Inside Diagnostics Ontario

The diagnostic Newsletter for Healthcare Providers

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MARCH 2020

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COVID-19 UPDATES

As of March 11, 2020, the World Health Organization officially declared the coronavirus (known as COVID-19) a pandemic, which is defined as the worldwide spread of a new disease.

For more information and ongoing COVID-19 updates please visit:
https://www.lifelabs.com/information-on-coronavirus-for-health-care-providers/

LABORATORY TESTING FOR MONITORING OF PATIENTS WITH COVID-19

The current COVID-19 pandemic is presenting challenges for both patients and their health care providers. Critically ill patients are hospitalized and have direct access to laboratory testing. On the other hand, patients who screen positive but are not confirmed or not critically ill may need ongoing monitoring. At LifeLabs we continue to help by providing access to testing for these patients.

Literature from sources with direct experience suggests some tests have significant predictive value. These tests can also have value for patients who have not screened positive but may be at risk.

Table 1. Highlights of the potential significance of some laboratory tests in prognosis of COVID-19. (adapted from the reference below)

	Laboratory Parameter	Potential Clinical Significance
Hematology Tests	Lymphopenia	Decreased immunological response
	Leukocytosis	Superinfection
	Neutrophilia	Superinfection
	↑ D-dimer	Activation of coagulation and/or disseminated coagulopathy
Chemistry Tests	↑ LDH	Pulmonary injury, widespread organ damage
	↑ CRP	Severe infection/sepsis
	↑ Cardiac troponins	Cardiac injury

Note, these are in addition to the routine tests for monitoring liver and kidney injury (transaminases, creatinine, etc)

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Clinical Biochemist

Reference:
1. Lippi,G and Plebani,M. The critical role of laboratory medicine during coronavirus disease 2019 (COVID-19) and other viral outbreaks., M; Clin Chem Lab Med, March 2020; doi: 10.1515/cclm-2020-0240. [Epub ahead of print]

IMPROVEMENTS TO MY RESULTS PORTAL – LIFELABS PARTNERING WITH LAB TESTS ONLINE TO HELP PATIENTS LEARN ABOUT DIAGNOSTIC TESTING

J. Timothy (Tim) Feltis
MD FRCPC
Ontario Medical Director, LifeLabs

LifeLabsLifeLabs is pleased to announce a partnership with Lab Tests Online, a highly-regarded and widely-used health information website resource for patients.

As of March 28. 2020 Lab Tests Online content will be available through "My Results", the LifeLabs platform for on-line viewing of laboratory results by patients.

WHAT IS LAB TESTS ONLINE?

Lab Tests Online provides in-depth information to help patients and caregivers understand the laboratory tests as an important part of their medical care.

Lab Tests Online content is maintained and curated by the American Association for Clinical Chemistry (AACC), a global non-for-profit organization of laboratory professionals dedicated to clinical laboratory science and its application to healthcare.

The test library included in Lab Tests Online covers most of the routine and specialized tests that are performed in the disciplines of Chemistry, Hematology and Microbiology. The content is easy to understand by the general public and is regularly updated by the editorial board consisting of experts in the field.

For more information, please visit https://labtestsonline.org/.

LAB TESTS ONLINE CONTENT AVAILABLE THROUGH LIFELABS 'MY RESULTS' PLATFORM

Through direct links associated with their results in LifeLabs 'My Results' platform, patients will be able to **find out more information about the clinical utility of the tests performed, what the test results could mean, and in some instances, what the next steps and possible treatment options are.** An example of this is presented in Figure 1.

It is hoped that this information will provide further support to patients, and also help Health Care Providers (HCP) when they discuss test results and specific clinical situations with their patients.

Lab Tests Online is a trusted worldwide resource, originating in the United States. As such, it is important to note that some recommendations in this database are based on the published American medical guidelines, which may differ from those used in Canada.

LifeLabs will be including a disclaimer (e.g. Figure 1 bottom of the page) to indicate to patients that Canadian guidelines may differ from those provided in Lab Tests Online, and that HCPs should be consulted on the Canadian guidelines.

IMPROVEMENTS TO MY RESULTS PORTAL – LIFELABS PARTNERING WITH LAB TESTS ONLINE TO HELP PATIENTS LEARN ABOUT DIAGNOSTIC TESTING (CON'T)

Additionally, the instructions around test preparation and specimen collection may differ between laboratories. Therefore, patients will be instructed to consult LifeLabs Test Information Directory at LifeLabs website (www.lifelabs.com) to obtain the specific preparation instructions.

J. Timothy (Tim) Feltis
MD FRCPC
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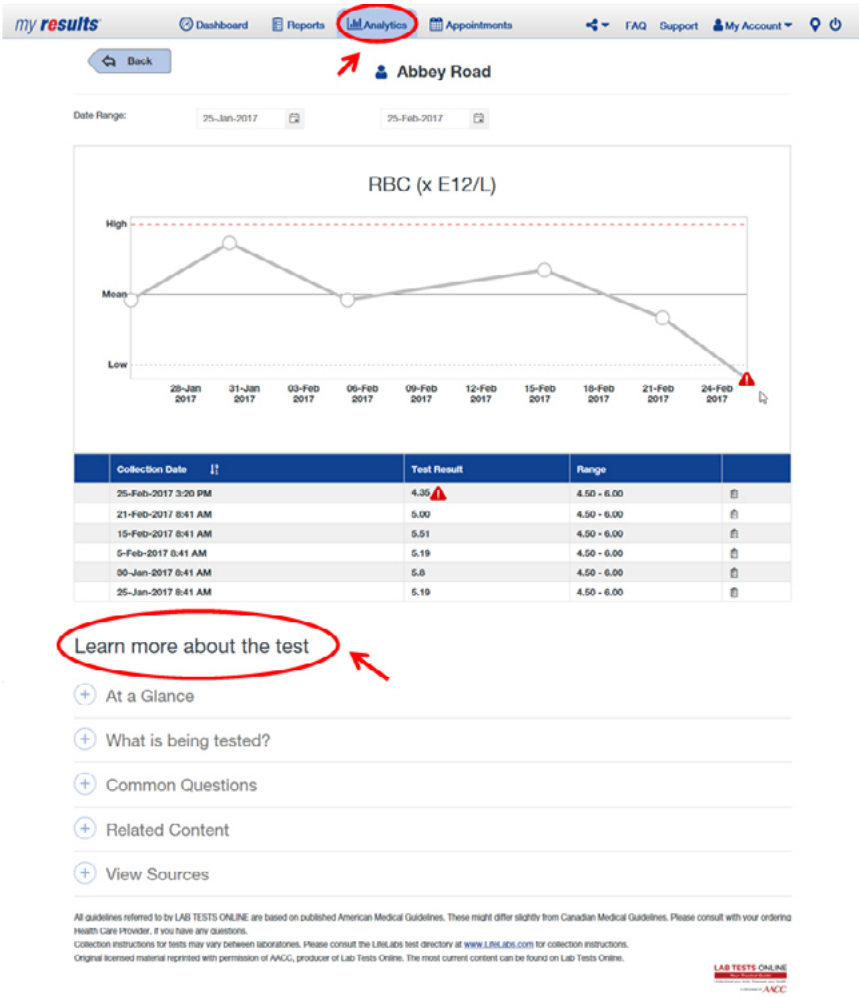
FIGURE 1. ACCESSING LAB TESTS ONLINE THROUGH MY RESULTS

Select a test (e.g. RBC) in 'Analytics' section of My Results. Lab Tests Online Information 'Learn More About the Test' will appear below the results.



MAINTAINING ACCURACY OF HEALTH CARE PROVIDER ADDRESSES

Ensuring that test results get back to the ordering Health Care Provider (HCP) is an item that LifeLabs takes very seriously.

In today's Ontario Healthcare landscape, HCPs often work at multiple sites, making delivery of these results to the correct address important, if not, more challenging. Delivery of the results to the correct HCP, but to the wrong practice address may be considered a privacy breech and we make every effort to get these details correct.

We endeavor to always enter the HCP office address noted on the requisition, when the patient presents at one of our Patient Service Centres. As this is a manual step, we do occasionally choose the wrong address. A recent audit of this demonstrated an extremely low incidence of errors. We are undertaking a number of steps internally, including training and education of our staff to prevent these errors from happening in the future.

As our valuable partner, there are a number of actions HCPs can also undertake to assist LifeLabs in maintaining the accuracy of the HCP address. These include:

- If you set up a new practice location, you should inform the laboratory through our Customer Service Centre (1-877-849-3637) about your new address. This will allow us to update your current file to include all of your practice locations and allow for us to support proper delivery of those results.
- In a similar vein, if you close a location, it is important that we are informed. Please remember that any requisitions that have been handed out and collected at a later date will be sent to the requisition address. You should make adequate provision to have these reports re-directed as required.

LifeLabs Approaches to Reducing Incidence of Misdirected Reports and Errors in Entry of Tests Ordered

We are currently doing another audit to assess misdirected reports, as well as other errors in entry of tests ordered.

We continue to ask the Ministry to move forward with electronic ordering of tests. The electronic ordering would ensure the results are reported to the correct address on the electronically submitted requisition, and that the orders are clearly recorded.

We are confident that our continuous improvement plans will facilitate excellent service to you. Thank you for your understanding and for continuing to notify LifeLabs of the errors when they happen.

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CCO FIT PROGRAM REMINDER – INSTRUCTIONS FOR ORDERING, COLLECTION AND MAILING OF FIT KITS

On June 24, 2019, Cancer Care Ontario transitioned from Guaiac Fecal Occult Blood Test (gFOBT) to Fecal Immunochemical Test (FIT) as the recommended primary screening test for people with average risk of developing colorectal cancer.

To ensure that your patients receive their FIT devices in a timely manner and to reduce interruptive calls to your office, please review the following:

1. Confirm each patient's full mailing address and OHIP information

- Please ensure that mailing address information is up to date.
    - » Check that addresses include the suite, unit, or PO box number. Also, make sure the suite, unit, or PO box number appears before the street number.
    - » Check that the street name is spelled correctly.
- Please confirm that OHIP numbers and **version codes** are correct.

2. Send completed requisitions to LifeLabs

- Please fax the one-page requisition to LifeLabs' FIT fax line at **1-833-676-1427.** Cover letters are not required.
- *Please only include one patient per form. The FIT requisition is the only acceptable requisition for this program—OHIP requisitions or other types of forms will not be accepted.*
- Please also ensure that the requester section is complete with CPSO and an OHIP billing number.

3. Talk to your patients about timely return of FIT kits

- FIT uses a centralized distribution model. Under the new program, eligible patients will receive their **pre-labelled** FIT collection kit from LifeLabs **in the mail.**
- Please instruct your patients to complete the test as soon as possible and no later than within six months of receipt.
- *Please remind your patients to mail back their completed FIT kits to LifeLabs, or drop them off at a LifeLabs location, ideally within 2 days of collection.*

4. Refer patients with abnormal FIT results for colonoscopy to ensure timely follow up

- If a patient has an abnormal FIT result, refer them for a colonoscopy as soon as possible. *The colonoscopy should be completed within eight weeks of the abnormal FIT result.*
- A list of facilities that are funded by Cancer Care Ontario to provide colonoscopies for people with abnormal FIT results is available at: *cancercareontario.ca/FITcolonoscopy.*

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CCO FIT PROGRAM REMINDER – INSTRUCTIONS FOR ORDERING, COLLECTION AND MAILING OF FIT KITS (CONT'D)

REMINDERS FOR YOUR PATIENTS:

Remind your patients to write the date on the FIT tube right before they collect their sample

- If a collection date is missing, LifeLabs will call your patient to try to get it. However, many patients cannot remember their collection date after they return their FIT kit.
- If LifeLabs cannot get the collection date from your patient and their FIT result is normal, they will need to repeat the test.

Remind your patients that the stool should not go past the grooves on the stick

- If LifeLabs receives a FIT device with too much stool, it will not be processed and your patient will have to repeat the test.

Remind your patients to close the FIT tube securely (snap closed)

- If LifeLabs receives a leaking FIT device, it cannot be processed and your patient will have to repeat the test.

CONTACTS:

- For questions about a patient's FIT kit status, please contact the LifeLabs FIT Phone Helpline at **1-833-676-1426.**
- For more information on screening with the FIT, please visit cancercareontario.ca/CCCrecommendations
- For information on colonoscopy and abnormal FIT results, please visit cancercareontario.ca/FITresult

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NEW IMMUNOASSAY TESTING PLATFORM

Effective March 02, 2020, LifeLabs implemented a new immunoassay testing platform, Roche Cobas e801, for the select tests indicated in Table 1 below.

Table 1: LifeLabs tests to be moved to the new Roche Cobas e801 immunoassay platform:

MEASURED TESTS:	
Tumor Markers:	**Endocrine Markers:**
Alpha1-fetoprotein (AFP)	Adrenocorticotropin hormone (ACTH)
Anti-Müllerian hormone (AMH)	Connecting Peptide (C-Peptide)
Anti-Thyroglobulin Antibody (ATG, Anti-Tg)	Dehydroepiandrosterone Sulphate (DHEA-S)
Anti-Thyroid Peroxidase Antibody (ATA, Anti-TPO)	Folate, Red Blood Cell
Cancer Antigen 125 (CA 125)	Folate, Serum
Cancer Antigen 15-3 (CA 15-3)	Human Growth Hormone (HGH)
Carbohydrate Antigen 19-9 (CA 19-9)	Insulin
Carcinoembryonic Antigen (CEA)	Parathyroid Hormone (PTH)
	Sex Hormone Binding Globulin (SHBG)
	Testosterone
CALCULATED TESTS:	
Bioavailable Testosterone (BAT)	
Free Testosterone (FT)	

Improvements that benefit patient care:

- The new platform is from the same manufacturer of the instrument currently used (Roche Cobas e602), but has updated technology that allows processing of patient samples with equal or better precision and accuracy.
- The new platform was incorporated with the high-volume chemistry track system which improves turnaround time for the assays and it enables tube consolidation where more tests can be performed from a single blood collection tube, decreasing the number of tubes collected from the patient.

Reference Intervals:

- No changes to reference intervals were required for any of the tests. Patient results are equivalent between the previous and the new platform.
- Test codes will also remain the same.

SHBG expected change explained:

The only significant change expected is for Sex Hormone Binding Globulin (SHBG) due to a reagent change by the manufacturer.

The manufacturer (Roche Diagnostics) has informed users of a gradual upward shift in SHBG results over the past 8 years due to a slow deterioration of their reference material during this time. Roche has recalibrated the SHBG assay and LifeLabs validation has indicated that the expected results will be 15 – 18% lower on the new platform.

NEW IMMUNOASSAY TESTING PLATFORM (CON'T)

Since SHBG is used in the calculation of Free Testosterone (FT) and Bioavailable Testosterone (BAT), a positive shift of up to 16% may be observed in FT and BAT results, with higher SHBG concentrations leading to a higher shift in FT and BAT results. Taking into consideration the biological variation of these analytes, no changes to reference intervals are expected, and this has been verified in our validation studies.

It should be noted that the gradual SHBG shift has had minimal impact on historical SHBG, FT and BAT results at LifeLabs. The analysis of greater than 100,000 historical LifeLabs results from 2013, 2016 and 2019 has indicated that there was no significant clinical impact of this deterioration on either male or female SHBG, FT or BAT results.

With the implementation of the platform change, the following temporary notification will appear on patient reports: ***New testing platform as of March 02, 2020. Results are equivalent, and reference intervals are unchanged.***

Please note, minor updates to interpretive comments for some of the tests will also be implemented to align with current clinical guidelines and improve interpretation of laboratory results.

For any clinical or technical questions regarding this change please contact the following LifeLabs biochemists:

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POINTS TO REMEMBER:

- New platform from the same manufacturer (Roche) was implemented at LifeLabs for a number of tumor and endocrine markers on March 02, 2020.
- Similar or better result precision and accuracy is expected.
- Benefits to patients and health care providers include decrease in number of tubes required for multiple tests, and faster result turnaround times.
- Clinically insignificant decrease in SHBG results, and increase in calculated FT and calculated BAT results, is expected due to a reagent change by the manufacturer.
- There is no change to reference intervals, including those for SHBG, calculated FT and calculated BAT.

HLA-B27 TESTING AT LIFELABS

LifeLabs is pleased to introduce an expansion of our flow cytometry testing.

As of March 9th, 2020 we are offering flow immunophenotyping for HLA-B27 antigen testing.

Flow cytometry is widely used for analyzing the expression of surface and intracellular molecules in order to differentiate and characterize different cell populations.

- **LifeLabs' test kit includes five different monoclonal antibodies specific for the HLA-B27 antigen for increased sensitivity.**
- **Any inconclusive result will be confirmed by molecular testing.**

HOW TO ORDER:

1. On the OHIP requisition enter **'HLA-B27 typing' under the "Other" category.** Send the requisition with the patient to any LifeLabs collection centre.
    - **LifeLabs collects these samples at any location on Monday – Thursday (no collection on Friday)**
    - **Turn-around time is 2-4 business days.**

Should you have any questions about HLA-B27 testing at LifeLabs, please do not hesitate to contact:

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

SCREENING FOR LYNCH SYNDROME IN ENDOMETRIAL AND COLONIC CANCERS

WHAT IS LYNCH SYNDROME?

Lynch Syndrome is an inherited genetic abnormality that affects both men and women. Lynch Syndrome is the most common hereditary cancer syndrome in Ontario and affects about 1:133 individuals.

Cancer arising from the lining of the uterus (endometrial cancer) is the most common presentation of Lynch Syndrome in women. This cancer is the most common gynecologic cancer; about 3000 cases will occur in Ontario this year.

Colonic cancer is the other major Lynch Syndrome malignancy and is the most common presentation of Lynch Syndrome in men.

The initial diagnosis of endometrial and colonic cancers is usually made by the histopathologic examination of endometrial and colonoscopic biopsies, respectively.

LifeLabs histopathology reports many such cases of endometrial and colonic cancers each year.

LIFELABS OFFERS SCREENING FOR LYNCH SYNDROME

The detection of potential Lynch Syndrome is now possible using immunohistochemistry to identify the absence of mismatch repair proteins in these tumours, the hallmark of potential Lynch Syndrome.

- **LifeLabs is now following Cancer Care Ontario's guidelines to detect Lynch Syndrome by performing this immunohistochemistry on all new colonic and endometrial cancer cases in individuals less than 70 years old.**

These results are available during the pre-operative work-up of the patient and could trigger essential investigations or referral.

In addition, detection of Lynch syndrome helps not only the client, but his/her family too.

Affected family members can be counselled and followed.

- **LifeLabs' immunohistochemistry results to detect potential Lynch Syndrome are shared with Cancer Care Ontario in order to ensure proper follow-up.**
- **This innovative testing is now routine at LifeLabs and funded by Health Ontario.**

If you have any questions, please contact us at 1-877-849-3637.

Terence (Terry) J. Colgan
MD FRCPC FCAP
Discipline Head - Histopathology

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PRIVATE PAY TESTING:
POLICIES AND BEST PRACTICES

1. Policy Changes for Uninsured Lab Tests – Out of Country Patients and Refugee Coverage

LifeLabs will be making policy changes regarding our collection of uninsured lab tests. As a reminder, it is our recommendation to direct all uninsured patients (out of country tourists, private pay tests etc.) to the nearest LifeLabs Patient Service Centre to more effectively process their required transaction.

- Uninsured patients can best be identified if they do not provide a valid Health Card number or a Universal Client Identification (UCI) number. Patients with refugee status with a valid UCI number must pay for any fertility tests as the Blue Cross does not cover these tests within their portfolio.
- Please advise your patients that outstanding payment for an uninsured test may result in delayed processing and/or reporting. Prolonged outstanding payments may result in the uncollected balance being sent to a 3rd party collection agency.

Please contact our Customer Care Centre at 1-877-849-3637 or visit www.lifelabs.com for a list of uninsured tests and to obtain current fees.
Any uninsured tests not on the pre-authorization credit card form can be ordered under the "OTHER" section of the form.

2. HPV Testing – Reminder that the test requires Patient's signature on the requisition

- LifeLabs has noted that a number of outdated Cytology & HPV Testing Requisition forms have been omitting patient signatures. This signature displays the acknowledgement that patients are aware that the tests being requested may not be covered by OHIP and that the patient may be liable for the costs.
- A requisition missing a patient's signature or current patient information (Address and Phone Number) may result in a rejection upon receiving the specimen.

3. Credit Card Pre-Payment Authorization Form for Uninsured Lab Tests

LifeLabs is pleased to announce the launching of our pre-payment authorization form for patients requiring uninsured testing. As you are aware, LifeLabs requires payment for any uninsured tests that are collected in your clinic/office.

- To assist with this process, LifeLabs is pleased to offer authorization form (Visa or MasterCard) for patients who would prefer to be tested in your clinic/office. This form was developed to increase transparency in test costs, and decrease communications with the patient regarding outstanding payment.
- If your patients would prefer to pay by cash or debit, it is preferred that samples are collected at a LifeLabs patient service centre to limit potential issues in the billing process.
  Note: Patients can book an appointment online or visit a LifeLabs patient service centre and use SaveMySpot. This will reduce their wait time at the LifeLabs location by booking ahead or saving their spot.

Filling out credit card pre-payment authorization form

- Once the patient has filled out this form, place the form in the sealed envelope provided by LifeLabs and send with the collected sample(s).
- LifeLabs will process the payment and will send a receipt of sale to the patient's address provided on the pre-authorization credit card form. If there are any issues with the information provided, LifeLabs will contact the patient directly.

PRIVATE PAY TESTING:
POLICIES AND BEST PRACTICES (CON'T)

- For your reference, the form includes a list of commonly ordered, uninsured tests and their fees for each. This is not an exhaustive list; please contact our Customer Care Centre at **1-877-849-3637** or visit www.lifelabs.com for additional uninsured tests and to obtain current fees.
  NOTE: Any uninsured tests not on the pre-authorization credit card form can be ordered under the "OTHER" section of the form.

** If your patient has a standing order for routine blood work, please ensure that they return to your office to have a new order generated every six months. LifeLabs can no longer offer courtesy draws for expired standing orders.

**Please ensure all requisitions are filled out clearly and include the patient's address, including apartment and unit number, and their telephone number. All requisitions require the healthcare provider's signature.

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

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CREDIT CARD AUTHORIZATION

HEALTH CARE PROVIDER INSTRUCTIONS

- Complete a Ministry of Health and Long-Term Care (OHIP) Laboratory Requisition
- Indicate the test requested below
- Advise patient of the fee
- Instruct the patient to complete the credit card authorization below if they would like to pay by credit card

For a complete list of un-insured tests, please visit www.lifelabs.com. For pricing inquiries, please call 1-877-849-3637, option # 2.

Health Care Provider's Signature:_____

☐ Anti-CCP $55	☐ CA 19-9 $50	☐ Insulin-Like Growth Hormone $90
☐ Anti-Mullerian Hormone $70	☐ CA 125 $35	☐ PSA Screening $33
☐ Anti-Phospholipid AB Studies $70	☐ Calprotectin Stool $125	☐ PSA Ratio $55
☐ Angiotensin Converting Enzyme $50	☐ Celiac Disease Testing $125	☐ Reverse T3 $55
☐ Apolipoprotein B $35	☐ Free Light Chains $55	☐ Sex Hormone Binding Globulin $55
☐ B-Type Natriuretic Peptide $75	☐ Homocysteine $75	☐ Tissue Transglutaminase $60
☐ Bile Salt/Acid $45	☐ Human Papillomavirus (HPV) $90	☐ Vitamin D 25 Hydroxy $37
☐ Bioavailable Testosterone $60		

PATIENT INSTRUCTIONS & PAYMENT OPTIONS

- Complete the credit card authorization below
  OR
- Visit a LifeLabs Patient Service Centre to have blood drawn and pay for the test (completion of credit card authorization not required)

Use this form only if paying by Credit Card

For any questions or comments on completing the form, please call 1-888-265-5227

To avoid delays, please print information clearly

Last Name:	**First Name:**	
Billing Address:		
City:	**Province:**	**Postal Code:**
Phone:	**Email:**	
Type of Card: ☐ VISA ☐ Mastercard	**Receipts by:** ☐ Mail ☐ Email (listed above)	
Name on Credit Card if different from above:		
Card Number:		
Expiry Date:	**CVD/CVV:**	
Amount Authorized: $		
Additional Notes:		

Service Terms:

I hereby authorize LifeLabs to charge my credit card for the requested laboratory services. If for any reason, my card is not accepted, I understand that I am financially responsible to LifeLabs and LifeLabs will bill me based on the full price for the laboratory work performed. Also, I understand the authorized amount is an approximate and the total amount charged to my credit card may differ based on the test requested by my medical practitioner and my coverage at the time of service.

Date:	**Signature of Card Owner:**

100 International Blvd
Toronto ON M9W 6J6

Expiration Date: