Inside Diagnostics Ontario

The Diagnostic Newsletter for Healthcare Providers

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DECEMBER 2017

LifeLabs®

LifeLabs ON Holiday Hours

Please be advised of LifeLabs Patient Collection Centers (PSC) Holiday Hours:

Monday Dec 25th	- All Locations **Closed**
Tuesday Dec 26th	- All Locations **Closed**
Wednesday Dec 27th	- All locations open - Regular Hours of Service
Thursday Dec 28th	- All locations open - Regular Hours of Service
Friday Dec 29th	- All locations open - Regular Hours of Service
Saturday Dec 30th	- All locations open - Regular Hours of Service
Sunday Dec 31st	- All locations **Closed**
Monday Jan 1st	- All locations **Closed**
Tuesday Jan 2nd	- All locations open – Regular Hours of Service

LIfeLabs Genetics Holiday Hours:

The Genetics Helpline reached at: 1 844 363 4357 (1 84 GENE HELP) will have modified hours during the holiday period between December 25th and January 2nd. If customers have urgent inquiries please email: Ask.Genetics@LifeLabs.com. This email address will be monitored regularly during the holiday season.

If you have any questions or concerns regarding our holiday hours of service or related questions, please contact us at:
1 844 363 4357 (1 84 GENE HELP) or **Ask.Genetics@LifeLabs.com**

WISHING EVERYONE A SAFE AND HAPPY HOLIDAY SEASON!

LifeLabs Ontario Medical Director Update

Staff Changes in Anatomic Pathology

Dr. Terry Colgan and Dr. Mona Kamel have joined the Medical-Scientific staff at LifeLabs. Dr. Colgan will be the Discipline Head for the Histology laboratory, while Dr. Kamel will assume the same role in Cytology. They will both play a significant role in the Quality Assurance program in Anatomic Pathology. This will also allow for changes to take place in our delivery of Gynecological Surgical Pathology. **Effective November 13. 2017, we will be moving to a model where only trained Gynecological pathologists will be reporting our gynecological surgical pathology.** This specialty is evolving quickly and we feel that this will provide a higher level of quality in the reporting of this branch of pathology.

Changes to HPV Reporting

Effective January 1. 2018, we will be changing our HPV reporting to be in line with the current Cancer Care Ontario (CCO) Guidelines. We currently have based our reporting on the ASCCP Consensus Guidelines, Journal of Lower Genital Tract Disease, Volume 17, Number 5, 2013. We felt, at the time we started co-reporting HPV with our PAP tests, that these guidelines gave the best possible follow-up for our patients. We now are of the opinion that the CCO guidelines provide for similar follow-up. There is really only one significant change. **When a diagnosis of ASCUS/LSIL is made in a patient 30 years of age or older, under our current recommendations with a negative HPV, we recommended a repeat PAP in one year. The CCO guidelines recommend that patients go back to routine screening every three years. Our new recommendations will now be in line with CCO.**

Physicians Ordering "STAT" Specimens

As a community laboratory, LifeLabs is not capable of responding to STAT requests through our Patient Service Centres. **We are able to handle URGENT specimens with an expected turnaround time of less than 12 hours, for most standard Chemistry and Hematology tests.** This allows for delivery to the testing location. **If you need results urgently, please write "URGENT" on the requisition. Also, you will need to provide us with a contact number so that we can report these to you.**

By Timothy Feltis MD FRCPC
Ontario Medical Director

Change To CEA Testing Methodology

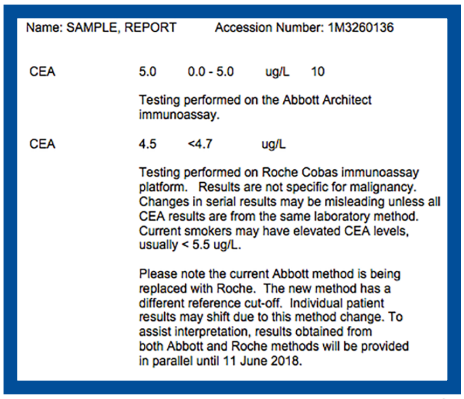
On December 11. 2017 LifeLabs Ontario will introduce a new methodology for carcinoembrionic antigen (CEA) testing, based on the Roche Cobas system.

Please note that patients whose samples are sent to hospital laboratories with the Cancer Care Ontario CEA requisition form are not affected by this change.
The change will only affect patients whose CEA levels are currently monitored at LifeLabs.

Due to the methodology change there will be a new reference cut-off of "<4.7 ug/L" which will be noted on reports.

Also, some individual patient results may shift significantly. **To assist result interpretation, LifeLabs will be testing all patient samples in parallel on the current Abbott Architect methodology and the new Roche Cobas methodology until June 11. 2018.**
We strongly recommend that health care providers have their patients tested for CEA before this date (June 11. 2018) in order to obtain results from parallel testing, and thus have baseline results for continued monitoring of CEA levels.

An example of the patient report to the right indicates the information that will be provided on lab reports



Name: SAMPLE, REPORT Accession Number: 1M3260136

CEA	5.0	0.0 - 5.0	ug/L	10

Testing performed on the Abbott Architect immunoassay.

CEA	4.5	<4.7	ug/L

Testing performed on Roche Cobas immunoassay platform. Results are not specific for malignancy. Changes in serial results may be misleading unless all CEA results are from the same laboratory method. Current smokers may have elevated CEA levels, usually < 5.5 ug/L.

Please note the current Abbott method is being replaced with Roche. The new method has a different reference cut-off. Individual patient results may shift due to this method change. To assist interpretation, results obtained from both Abbott and Roche methods will be provided in parallel until 11 June 2018.

Please contact the LifeLabs Customer Care Centre 1-877-849-3637 for all enquiries. We welcome your feedback!

By Patrick St. Louis PhD, FCACB
Chemistry Discipline Head

Changes To Therapeutic Drug Monitoring Tests And Tests For ASOT, Ceruloplasmin And Haptoglobin

LifeLabs is introducing new instrumentation for therapeutic drug monitoring (TDM) tests, and for ASOT (antistreptolysin O antibodies / titer), ceruloplasmin and haptoglobin testing. For some tests this means a change in the assay platform. A major benefit from these changes is the standardization of the assay methods and reporting across all LifeLabs laboratory sites.

Overall, there will be no significant change to reported results. However we have taken this opportunity to update some of the therapeutic ranges, in accordance with current guidelines, and where appropriate, to update analyte reference intervals.

The change will take place on December 11, 2017. At that time, a message will appear on the affected lab reports indicating the details of the change for each test. Please refer to the lab report for analyte specific messages, therapeutic ranges, orreference intervals.

The following tests are affected:

Therapeutic drugs	Specific Proteins
Carbamazepine	ASOT
Digoxin	Ceruloplasmin
Phenobarbital	Haptoglobin
Phenytoin	
Primidone	
Theophylline	
Tobramycin	
Valproic acid	

For **Gentamicin**, testing will be referred out to the Laboratory at the Hospital for Sick Children, Toronto.

As usual, these changes are being implemented in the context of our continuing effort to provide better quality and more reliable services to our clients. We welcome your feedback.

Please contact the LifeLabs Customer Care Centre at 1-877-849-3637 for all enquiries.

By Patrick St. Louis PhD, FCACB
Chemistry Discipline Head

Protein C And Protein S Testing At LifeLabs

Protein C and Protein S deficiency are rare inherited thrombophilias. Several laboratory tests exist to diagnose and distinguish between the different subtypes of each disorder. However, several of these tests are either subject to uncontrollable variability often rendering the test unreliable or the test result may purely be of academic interest and not change patient management.

Protein C Deficiency:

• Protein C deficiency can be diagnosed by using the protein C functional assay (protein C activity), while the two sub-types of protein C deficiency can be distinguished using the protein C total antigen assay.
• However, there is no accepted difference in thrombotic risk between type I and type II protein C deficiency. Therefore, the protein C total antigen result is not clinically useful and is purely of academic interest.
• LifeLabs has chosen to only offer the protein C functional assay. The assay offered is the preferred protein C chromogenic functional assay rather than a clot based test – chromogenic assays are not affected by the same interferences that plague clot based methods such as lupus anticoagulant, elevated FVIII levels, and the presence of the FV Leiden mutation.

Protein S Deficiency:

• Protein S deficiency is the most difficult hereditary thrombophilia to document.
• Three different assays exist to help facilitate a diagnosis – protein S functional assay (protein S activity), protein S free antigen, and protein S total antigen.
• Protein S functional assays are notoriously unreliable due to several known interferences causing false negative or false positive results; these interferences can include but are not limited to elevated FVIII levels, lupus anticoagulant, and the presence of FV Leiden mutation. Due to these interferences most laboratories no longer perform the functional assay .
• The protein S antigen immunoassays are generally the routine protein S tests offered by most laboratories. Occasionally, protein S total antigen results are unreliable as some assays give normal results for type I deficient specimens.
• This leaves protein S free antigen as the preferred and most common screening test for protein S deficiency, with some laboratories opting to use this test exclusively while others also perform protein S total antigen. Unfortunately there are no published guidelines recommending exclusive use of the free antigen test or use of both tests in combination.
• LifeLabs has chosen to only offer protein S free antigen due to the limited clinical utility and reliability of protein S total antigen assays.

Given that the majority of protein C and protein S deficiencies are acquired, it is advised that all acquired causes be excluded even if a protein S deficiency is truly present.

POINTS TO REMEMBER:

• There are a number of Protein C and Protein S tests used to diagnose and distinguish between different subtypes of inherited thrombophilias
• LIfeLabs offers the protein C functional assay and the protein S free antigen test
• All acquired causes of protein C and protein S deficiency should be excluded

1.Van Cott EM, et al. Protein S Assays: An Analysis of North American Specialized Coagulation Laboratory Association Proficiency Testing. Am J Clin Pathol 2005; 123:778-785.
2.Mackie I, et al. Guidelines on the Laboratory Aspects of Assays Used in Haemostasis and Thrombosis. Int Jnl lab Hem 2013; 35:1-13.
3.Bauer, KA. Protein S Deficiency. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA 2016.
4.Kottke-Marchant, K. (2008) An Algorithmic Approach to Hemostasis Testing. Illinois, Chicago: College of Americal Pathologists.

By Miranda Wozniak MD FRCPC
Ontario Deputy Medical Director
Discipline Head, Hematology

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For more information, please visit our site at **www.lifelabs.com**

Dr. Huda Almohri
Ontario Deputy Medical Director,
Discipline Head, Microbiology
416-675-4530 ext.42105
huda.almohri@lifelabs.com

Dr. Abdel Belhaj
Medical Microbiologist
416-675-4530 ext.42344
abdel.belhaj@lifelabs.com

Dr. Afaf Erfaei
Hematopathologist
416-675-4530 ext.42944
afaf.erfaei@lifelabs.com

Dr. Timothy Feltis
Ontario Medical Director,
416-675-4530 ext.42801
tim.feltis@lifelabs.com

Dr. Danijela Konforte
Clinical Biochemist
416-675-4530 ext.42208
danijela.konforte@lifelabs.com

Dr. Daniela Leto
Medical Microbiologist
905-565-0433 ext.42310
daniela.leto@lifelabs.com

Dr. Patrick St.Louis
Discipline Head, Chemistry
416-675-4530 ext.42029
patrick.st.louis@lifelabs.com

Dr. Tracy Morrison
Clinical Biochemist
416-675-4530 ext.42975
tracy.morrison@lifelabs.com

Dr. Krystyna Ostrowska
Medical Microbiologist
416-675-4530 ext.42892
krystyna.ostrowska@lifelabs.com

Dr. Kika Veljkovic
Clinical Biochemist
416-675-4530 ext.42832
kika.veljkovic@lifelabs.com

Dr. Miranda Wozniak
Ontario Deputy Medical Director
Discipline Head, Hematology,
416-675-4530 ext.42040
miranda.wozniak@lifelabs.com