Inside Diagnostics Ontario

The diagnostic Newsletter for Healthcare Providers

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LifeLabs®

A YEAR IN REVIEW: MEDICAL AND SCIENTIFIC TEAM AT LIFELABS

Over the last year, LifeLabs has continued to advance its mission to build a healthier Canada through the practice of laboratory medicine by delivering the highest level of service to patients and their health care providers. **We are proud of our quality and accreditation record.**

During this time, LifeLabs performed more than 112 million lab tests for Canadians nationally while supporting more than 36,000 health care providers. Significant improvements were made in patient wait times while increasing safety, and new sample collection services were launched in the Regina and Saskatoon communities. Partnerships were formed with provincial governments to lend LifeLabs' expertise in fighting the opioid crisis, while continuing to build the invaluable partnership with the Pediatric Oncology Group of Ontario (POGO) to champion care for children with cancer.

The Medical and Scientific (MedSci) department at LifeLabs is essential to this work. MedSci is made up of pathologists, clinical scientists and lab scientists, as well as cardiologists who support ECG and holter work. The work of these pathologists, cardiologists and scientists are critical for the prevention, early detection, diagnosis and treatment of many of the leading causes of disease. In fact, pathologists provide the diagnostic test information that facilitates 70 per cent of all the diagnoses made by health care providers.

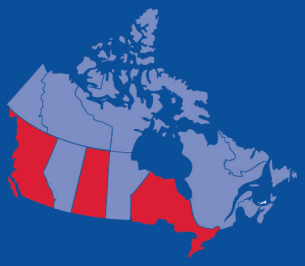
The MedSci team also represents LifeLabs on a national and international scale within the realm of laboratory medicine. Last year, MedSci staff participated and presented in conferences around the world and published work related to their profession. **In addition, these staff are fostering the next generation of lab medicine experts through the supervision of residents and students on rotations at LifeLabs facilities.**

Our newly refreshed LifeLabs website (LifeLabs.com) provides information on our core team and ways in which you can seek out advice for the tests that we offer at LifeLabs. We also offer medical consults. Contact information for our core team can be found on the last page of each Inside Diagnostics newsletter. **We are here to help you do the best for your patients.**

Andrew Don-Wauchope
MD FRCPEdin FRCPath
Vice President, Clinical Affairs

LifeLabs® BY THE NUMBERS

16 LifeLabs laboratories



Proudly serving **British Columbia, Ontario and Saskatchewan**

Perform over **112** million laboratory tests in 2017

90% customer satisfaction rate

79K patient visits per day

Partnerships and reference testing for **over 80 hospitals**

36,000 health care providers supported

MedSci BY THE NUMBERS

37
Pathologists
Clinical Scientists
Laboratory Scientists

41 publications in journals or internal communications

Supervised **18** residents and students

37 Participated in international and national clinical or scientific conferences or symposia

Delivered a total of **113 presentations** in Canada and internationally

Provided reviewer services for **16** journals and surveyor services for **3** accreditation bodies

55 positions on external committees representing their professional role

BACTERIAL VAGINOSIS – TO TEST OR NOT TO TEST

Bacterial Vaginosis - Background Information and Laboratory Testing

Bacterial vaginosis (BV) is one of the most common vaginal syndromes affecting women of child bearing age. An estimated 7.4 million cases occur annually in US.[1] In Canada, BV is diagnosed in up to 10% of Family Practice patients. The prevalence in pregnant women can reach 30%.[5]

BV occurs when normal vaginal microbiota (lactobacillus) are overgrown by various anaerobic organisms, including Mobiluncus and Bacteroides. Depletion of lactobacilli results in change of vaginal pH to alkaline.

Overgrowth of some facultative bacteria, mostly Gardnerella vaginalis, coincides with symptoms of BV. Gardnerella adheres to vaginal squamous epithelial cells, creating "clue cells".[2]

Laboratory diagnosis of BV is based on microscopic examination using the scoring system described by Nugent.[4] A high score (7-10), indicating presence of BV, is given when there is: a depletion of Lactobacilli, presence of "clue cells" and abundance of curved Gram variable rods (Mobiluncus).

Changes of Vaginal Microbiota Associated With Levels of Circulating Estrogen

Vaginal microbiota undergoes numerous changes throughout the lifetime of a woman. Those changes occur due to circulating estrogens. **Newborns** have high levels of circulating maternal estrogens. As a result, their vaginal mucosa is relatively thick, with glycogen being secreted in abundance by epithelial cells. Within the first 24 hours of life, lactobacilli colonize the child's vagina. As maternal estrogens are metabolized in the next 4-6 weeks, vaginal microbiota change, lactobacilli become sparse, pH becomes neutral or alkaline. Vaginal microbiota is replaced by skin organisms, various coliforms and anaerobes.

Puberty is marked by gradual rise in estrogen levels, leading to thickening of the vaginal mucosa and increase in glycogen production. Lactobacillus, Gardnerella, and other anaerobes become part of normal vaginal microbiota. Menstrual cycle further influences the number of lactobacilli, closely correlating with the levels of estrogens. In contrast, non-Lactobacilli (agents associated with BV) flourish when the levels of estrogens are the lowest. Hence, the most vulnerable time period for development of BV is during menstruation, and the least likely, during ovulation.

Menopause is accompanied by decrease in estrogen secretion, atrophy of vaginal epithelia, elevated vaginal pH and decrease in lactobacilli. Hormone replacement therapy has been shown to re-establish the dominance of lactobacilli in the vagina of post-menopausal women.[3]

Laboratory diagnosis of BV is based on disruption of normal vaginal microbiota, which is influenced by physiologic levels of estrogens. Pre-pubescence and menopause are associated with natural depletion of estrogens, leading to natural changes in vaginal microbiota similar to those seen in BV. For those reasons, the laboratory diagnosis of BV can only be made in women of child bearing age.

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POINTS TO REMEMBER:

- Diagnosis of BV is based on Microscopic exam and Nugent's scoring system. Changes in normal, estrogen stimulated vaginal flora are the basis for diagnosis of BV.
- No diagnostic criteria for BV exist for pre-pubertal girls and post-menopausal women due to physiologic depletion of estrogen.
- Please submit a vaginal specimen on rayon swab for microscopic examination to rule out BV. High score (7-10), indicates presence of BV.

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UPCOMING CHANGES TO THE ColonCancerCheck PROGRAM BY CANCER CARE ONTARIO – THE FIT PROGRAM

Data for 2018 shows that colorectal cancer is the second most commonly diagnosed cancer in Ontario. Among cancers, it is the second leading cause of death in men and the third leading cause of death in women. However early detection improves survival rates and regular screening can delay the progression of, or even prevent, colorectal cancer.

Cancer Care Ontario (CCO) has a long-established program – the ColonCancerCheck program – for screening for colorectal cancer in Ontario. This program uses the **Fecal Occult Blood Test (FOBT)** as the screening test. The test looks for occult blood (hidden, not detectable with the naked eye) in the patient stool. Another test for occult blood that is more sensitive and easier to perform is now available. This is called the **Fecal Immunochemical Test (FIT).**

Apart from better sensitivity and ease of use, the FIT has other advantages over the FOBT. There are no dietary restrictions prior to testing. As well, the more common abnormal hemoglobins that may be present in the blood of some persons do not affect the test result. An added advantage for the patient is the need for a single sample from one stool collection and the sample is placed directly into a special collection device that can be returned for testing.

CCO has therefore decided to replace the FOBT with the FIT in their ColonCancerCheck program. It should be noted that other Provinces have also adopted the FIT for their colorectal cancer screening programs.

LifeLabs will be responsible for this new CCO ColonCancerCheck program. Testing will be performed at the LifeLabs Kennedy Lab (KL) site. **The FIT program is scheduled for implementation in June 2019.** Once the FIT program is implemented the CCO FOBT program will be phased out.

CHANGES ASSOCIATED WITH THE NEW CCO COLONCANCERCHECK PROGRAM

- Using CCO's criteria, the doctor will provide LifeLabs with the required information on the patient who needs to be tested.
- The collection device, along with the instructions for handling, is sent directly from LifeLabs to the patient.
- Once inoculated with stool this device is returned to LifeLabs for testing. Return options include Canada Post or bringing to a LifeLabs PSC from where the sample will be sent to KL for immediate testing.
- Test results are sent both to CCO and to the patient's doctor. Any required follow up actions are agreed upon by CCO and the doctor and communicated to the patient.

As noted, the most significant clinical advantage of the FIT is the increased sensitivity, permitting better identification of patients who can benefit from immediate follow up. The test itself is also more reliable and robust than the FOBT. From a patient perspective advantages include not having to avoid certain foods and medications and a much simpler procedure for obtaining the sample.

As your partner in health care, LifeLabs will continue to ensure a reliable and trouble-free process. Please feel free to contact us for further information: **1-877-849-3637**

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Discipline Head, Chemistry

CAUSES OF DISCREPANT HEMOGLOBIN RESULTS ARE MOSTLY PREANALYTICAL

We occasionally receive calls regarding discrepant hemoglobin results, often because our result is lower than a hospital result. This is understandably frustrating and inconvenient for the patient, their family, and medical staff - especially if a patient was transferred to hospital only to be sent back without receiving a transfusion.

Hemoglobin values are prone to fluctuations for a variety of reasons. Recollection of a new CBC sample for analysis at a different laboratory (i.e.: when the patient is transferred to hospital) can introduce several sources of uncontrollable variation of the hemoglobin result.

However, **when the same CBC sample is analyzed at two different laboratories the hemoglobin value is reproducible.** To support this statement, LifeLabs has conducted CBC correlation studies with 6 different hospital laboratories in the Greater Toronto Area; 20 CBC samples with low hemoglobin values were sent from LifeLabs to a hospital laboratory on 6 different occasions.

The table in figure 1 displays the results from those studies.

LL	H1	LL	H2*	LL	H3*	LL	H4	LL	H5*	LL	H6
72	75	63	64	37	38	64	61	73	73	83	82
73	67	71	71	65	65	62	61	73	73	83	84
70	73	77	77	75	75	59	62	76	76	68	71
73	75	52	53	73	73	63	66	73	74	57	58
72	64	55	56	76	76	76	79	64	64	59	60
74	77	80	81	79	80	72	76	68	69	49	42
71	74	71	70	76	78	75	80	69	69	57	58
68	70	79	79	73	74	71	75	70	71	52	53
72	76	78	79	74	74	78	80	58	58	66	69
79	68	67	66	79	80	74	77	77	79	71	74
69	72	77	79	77	78	77	80	78	78	85	86
57	60	72	73	77	77	77	80	43	43	95	97
72	76	76	75	64	65	79	83	66	66	96	94
69	72	77	79	72	72	53	52	67	67	97	98
66	70	75	75	78	79	76	74	80	79	77	79
71	73	65	66	79	81	66	67	75	75	87	85
67	70	58	58	69	68	79	81	74	75	82	81
45	40	77	78	76	77	79	80	74	76	89	90
73	77	61	62	79	80	78	81	78	79	88	87
74	77	74	76	66	67	75	77	75	77	88	90

Figure 1.

LL: LifeLabs, H: Hospital
*Denotes hospital laboratory with the same CBC instrumentation as LifeLabs.

The hemoglobin results best correlated when each of the testing laboratories used the same CBC instrumentation vendor (Table 1), where analysis of the same sample yielded a maximum difference of 2 g/L. If the hospital laboratory used a different CBC instrument vendor, analysis of the same sample yielded a maximum difference of 8 g/L in hemoglobin value (Table 1, LL vs. H1).

This data supports that large hemoglobin discrepancies (e.g.: >10 g/L) are rarely due to laboratory analytical error and are often a result of pre-examination and/or physiologic variables. A different CBC sample collected on a different day (or different time of day) and analyzed on different CBC instrumentation at another laboratory introduces uncontrollable variables leading to a wide variation of hemoglobin results. If you do encounter a discrepant hemoglobin result in your practice, keep in mind the following sources of error that affect hemoglobin levels:

1. Tourniquet technique: Prolonged tourniquet time can cause significant error. After one minute of tourniquet time the hemoglobin value can increase by 3% (4 g/L) due to hemo-concentration.

2. Time of day differences: A patient may show daily hemoglobin variation of up to 8% (11 g/L) with the highest values in the morning and the lowest in the evening.

3. Position of patient at time of collection: an upright patient as opposed to one lying down produces lower hemoglobin values due to fluid shifts amounting to about 10 g/L in healthy subjects and even greater in some patients.

4. Patient fasting: Fasting specimens have lower hemoglobin values than those after a fatty meal. This may be due to lipemia interference with the latter.

5. Hydration Status: Hemoglobin results are dependent on plasma volume. If a patient is dehydrated the hemoglobin result will be higher than if the patient were normovolemic. If a patient is fluid overloaded the result will be lower.

6. Patient mis-identification: If a result varies by more than would be expected due to pre-analytical or physiologic variables (e.g.: >15 g/L difference), the possibility of patient misidentification should be considered.

The decision to transfer or direct a patient to hospital for transfusion should be based on laboratory values in addition to clinical signs and symptoms. If the laboratory value is unexpected or not consistent with the clinical picture, a repeat value should be obtained.

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