LIFELADS INSIDE Diagnostics NOVEMBER 2021

THE NEWSLETTER FOR HEALTHCARE PROVIDERS

2021/2022 Holiday Hours

3 OHIP-covered Combined Test for COVID-19/Flu/ RSV Available at LlfeLabs

Upgrades to LifeLabs Urinalysis Testing Platform

B H.Pylori Stool Antigen Testing

> Improvements to Growth Hormone Suppression Test

CLOSED FOR Christmas and New Year Holidays

Please note that we will be CLOSED on: December 25, 26, 27, 2021

(some locations will be closed on Dec. 28) January 1, 2, 3, 2022

Closed at 12:00 Noon:

- December 24
- December 31

Regular Working Hours:

- December 28 ** limited number of locations open
- December 29
- January 4

** Please see www.LifeLabs.com or call our Customer Care Cente 1-877-849-3637 for locations and hours



www.LifeLabs.com

COMBINED MOLECULAR TEST FOR SARS-COV-2, FLUA, FLUB, AND RSV OFFERED BY LIFELABS

Respiratory viruses account for most respiratory tract infections. Viral infections can be simple upper respiratory infections or more severe syndromes such as: pneumonia, bronchiolitis, croup, and tracheobronchitis.

The type of disease, symptoms, and severity of illness vary by age and other host factors. For example, RSV infection occurs at all ages from infants to adults but causes upper respiratory infections in adults and more severe lower respiratory infections (eg. bronchiolitis) in children. RSV is most severe in children, especially those less than 6 months of age, where pneumonia is a common presentation.

Adults, especially those who are immunocompromised, can also experience severe respiratory viral infections. For example, pneumonia caused by influenza is a leading cause of morbidity and mortality in elderly patients. Rapid diagnosis of viral respiratory pathogens can reduce morbidity and mortality in patients.

Clinically it is difficult to differentiate SARS-CoV-2 infections from other respiratory infections.

We are pleased to inform you that LifeLabs is now offering molecular PCR testing for the combined detection of SARS-CoV-2, Flu A, Flu B, and RSV for our community patients. This new OHIP-covered test will assist in differentiating some of the possible viral causes of respiratory tract infection and flu-like symptoms.

INDICATIONS FOR ORDERING COMBINED COVID AND RESPIRATORY VIRUS TEST

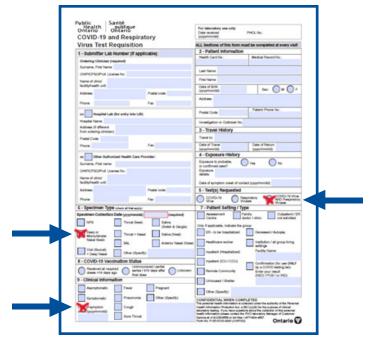
The combined COVID and respiratory virus test will only be available to patients experiencing COVID or flu-like symptoms. Therefore, this test cannot be accepted for the purposes of travel. If a patient inquires about COVID testing for travelling, they can be directed to our FlyClear page www.lifelabs.com/flyclear/predeparture/. At this time, LifeLabs can only perform this testing on samples collected by health care providers. The test is not currently available for collection at LifeLabs' patient service centres.

ORDERING AND SAMPLE REQUIREMENTS

If you require molecular testing for respiratory viruses for your patient, please send us an appropriately-collected nasopharyngeal swab in the proper collection device, and fill in the Virus Test requisition from Public Health Ontario (please see below).

Samples other than Nasopharyngeal swabs collected by health care providers, cannot be accepted for testing for respiratory viruses (e.g., saliva, anterior nasal, or buccal swabs are not accepted for testing for respiratory viruses at LifeLabs).

Please indicate that Nasopharyngeal swab is collected, choose the combo test COVID+Flu and indicate that the patient is symptomatic to accept the sample for testing.





To order the respiratory viral collection swabs, please fill in the Client order form for Lifelabs. Add Copan respiratory viral swabs under Other:

	1. CLIENT	INFORMATION			
lien	t ID #:	Client Name:			
Date		Address:			
	t Office Contact Name:	Phone #:			-
-11411	t onice contact Name:	Phone #;			
Index	las a Mandalory Field				
	2.0	RDER	a second as		
	Item Description		Units	Qty. Req.	Item #
	Culture Swab Transport System – Charcoal		Bag/50		24307
	Chlamydia &/or GC BD ProbTec Swabs Female		Each		1012045
	Chlamydia &/or GC BD ProbTec Swabs Male		Each		101204
~	Fungus Scraping Kit		Each		1017605
8	Stool Culture & Sensitivity (C&S) Kit		Each		1012577
10	Stool Parasites - PCR Method (Parasite Swab)		Each		1017801
-8	Pinworm Kit	-	Each		101259
Microbiology	Sputum Culture & Sensitivity (C&S) Kit		Each		1012597
2	Urine Culture & Sensitivity (C&S) Kit		Each		1012594
	Sterile 90ml Container with Orange Cap		Bag		10953
	Collection, Urine Ped, URC-010		BOX/10		1015425
	Castle Soap Towelette		Box/100		10251
_	Pap Liquid Based Collection Vial (also for HPV t	(anitan)	PK/25		101708
	Pap Collection Broom (Blue) (Rover)	(((((((((((((((((((PK/25		28124
8	Pap Collection / Spatula With Brush (Purple) (Su	(diameth)	PK/25		1009216
Cytology	HPV & Cytology Regulation	a albear of	PD/25		1018004
Ť,	Fine Needle Aspiration Kit (Cytology)		Each	-	1012595
0	Urine Collection Kit (Cytology)		Each		1012500
	Soutum Collection Kit (Cytology)		Each		101258
-	Small Biopsy 40ml Container (Histology)		Each		1015817
	Medium Biopsy 90ml Container (Histology)		Each		1015816
	6x9 Ziploc Histology Bag		PK/100		
è.	13x9 Zploc Histology Bag		PK/100	_	1015811
-	Histopathology Requisitions		PR0100		1015613
Sistology	Surgical Pathology Regulation (General Use	1	PD/25		
Ŧ	Gastrointestinal Pathology Requisition	/	PD/25		1018003
	Gynecologic Surgical Pathology Requisition		PD/25 PD/25		1018003
	Dermatopathology Requisition		P0/25	-	1014494
-	FOBT (CCC Occult Blood) Statementary		PU/20 PK/20		1018004
	Semen Analysis Kt		Fach	-	1015448
	Poly Bag 6 x 9		Each PK		101259
2	LTC On-Ste Lab Services			-	12640
1	FORT (Non CCC Occult Blood)		PK/100 Each	-	1014939
4	Client Order Form			-	1011115
3	Flow Cytometry Regulation		PD PD/25	-	1009250
ŝ.	Other		PUIZO	-	101063
_			-		
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		LSPECIALIST			
licks	d By:		Date (D/I	M/Y):	

If you have any questions, please contact 1-877-849-3637, or refer to our <u>Notifications & Alerts</u> page on our website.

Huda Almohri, MD FRCPC

Deputy Ontario Medical Director, Discipline Head, Microbiology



UPGRADE TO URINALYSIS TESTING PLATFORM

As part of ongoing efforts to provide high-quality results our customers can trust, LifeLabs has upgraded chemical and microscopic urinalysis instrumentation at our laboratories nationally, including all testing sites in Ontario.

The new instrumentation has shown similar or improved precision, accuracy, and sensitivity during LifeLabs internal validation. With the change to this new instrumentation, LifeLabs will align urinalysis processes and reporting on a national scale. LifeLabs laboratories that are currently performing manual microscopy will now switch to automated microscopy.

WHAT THIS MEANS FOR YOU?

The new platform will enable discontinuation of obsolete manual processes and delivery of improved clinical information through standardized reports and reference intervals.¹ Please see below for reporting changes that are implemented with the new urinalysis testing platform.

In chemical urinalysis:

- The comparison between the current and the new reporting is summarized in Table 1. Changes to the reporting categories and units for Blood should be noted (in bold).
- The reference interval for Specific Gravity (SG) is replaced with an interpretive comment for dilute urine. Other reference intervals will not change.
- LifeLabs will continue to report chemical urinalysis results in SI units. Conversion to the "Plus" reporting system is provided in Table 1 for convenience.
- NOTE: There is no change to reporting of critical urinalysis result. Glucose of =OR> 55 mmol/L AND Ketone of 3.9 mmol/L or higher will be phoned except in patients ≥ 12 years old with a critical (> 30.0 mmol/L) blood glucose result.

In microscopic urinalysis:

- The following urine sediment elements will always be reported, even if not detected (i.e. result is negative): RBCs, WBCs, Squamous Epithelial Cells, Non-Squamous Epithelial Cells, Pathological Casts, and Crystals. Other rare elements will be reported only if detected.
- All enumerated microscopic elements will be reported per HPF (high power field), including Pathological Casts previously reported per LPF (low power field).
- Reference interval for Squamous Epithelial Cells was removed, due to clinical insignificance; the presence of Squamous Epithelial Cells indicates that the sample was not a "clean catch" (midstream) urine.¹
- Both chemical and microscopic urinalysis will be reported when microscopic urinalysis only is requested.
- Bacteria is no longer reported, as the presence of bacteria in urine commonly indicates specimen contamination, and it is not recommended among the clinically significant parameters in urine.²⁻⁴

WHEN WAS THE NEW INSTRUMENTATION IMPLEMENTED?

Implementation of the new platform took place gradually across Ontario testing sites, during October and November 2021. Once implemented at each site, a comment attached to testing results will indicate the new methodology.

A REMINDER REGARDING SPECIMEN COLLECTION AND HANDLING FOR URINALYSIS

We would like to take this opportunity to remind our clients that proper collection and handling of specimens for urinalysis are of utmost importance to obtaining accurate urinalysis results.

• When urinalysis specimen is collected (preferably midstream), date and time of collection should be included in the designated spot on OHIP requisition and/or on the specimen container.

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- Urinalysis analytes are stable for two hours at room temperature and 24-48h refrigerated. Therefore, all specimens sent to LifeLabs must be refrigerated as soon as possible and within two hours of collection, and transported promptly to the testing laboratory under refrigerated conditions.
- When date and time of collection are not provided, or when specimen is 24-48h old, the report will alert the healthcare provider to interpret results with caution, as accurate results cannot be guaranteed.
- Specimens older than 48h will be rejected.

For further details regarding this topic, please refer to the September 2020 issue of Inside Diagnostics, LifeLabs healthcare provider newsletter: <u>Inside-Diagnostics-</u> <u>September-2020_Final.pdf (azureedge.net).</u>

Patient collection instructions, as well as specimen handling instructions for urinalysis, are available through our patient service centres or in LifeLabs Test Information Directory: http://tests.lifelabs.com/Laboratory_Test_Information/ Homepage.aspx We are very excited about the new urinalysis platform implementation and the benefits it will deliver to our clients. If you have any questions or concerns, please contact the LifeLabs Clinical Biochemist below or LifeLabs Customer Care Centre at 1-877-849-3637.

We welcome your feedback!

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Analyte	Current Platform (Beckman)	LifeLabs Reporting Units (SI)	NEW Platform (Siemens)	LifeLabs Reporting Units (SI)	Reference Interval	Conversion to "Plus Reporting System
COLOUR	Yellow		Yellow			
	Straw		Dark Yellow			
	Amber	1 1				
	Orange		Orange			
	Red	-	Red	-		
		n/a	Pink	n/a	n/a	n/a
	Green		Green			
				-		
	Blue	-	Blue 	-		
	Colorless	-		-		
	Brown	-	Brown	-		
	Black		Black			
APPEARANCE	Clear		Clear	_ n/a		
		- n/a -			Clear	n/a
	Cloudy		Cloudy			
	Turbid		Turbid			
GLUCOSE	Negative		Negative			Negative
	2.8	ļ	5.5			Trace
	8.3	mmol/L	14	mmol/L	Negative	1+
	28		28			2+
	=OR> 55	1	=OR> 55			3+
-	Negative	mmol/L	Negative	mmol/L	Negative	Negative
	0.5					
	2.0		1.5			1+
KETONE			3.9			2+
-	=OR> 8.0		7.8			3+
			=OR> 15.6			4+
SPECIFIC GRAVITY	<or= 1.005<="" td=""><td rowspan="6">n/a</td><td><or= 1.005<="" td=""><td rowspan="6">n/a</td><td rowspan="6">n/a (replaced with interpretive comment indicating dilute urine)</td><td></td></or=></td></or=>	n/a	<or= 1.005<="" td=""><td rowspan="6">n/a</td><td rowspan="6">n/a (replaced with interpretive comment indicating dilute urine)</td><td></td></or=>	n/a	n/a (replaced with interpretive comment indicating dilute urine)	
	1.006-1.029		1.010			n/a
	=OR> 1.030		1.015			
			1.020			
			1.025			
			=OR> 1.030			
BLOOD	Negative	mg/L	Negative	RBC/uL		Negative
	0.3		Trace			Trace
			25		Negative	1+
	2		80			2+
	=OR> 10		200			3+
pH	5.0		5.0			<u>_</u>
		-	5.5	-		
	6.0	n/a	6.0	-	5.0 - 8.0	n/a
			6.5			
	7.0		7.0	n/a		
	7.0		7.5	1//d		
	8.0		8.0			
			8.5	-		
-	00.00		00 00		1	1
	=OR> 9.0		=0R> 9.0			
	Negative		Negative			Negative
	Negative 0.3		Negative 0.3	_		1+
PROTEIN	Negative 0.3 1.0	g/L	Negative 0.3 1.0	g/L	Negative	1+
PROTEIN	Negative 0.3 1.0 	g/L	Negative 0.3 1.0 3.0	g/L	Negative	1+ 2+ 3+
PROTEIN	Negative 0.3 1.0 = OR> 5	g/L	Negative 0.3 1.0 3.0 = OR> 10	g/L	Negative	1+ 2+
	Negative 0.3 1.0 = OR> 5	-	Negative 0.3 1.0 3.0 = OR> 10	_		1+ 2+ 3+ 4+
PROTEIN	Negative 0.3 1.0 =OR> 5 Negative	g/L n/a	Negative 0.3 1.0 3.0 =OR>10 Negative	g/L n/a	Negative Negative	1+ 2+ 3+
	Negative 0.3 1.0 =OR> 5 Negative Positive	-	Negative 0.3 1.0 3.0 =OR>10 Negative Positive	_		1+ 2+ 3+ 4+ n/a
	Negative 0.3 1.0 =OR> 5 Negative Positive Negative	-	Negative 0.3 1.0 3.0 =OR>10 Negative Positive Negative	_		1+ 2+ 3+ 4+ n/a Negative
NITRITE	Negative 0.3 1.0 =OR> 5 Negative Positive Negative 25	n/a	Negative 0.3 1.0 3.0 =OR>10 Negative Positive Negative 25		Negative	1+ 2+ 3+ 4+ n/a Negative Trace
	Negative 0.3 1.0 =OR> 5 Negative Positive Negative	-	Negative 0.3 1.0 3.0 =OR>10 Negative Positive Negative	_		1+ 2+ 3+ 4+ n/a Negative

Table 1. Changes to Chemical Urinalysis Reporting (significant changes indicated in bold):

Abbreviations: "n/a", not applicable; "-", not available *Note test name change from "Leukocyte Esterase" to "Leukocytes"

Kika Veljkovic, PhD, FCACB Clinical Biochemist and Discipline Head, High Volume Chemistry LlfeLabs, Ontario



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HELICOBACTER PYLORI STOOL ANTIGEN TEST

Helicobacter pylori (H. pylori) is a bacteria that grows in the inner lining of the stomach.¹ It has been associated with gastric and duodenal ulcers, gastric cancer, gastric mucosa associated lymphoid tissue lymphomas and dyspepsia.^{2,3}

H. pylori infection affects 50% of the world's population.⁴ The prevalence in ON for 50 to 80 year old age bracket is 29.4% for men and 14.9% for women.⁵

Certain groups of people continue to have a higher predilection for this infection, such as First Nations communities, those in lower socioeconomic groups, and immigrants from countries such as Japan, Korea and China where there is a high incidence of *H. pylori* infection.¹

The Toronto Consensus for the Treatment of *Helicobacter pylori* Infection in Adults strongly recommends a treatment of 14 days in patients with *H. pylori* infection.⁶ It is therefore imperative to diagnose these infections so that patients can receive timely treatment.

DIAGNOSTIC TESTING FOR H. PYLORI

Although **Urea Breath Test (UBT)** has a high diagnostic accuracy for the detection of H. pylori infection⁴, the sample collection for this test could not be performed at LifeLabs patient service locations during the COVID-19 pandemic because of infection prevention and control implications. **LifeLabs will resume UBT in early 2021.**

The *H. pylori* **stool antigen test** is an accurate and reliable alternative test to UBT. This test has a high sensitivity and specificity. A systematic review of the stool antigen test in untreated patients with *H. pylori* infection demonstrated an overall sensitivity of 91%, specificity of 93%, and positive and negative predictive values of 92% and 87%, respectively.⁷ Chisolm et al reported a 94% sensitivity and 100% specificity in pretreatment dyspeptic adults in England.⁸

LIFELABS ONTARIO HAS RECENTLY STARTED TO OFFER A STOOL ANTIGEN TEST FOR H. PYLORI DETECTION.

Key Features:

- The test is an Enzyme Immuno Assay (EIA) that detects *H. pylori* antigens in stool.
- Non invasive, easy sample collection,
- Can be used both for diagnosis and assessing effectiveness of therapy.
- Results are qualitative (detected, not detected, indeterminate) and they must be interpreted in context of other clinical information,
- Proton Pump Inhibitors (PPIs), Bismuth preparations, antibiotics suppress *H. pylori* and can lead to false Negative results. (However, a positive result should be considered accurate).
- Performance characteristics of the test have not been established in asymptomatic populations

Ordering and Cost:

- The *H.pylori Stool* Antigen Test can be ordered by writing 'H.pylori Stool' in the 'Other Tests' section of the standard Ontario MOH requisition. The patient must obtain a collection container and provide a stool sample at any of LifeLabs' Patient Service Centers.
- Samples without a signed requisition by a physician or health care provider will not be accepted.
- This test is uninsured and it costs \$180.00 CAD/ test.

Sample Collection:

- Collect stool in a sterile leak proof container and transport at 2-8°C within 96 hours of collection or frozen.
- Stool samples in Cary Blair media are acceptable
- Preferred Specimen(s): Minimum volume of 0.5ml / 0.5 grams of stool or 20 mm diameter of solid stool

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 Reasons for sample rejection: stool in formalin or alcohol based fixative, concentrated stool specimens, swabs, insufficient quantity.

Turnaround Time, Results Reporting and Interpretation:

- Results of the test will be available to the ordering physician within 8 days of the specimen drop off.
- The results of this test are reported as *H. pylori* antigen detected, not detected, or indeterminate. The presence of *H. pylori* is indicated as a positive result (antigen detected). A negative result (antigen not detected) typically indicates the absence of *H. pylori*, or possibly an antigenic level below the immunoassay detection limit.
- Important Consideration for result interpretation: If your patient has initiated ulcer therapy during the two-week period leading up to specimen collection, a false-negative result is possible. If that occurs, the patient should wait for two weeks after treatment is completed to have the test redone on a new specimen. If an indeterminate result is reported, retesting with a new specimen will be required.

For more information, please contact our Customer Care Centre at: 1-877-849-3637

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Yasmeen Marbaniang Vincent, MBBS, MD Medical Microbiologist, LlfeLabs ON

Nader Boctor, MBBCh MSc DipM Product Manager, Business Development



GROWTH HORMONE SUPPRESSION TEST NOW AVAILABLE AT LIFELABS

We are pleased to let you know that Growth hormone (GH) suppression test is now available at LifeLabs, as an aid in the diagnosis of growth hormone excess.

CLINICAL UTILITY FOR GROWTH HORMONE SUPPRESSION TEST:

Biochemical diagnosis of GH excess starts with the measurement of IGF-1. This is the recommended first line test and may be used to rule out acromegaly.

For elevated or equivocal measurements of IGF-1, a growth hormone suppression test is recommended for confirmation of diagnosis.

- A nadir serum GH level <1 ug/L within 2 hours after 75g oral glucose usually excludes the diagnosis of GH excess.¹
- The measurement of a single random GH is not recommended due to the pulsatile nature of GH secretion.

What this means for you?

Following the Endocrine Society clinical practice guidelines¹, LifeLabs now offers the growth hormone suppression test which replaces the previously offered timed collections of growth hormone, and includes the following:

- measurement of GH and glucose in a fasting serum sample,
- followed by the administration of a 75 g glucose drink.
- subsequently, GH and glucose measurements are made on the two additional serum samples collected 1 hour and 2 hours post glucose drink ingestion.

Result Reporting:

The result report includes the required measurements along with an interpretive guide for glucose (for the diagnosis of diabetes as outlined by Diabetes Canada guidelines²) and an interpretive statement for growth hormone (based on the Endocrine Society Guidelines for acromegaly¹). The latter indicates the following: "Hyperglycemia due to a 75 g dose of glucose suppresses growth hormone to <1 ug/L within 2 hours of glucose administration. Lack of GH suppression is consistent with a diagnosis of GH excess."

No reference intervals will be provided for the growth hormone test results due to its pulsatile nature. A random growth hormone is still available to order if required.

Ordering:

Heath Care Providers can order the GH suppression test as a single test, which replaces the previously offered timed collection of growth hormone.

Please see Test Information Directory for further details on ordering and reporting of GH suppression test: <u>https://tests.lifelabs.com/Chemistry/G/GROWTH_</u> HORMONE_SUPPRESSION_TEST.aspx?s=1

This new offer does not impact the currently available IGF-1 and random growth hormone tests.

We welcome your feedback!

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Uvaraj Uddayasankar, PhD FCACB Clinical Biochemist, LifeLabs, ON

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

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

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

Dr. Mona Kamel Discipline Head, Cytopathology 416-675-4530 Ext. 42753 mona.kamel@lifelabs.com

Dr. Terry Colgan Discipline Head, Histopathology 416-675-4530 Ext. 42980 Terry.Colgan@lifelabs.com **Dr. Abdel Belhaj** Medical Microbiologist 416 - 675 - 4530 ext. 42344 abdel.belhaj@lifelabs.com

Dr. Uvaraj Uddayasankar Clinical Biochemist 416 - 675 - 4530 ext. 42211 Uvaraj.Uddayasankar@lifelabs.com

Dr. Mohamed Abouelhassan Clinical Biochemist 416 - 675 - 4530 ext. 42216 Mohamed.Abouelhassan@ Ilifelabs.com

Dr. Afaf Erfaei Hematopathologist 416 - 675 - 4530 ext. 4294 afaf.erfaei@lifelabs.com **Dr. Theano Karakosta** Mass Spectrometry Specialist 416 - 675 - 4530 ext. 42029 theano.karakosta@lifelabs.com

Dr. Danijela Konforte Discipline Head, Special Chemistry 416 - 675 - 4530 ext. 42207 danijela.konforte@lifelabs.com

Dr. Daniela Leto *Medical Microbiologist* 416 - 675 - 4510 ext. 32310 daniela.leto@lifelabs.com

Dr. Tracy Morrison *Clinical Biochemist* 416 - 675 - 4530 ext. 42975 tracy.morrison@lifelabs.com **Dr. Dorothy Truong** *Clinical Biochemist* 416 - 675 - 4530 ext. 42208 dorothy.truong@lifelabs.com

Dr. Nicole White-Al Habeeb Clinical Biochemist 416 - 675 - 4530 ext. 42099 Nicole.White-AlHabeeb®lifelabs.com

Dr. Krystyna Ostrowska Medical Microbiologist 416 - 675 - 4530 ext. 42892 krystyna.ost<u>rowska@lifelabs.com</u>

Dr. Difei Sun Mass Spectrometry Specialist 416 - 675 - 4530 ext. 42296 difei.sun@lifelabs.com Dr. Kika Veljkovic Discipline Head, High Volume Chemistry 416 - 675 - 4530 ext. 42832 kika.veljkovic@lifelabs.com

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

Dr. Yasmeen M Vincent Medical Microbiologist 416 - 675 - 4530 Ext. 42813 yasmeen.vincent@LifeLabs.com

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