LifeLabs® Medical Laboratory Services

Inside Diagnostics

THE ONTARIO LABORATORY INFORMATION SYSTEM (OLIS)

On February 25, 2008 we will begin to copy test results to the Ontario Laboratory Information System (OLIS). We are proud that we have been selected as one of the initial community laboratories to participate in this initiative. As you may already know, all major community labs will be adopting OLIS within a few months of our start date.

What is OLIS

The Ministry of Health and Long Term Care (MOHLTC) has forwarded information materials about OLIS to you, for both yourself and your patients. We have included a very brief description of OLIS for your added benefit.

OLIS is an initiative of the MOHLTC through its eHealth Program. It is the first step towards the establishment of province-wide electronic health records. Once the system is mature, all laboratories including community labs and hospitals will forward test results to OLIS where they will be available online to health care professionals. The great advantage of OLIS is that it will offer health care providers a secure, electronic, single point of access to all of a patient's test results, regardless of which laboratory generated those results. Over time the MOHLTC anticipates that OLIS may evolve to be the common means of viewing test results electronically. In the interim, OLIS will provide an additional source of accessing test results. Viewing functionality is not expected to be available until sometime later this year.

IN THIS ISSUE

How does OLIS affect your relationship with LifeLabs?

Initially there will be little change. We will continue to process your signed paper requisitions and deliver reports in the same manner as today. Because of the stringent patient identification requirements within OLIS, great precision will be necessary in identifying patients by completing all required fields on requisitions. This is particularly important when LifeLabs does not have direct contact with your patients. OLIS identifies physicians by CPSO number and this is a required field, so LifeLabs must know both your OHIP billing number and CPSO number. The new OHIP requisition includes fields to provide this information.

Privacy and Patient Consent

OLIS is an electronic network provider for laboratories and consequently falls under the Personal Health Information Protection Act (PHIPA); therefore, a separate patient consent is not required for the transmission of lab results to OLIS.

Blocking

Patients have the right to require OLIS to restrict access to their test results. If they choose to restrict access, only the health professional who ordered the tests and the health professionals who were specifically listed as "copy to" physicians will be able to view the results in OLIS when the viewing utility is implemented. This is called "blocking". If a patient decides to restrict access, she or he still has the option to provide consent to a practitioner to temporarily view the restricted information.

The materials forwarded to you by the MOHLTC included a patient brochure explaining blocking in detail and have as an attachment the Restricting Access form. If a patient completes and signs this form, it will be attached to the requisition and a block request will be sent to OLIS. OLIS will then block **all of the test results for the accompanying requisition.** A separate Restricting Access form should be completed for each requisition provided.

By contacting OLIS INFOline directly (1-800-291-1406 or OLIS.MOH@Ontario.ca), a patient will also have the ability to

request that a test result be blocked after it has been generated or to remove a block. Please refer to the patient information brochure or the OLIS website at **www.health.gov.on.ca/olis** for more information.

We anticipate that blocking will be a very rare occurrence since it restricts persons entitled to view a patient's test results in OLIS and it means that patients may not receive optimal care due to an incomplete medical profile being provided to clinicians, including in an emergency situation.

Requisitions

Because OLIS is a province-wide electronic system, unique identification of patients is crucial. We therefore request that you ensure that the patient's full name on the requisition be precisely the same as on his or her OHIP health card. **Nicknames and short forms such as Bob instead of Robert or Judy instead of Judith will be rejected by OLIS** (Note: if the health card contains only an initial, please include the full name, as well as what is provided on the health card i.e. if the health card says B. Jones, please include Barbara (B.) Jones). This will assist in the identification of patients in OLIS.

Further information

As indicated above, if you or your patients require further information with respect to OLIS, please visit the website at: www.health.gov.on.ca/olis or contact OLIS INFO line at 1-800-291-1406 TTY 1-800-387-5559 or via e-mail at OLIS.MOH@Ontario.ca ■

VITAMIN D ASSESSMENT – WHAT TEST DO I ORDER?

Clinical significance

The role and significance of Vitamin D in maintaining good health has received a great deal of attention in recent years. In addition to its role in skeletal development and maintenance, Vitamin D is associated with decreased risk of many cancers, diabetes mellitus, multiple sclerosis, rheumatoid arthritis, cardiovascular disease, and lowered mortality in patients with chronic kidney disease.

Vitamin D_2 and D_3 from the diet and skin are metabolized in the liver to produce 25-hydroxyvitamin D (25[OH]D_3), which undergoes further metabolism in the kidney to produce the biologically active form, 1,25-dihydroxyvitamin D (1,25[OH]$_2D_3$). The latter binds to the vitamin D receptor and plays a central role in regulating calcium homeostasis and promoting cellular differentiation.

Common Name	Alternative Name	Biological Function
Vitamin D_2	Ergocalciferol	Precursor of 25-hydroxyvitamin D; biologically inactive
Vitamin D_3	Cholecalciferol	Precursor of 25-hydroxyvitamin D; biologically inactive
25-hydroxyvitamin D_3	25-hydroxycholecalciferol	Precursor of 1,25-dihydroxyvitamin D; biologically inactive; major circulating metabolite of vitamin D
1,25-dihydroxyvitamin D_3	1,25-dihydroxycholecalciferol; Calcitriol	Biologically active

25-hydroxyvitamin D is the major circulating metabolite of vitamin D and reflects precursor levels of vitamin D derived from cutaneous metabolism and dietary intake. In addition, 25-hydroxyvitamin D is less subject to hormonal fluctuations than 1,25-dihydroxyvitamin D and correlates with bone mineral density.

What test do I order?

For the reasons above, 25-hydroxyvitamin D is considered the test of choice for assessing vitamin D status. It is most useful in patients at risk of vitamin D deficiency including those who are elderly, infirm, with increased skin pigmentation and patients with fat malabsorption syndromes or osteoporosis. The 25-hydroxyvitamin D test can also be used for monitoring of vitamin D therapy. Clinical ranges for the assessment of vitamin D status, based on 25-hydroxyvitamin D concentrations, were published in the Fall 2007 edition of Inside Diagnostics.

It is not necessary to request 1,25-dihydroxyvitamin D testing when assessing vitamin D status. This test is, however, valuable in the investigation of hypocalcemia related to renal failure, hyperphosphatemia, and pseudovitamin D resistant rickets, and hypercalcemic disorders, including those patients with hypercalcemia due to extrarenal production of the hormone. The latter situation occurs in sarcoidosis and certain lymphomas.

LifeLabs offers quantitative serum analysis of both 25-hydroxyvitamin D and 1,25-dihydroxyvitamin D. ■

REFERENCES

1. Holick, MF. High Prevalence of Vitamin D inadequacy and implications for health. Mayo Clin Proc. (2006) 81(3): 353-373.
2. Jones, G. The Clinical Utiliy of Blood 25-OH-D Measurement – New Uses for an old Tool? DEQAS Proficiency Summary Report. September 2005.
3. Hollis, BW. Circulating 25-hydroxyvitamin D levels indicative of vitamin D sufficiency: implications for establishing a new effective dietary intake recommendation for vitamin D. J Nutr. (2005) 135: 317-322.
4. Holick, MF. Defects in the synthesis and metabolism of vitamin D. Exp Clin Endocrinol (1995) 103: 219-227.
5. Laboratory Test Handbook. DS Jacobs, DK Oxley, and WR DeMott, editors. Lexi-comp, Inc. 5th Edition. 2001.

IMPORTANT TECHNOLOGY CHANGE FOR CHEMISTRY ANALYSIS: IMPLEMENTATION 2008

As announced in our Inside Diagnostics article of November 2007, we would like to remind you that our laboratory will soon implement a new generation of Chemistry analyzers. The change in technology will be phased in across LifeLabs Ontario laboratories with the following schedule:

Toronto	February
Thorold	March
Kitchener	April
London	April
Ottawa	April
Belleville	April
Thunder Bay	May
Sudbury	May

The new instrumentation offers many technological advances which, when fully implemented, will improve service and reduce turnaround time. In addition, the technology is able to perform a greater number of assays using a smaller volume of serum and supports our ongoing initiative to reduce the amount of blood taken from your patients. Please understand that this change in technology is a major undertaking for LifeLabs that will prepare us for the future.

Reference interval studies have been completed using the new assay format and as a result, you will note a change to reference intervals for many analytes. Updates to reference intervals will be highlighted on the patient report together with the effective date of implementation for your geography. The following assays require reference interval changes:

$Alpha_1$- Antitrypsin	C3 Complement C4 Complement	Lipase	Total Iron Binding Capacity (TIBC) and % Saturation
Alkaline Phosphatase (ALP) (adult)	Calcium	Lithium	Transferrin
Alanine Aminotransferase (ALT)	Chloride	Potassium	Immunoglobulin A (≥ 10 years only)
Amylase (Serum and Urine)	Creatine Kinase (CK)	Total Protein (Serum and Urine)	Immunoglobulin G
Aspartate Aminotransferase (AST)	Creatinine	Urea (< 18 years only)	Rheumatoid Factor
Bilirubin	Lactate Dehydrogenase (LDH)	Uric Acid (Urine only)	

We thank you in advance for your patience and support during implementation of this change. Please bring this notice to the attention of your staff as required.

Immunoassay Technology Changes: Implementation February 4, 2008

Effective February 8, 2008, new immunoassay technology based on chemiluminescent detection will be introduced for the following analytes.

* Testosterone	* Tobramycin
* Progesterone	Gentamicin
* Estradiol	Carbamazepine
* Vitamin B12	Valproic Acid
* Folate	Phenobarbital

The new format offers improved sensitivity and equal or better performance and will result in improved service provided to you and your patients.

Reference intervals have been reviewed and validated for all analytes, those marked with an asterisk in the table above require revision. Patient reports will include a message highlighting the change and effective date. ■

MEETING SPECIMEN REQUIREMENTS

Clearly when clinicians order tests on a requisition they expect a result and our job as a laboratory is to provide accurate results which serve the clinical need.

When a test is ordered but no analysis occurs at the very least this leads to frustration, a waste of time and resources and a need to recall a patient. Sometimes the consequences are more significant.

At LifeLabs we are doing our best to remove wasteful effort and deliver an excellent service to our client clinicians and patients while complying with the quality and accreditation requirements which guide our practices.

There are two principal contributors to our inability to deliver results for tests ordered on a requisition which are directly under the control of the clinicians and office staff who procure samples outside of LifeLabs Patient Service Centers.

1) Failure to procure the correct specimen for the assay or sufficient volume or number of tubes to permit analysis for all tests ordered.

2) Arrival of specimens in the laboratory beyond the "age limit" for accurate analysis. (These samples must be rejected.) Aged samples are more numerous after the weekend.

We do our best to mitigate in the first situation but this is often impossible. We encourage you and your staff to make sure you understand and precisely follow the Specimen Requirement Chart provided by LifeLabs and understand the stability of samples or the time by which they must be received in our laboratory for accurate analysis. ■

TESTS TO BE DISCONTINUED

Periodically we review our test menu with a view to adding clinically useful assays when this is possible or upgrading the analytical platforms for existing assays in order to improve performance. We also review tests which may be obsolescent or cannot be performed in a rigorous standardized fashion in the Community environment and when appropriate remove these from our test menu.

After literature review and consultation with experts and users of the laboratory we have decided to discontinue the examination of sputum and nasal secretion for the presence of eosinophils as noted below.

NASAL SMEAR FOR EOSINOPHILS: TO BE DISCONTINUED APRIL 7, 2008

LifeLabs will no longer perform this test. This decision was achieved after a careful review of the literature, after

consultation with experts in the field of allergy and laboratory medicine in several academic centers, and with the advent of better tests for allergy.

There are very few studies that have evaluated the sensitivity and specificity of nasal smears for allergic rhinitis. The two studies listed below indicate a sensitivity of only 62-76%. In addition, the reported false positive rate is as high as 15%. Equally important, is the absence of good data on reproducibility. Because this is a subjective test, and given the uneven distribution of eosinophils in the submitted samples as well as the difficulty in obtaining representative samples, and the occurrence of cellular degeneration due to delays in testing, reproducibility of results is poor.

To aid in the diagnosis of allergic rhinitis as well as other allergic conditions, LifeLabs offers allergen specific IgE measurements determined on blood samples. This is done in the laboratory by using the Unicap Flouro-immunoassay from Pharmacia. The "Allergen Test Requisition" is available from http://www.lifelabs.com/files/requisitions/Test_requisition_allergy_.pdf .

REFERENCES

1. Takwoingi Y, Akang E, Nwaorgu G, Nwawolo C. Comparing nasal secretion eosinophil count with skin sensitivity test in allergic rhinitis in Ibadan, Nigeria. Acta Otolaryngol 2003; 123:1070-4.
2. Miri S, Farid R, Akbari H, Amin R. Prevalence of allergic rhinitis and nasal smear eosinophilia in 11-15 year old children in Shiraz. Pediatr Allergy Immunol 2006; 17:519-23.

SPUTUM SMEAR FOR EOSINOPHILS: TO BE DISCONTINUED APRIL 7, 2008

Sputum eosinophilia has been used for investigating airway inflammation in asthma, chronic cough, and chronic obstructive pulmonary disease. As noted below, to be meaningful, this test must be carefully standardized in a way which is not possible in the community environment. Because of this, LifeLabs will no longer perform this test. This decision was achieved after a careful review of the literature, and in consultation with experts in several academic centers.

There are several drawbacks to the use of this test in the community at the present time. Firstly, samples submitted are spontaneously produced by patients (i.e. they are not induced), and may be mixed with saliva, or be mostly saliva and, therefore, may not be reflective of the true disease process. Secondly, routine handling of the specimen in the laboratory consists of making a smear from a random part of the specimen and eosinophils are reported only as present or absent, a cell count not being possible. Thirdly, rapid processing of the specimens to avoid cellular degeneration is not possible. Therefore, given these factors, the reproducibility of results is likely to be suboptimal.

The American College of Chest Physicians' (ACCP) guidelines for evaluating children with chronic cough state that "...the use of an airway cellular and inflammatory profile in children with chronic cough is currently limited to a supportive diagnosis and research rather than a definitive diagnosis." In adults, there is some literature to suggest the use of an airway inflammatory profile to direct therapy. However, this literature is based on studies that use induced sputum samples, and very standardized and laborious methodology for analysis in dedicated laboratories, providing the practitioner with a reproducible total cell count as well as a percentage eosinophil count. In support of this, the ACCP guidelines for evaluating chronic cough that may be due to nonasthmatic eosinophilic bronchitis state, that this diagnosis be "...confirmed by the presence of an airway eosinophilia, either by sputum induction or bronchial wash fluid obtained by bronchoscopy". ■

REFERENCES

1. Chang AB, Glomb WB. Guidelines for evaluating chronic cough in pediatrics: ACCP evidence-based clinical practice guidelines. Chest 2006; 129:260S-283S.
2. Hargreave FE, Leigh R. Induced sputum, eosinophilic bronchitis, and chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1999; 160:S53-S57
3. Gibson PG, Wlodarczyk JW, Hensley MJ, et al. Epidemiological association of airway inflammation with asthma symptoms and airway hyperresponsiveness in childhood. Am J Respir Crit Care Med 1998; 158:36-41.
4. Brightling CE. Chronic cough due to nonasthmatic eosinophilic bronchitis: ACCP evidence-based clinical practice guidelines. Chest 2006; 129:116S-121S.

TRACKING SPECIMENS TO THE LABORATORY AND REPORTS BACK TO THE OFFICE

Ideally a foolproof tracking system would be in place for all laboratory tests. Clinical Management Systems set up to order tests electronically and able to receive results back into an electronic medical record promise to deliver such a tracking system. We can only dream but in the meantime we are forced to use paper requisitions.

It is advisable to set up an office log to verify receipt of reports generated on irreplaceable specimens or those which may detect the early curable stage of a serious disease.

Tissue biopsies and cytology specimens clearly fall into this category. It is a good idea to confirm logging of receipt of all reports a few weeks after such a report would have been expected.

This should prevent all reasons for a report not making it to the medical record under the control of the office staff or the laboratory except perhaps for misfiling. We do receive specimens without requisitions without sufficient information on the specimen vial to identify either the patient or submitting clinician.

Prevention is the best cure but the log of pending specimens in the office provides a safeguard which should allow identification of many of these samples. ■

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