gc.ca/std-mts/hpv-vph/hpv-vph-vaccine\\_e.html](http://www.phac-aspc.gc.ca/std-mts/hpv-vph/hpv-vph-vaccine_e.html)

## “ALERT” LABORATORY RESULTS

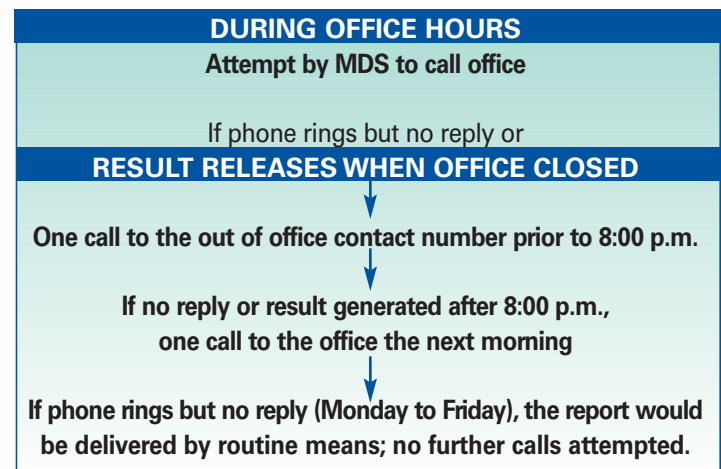
Most laboratory results, including those falling outside of reference ranges, are delivered in a routine fashion.

Results that deviate significantly from reference intervals, but that are not considered “Critical”, are designated as “Alert” values. If unexpected by the ordering physician these results may signal a need for re-evaluation of the clinical situation prior to the scheduled arrival of results by routine means.

Alert values are called to clinicians between 8:00 a.m. and 8:00 p.m., in accordance with MDS<sup>1</sup> and the Ontario Association of Medical Laboratories<sup>2</sup> (OAML) Protocols, 7 days a week up to the time when a report will have been delivered to the ordering physician’s office by routine means. Clinicians should make arrangements to receive these reports and act upon them during absences from the office.

A summary of the communication protocol is as follows:

### ALERT VALUES GENERATED



Patients having unexpected Alert results may experience significant deterioration in their clinical condition over the course of a few days. It is particularly important that clinicians make arrangements to receive or delegate receipt of Alert values by telephone during periods of absence or over long weekends. Arrangements should also be made for review of reports delivered by routine means when a clinician is away from the office.

An important part of this responsibility is to provide effective after hours contact information to the laboratory. This is of vital importance to physicians who received our laboratory reports by Canada Post.

Finally, it is important that a clinician ordering laboratory tests is the individual who will take responsibility or delegate responsibility for actions that may be required in response to the results. Specialists should not order tests for which they expect a primary care physician to take this responsibility. On occasion, patients are discharged from hospital on anticoagulants with an

order for INR signed by the hospital physician with the result copied to a primary care physician who has no idea of the situation. When this occurs, the ordering physician has the responsibility to adjust the dose of anticoagulant until such time as the primary care physician orders the anticoagulant monitoring. Clearly, patient safety is enhanced by effective communication between the various clinicians and institutions responsible for management of a patient in order to hand off responsibility for ongoing care. ■

## REFERENCES

1. MDS Diagnostic Services, Directory of Laboratory Services [http://www.mdsdx.com/files/Ont\\_Directory/ontario\\_directory\\_of\\_laboratory\\_services.pdf](http://www.mdsdx.com/files/Ont_Directory/ontario_directory_of_laboratory_services.pdf)
2. OAML Protocol for the Reporting of Laboratory Test Results <http://www.oaml.com/PDF/C020.pdf>

## BE AWARE OF SOME LIMITATIONS OF THE ESTIMATED GLOMERULAR FILTRATION RATE (EGFR)

For more than a year, together with other community laboratories, we have reported an eGFR with every serum creatinine result for all patients above the age of 18. The eGFR is calculated using a modified 3 factor MDRD (Modification of Diet in Renal Disease) equation based on age, sex and serum creatinine. Correction for ethnicity must be considered in the interpretation by the ordering physician (eGFR x 1.21). Serum creatinine values used in the eGFR calculation are corrected to correlate with the reference technique, IDMS (isotope dilution mass spectrometry).

We believe that this has been a worthwhile enhancement to patient reports, but would like to remind physicians of the limitations of the eGFR as described in a previous issue of Inside Diagnostics (December 2005).

Since implementation, the limitations of the MDRD formula for eGFR values greater than 60 ml/min/1.73 m<sup>2</sup> have been emphasized. A decrease in accuracy of the MDRD equation has been noted when eGFR is greater than 60 ml/min/1.73 m<sup>2</sup>. Some authors recommend that specific values should be given only if the eGFR is less than 60 ml/min/1.73 m<sup>2</sup> and higher values should be reported simply as > 60 ml/min/1.73 m<sup>2</sup>. The CSN position affirms that an eGFR > 60 in "the absence of significant proteinuria or urinary anatomical abnormalities, no further investigation, treatment or referral is required"<sup>1</sup>. In effect, risk factors for chronic kidney disease (CKD) dictate the need for screening for CKD in those with an eGFR of greater than 60 ml/min/1.73 m<sup>2</sup> not the actual reported eGFR.

As was pointed out in our initial communications, values between 60 to 89 ml/min/1.73 m<sup>2</sup> may be a normal aging phenomenon and should not trigger screening for chronic kidney disease unless the patient exhibits risk factors, significant albuminuria or abnormalities on imaging studies. Routine measurement of 24 hour urine is no longer recommended, however, this measurement may be helpful in individuals without risk factors or other positive markers and in those with extremes in body mass or dietary intake. Albumin excretion measured as the urine albumin to creatinine (ACR) ratio is suggested. Serial monitoring within 1-3 months provides confirmation of kidney function. The Canadian Society of Nephrologists (CSN) recommends referral to a Nephrologist when there is:

1. eGFR < 30 mL/min/1.73 m<sup>2</sup>
2. Acute renal failure
3. Progressive decrease in kidney function (> 20% decline in eGFR)
4. Persistent proteinuria on dipstick or ACR > 60 mg/mmol creatinine
5. Inability to achieve treatment targets for blood pressure ■

## REFERENCES

1. Canadian Society of Nephrologists. CSN Position Paper on Care and Referral of Adult Patients with Reduced Kidney Function. September 2005. <http://www.csnscn.ca/local/files/CSN-Documents/CSN%20Position%20Paper%20Sept2006.pdf>
2. Rainey, PM. Automatic reporting of Estimated Glomerular Filtration Rate- Jumping the Gun Clin. Chem. 52(1): 2184-2187; 2006.
3. Levey, AS, Stevens, LA, Hostetter, T. Automatic reporting of Estimated Glomerular Filtration rate – Just What the Doctor Ordered. Clin. Chem. 52(1): 2188-2193; 2006.
4. Stevens, LA, Coresh, J, Greene T and Levey AS., Assessing Kidney Function- Measure and Estimated Glomerular Filtration Rate. NEJM, 354: 2473-2483; 2006.
5. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification.  
Part 4: Definition and classification of stages of chronic kidney disease  
Part 5: Evaluation of laboratory measurements for clinical assessment of kidney disease  
[http://www.kidney.org/professionals/kdoqi/guidelines\\_ckd/p4\\_class\\_g1.htm](http://www.kidney.org/professionals/kdoqi/guidelines_ckd/p4_class_g1.htm)

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