

Inside Diagnostics Ontario

The Diagnostic Newsletter for Healthcare Providers

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LifeLabs Ontario Medical Director Update

Re: Critical Values reporting after hours.

LifeLabs would appreciate your help in ensuring best patient care when critical values become available after office hours on the tests that you order on your patients. If we do not currently have this information, please contact Pam Bissoo at the LifeLabs Customer Care Centre (pam.bissoo@lifelabs.com 905-795-3151 ex.47055).

Best practice indicates that laboratories expedite reporting of laboratory tests that demonstrate critical values. In so doing, laboratories have to ensure that the results are communicated directly to the ordering physician, even if this is after office hours (which is often the case with community laboratories). This is a patient safety issue to ensure that potentially life-threatening abnormalities are dealt with promptly by the physician caring for the patient and ordering the test.

Most physicians do provide us with after-hours contact numbers, but recently we have seen an increase in critical results that cannot be communicated to the physician or other health care provider, as we do not have this after-hours information. LifeLabs does have on-call physicians who will convey these results directly to the patient, when we are unable to reach the physician. However, it is most appropriate for the patient's Health Care Provider (HCP) to give advice to the patient.

The Ontario Association of Medical Laboratories (OAML) "Guideline for Reporting Laboratory Test Results" (CLP-025 Sept. 2009) stipulates:

"These are results that show a marked deviation from reference ranges, with no clear indication to the laboratory that these are expected deviations. Results of this nature may indicate a significant risk of a life-threatening event. Prompt medical intervention may be required. As such, these results are considered critical and will be called to the clinician 24 hours per day, 7 days a week."

We are asking all physicians to please ensure LifeLabs has your after-hours contact number. The College of Physicians and Surgeons of Ontario (CPSO) policy statement #1-11 on "Test Results Management" (February 2011) recommends the following:

Providing Current Contact Details to Laboratories - "to ensure laboratories can communicate critical test results to physicians, physicians MUST provide the laboratory with their current contact details so that critical results can be communicated both during and after office hours." The Policy Statement further goes on to say that it recognizes that physicians cannot always be available but should participate in an on-call group or have a specific on call arrangement with other doctors or the local emergency department to ensure communication of the results."

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

Trichomonas Vaginalis Testing

Due to recent advances in the available testing methods for the sexually transmitted pathogen *Trichomonas vaginalis*, there have been increased opportunities for diagnosis and treatment of this important sexually transmitted infection. Traditionally, the most commonly used lab test for the investigation of *Trichomonas vaginalis* was performing a microscopic wet mount. However, the sensitivity for detection is very low and therefore

this method is considered far inferior to molecular diagnostic testing.⁽¹⁾ Molecular testing methods are quickly becoming the gold standard and test of choice for the diagnosis of trichomonas infection.

Microscopic examination of a wet mount preparation of vaginal secretions mixed with normal saline has been the most common diagnostic evaluation for T vaginalis infection in women.⁽²⁾ Studies

comparing wet mount microscopy with highly sensitive molecular detection tests document the poor sensitivity of microscopy, which ranges from 44% to 68%, even with experienced microscopists, and prompt examination of vaginal specimens.^(3,4) Delays as short as 10 to 30 minutes between specimen collection and microscopic examination can dramatically reduce the sensitivity of the test. In addition, suboptimal specimen storage or

transportation conditions further reduce parasite motility and thus wet mount sensitivity. ⁽⁵⁾

Overall, due to the above mentioned low sensitivity and the very specific specimen temperature and timing requirements, wet mount microscopy is no longer a reliable or suitable method given the availability of the highly sensitive molecular tests that

physicians have come to trust and rely on to diagnose this infection.

As of February 26, 2018, testing for *Trichomonas vaginalis* using molecular technology on the BD Viper XTR will be available upon request at LifeLabs Medical Laboratories. This test offers high sensitivity for the detection of *Trichomonas vaginalis* as demonstrated in the following table. ⁽⁶⁾

(Please note, the following test performance data are applicable only to samples from females, since *Trichomonas vaginalis* testing on BD Viper XTR is approved ONLY for female specimens. Urines from male patients can be submitted and testing will be performed, however results should be interpreted with caution).

Specimen Type	Sensitivity	Specificity
Urine	95.5%	98.7%
Vaginal swab	98.3%	99.0%
Endocervical swab	96.7%	99.1%

Based on this change we will no longer provide microscopy results on vaginal swabs - Bacterial Vaginosis and Yeast will continue to be reported by microscopy.

If *Trichomonas vaginalis* infection is suspected, please indicate this on the requisition and submit for molecular testing.

Acceptable specimen types include:

- male and female urine specimens
- female vaginal/endocervical molecular swabs (same ones as those currently used for Chlamydia & Gonorrhea testing).

Acceptable collection containers: (Storage Conditions are the same as those currently used for Chlamydia & Gonorrhea molecular testing for both swabs and urine.)

- Vaginal or Endocervical: BD ProbeTec CT/GC Qx Amplified DNA Assay collection kit (pink)
- Female or Male Urine: 90mL sterile container (refrigerate urine if expected transport to lab is greater than 24 hours).

Key Points About New Molecular *Trichomonas* Testing



- Molecular testing for *Trichomonas* replaces the wet mount microscopy testing
- Molecular testing offers far superior sensitivity and specificity
- Testing is validated and approved for female specimens only, however, the testing of male urine specimens WILL be performed but results should be interpreted with caution
- Molecular testing for *Trichomonas* can be done together with molecular testing for Chlamydia & Gonorrhea on the SAME sample

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(2) Marcia M Hobbs and Arlene C Seña. Modern Diagnosis of *Trichomonas vaginalis* infection. *Sexually Transmitted Infections* 2013 Sept; 89 (6): 434-438. (3) Patil MJ, Nagamoti JM, Metgud SC. Diagnosis of *Trichomonas vaginalis* from vaginal specimens by wet mount microscopy, In Pouch TV culture system, and PCR. *Journal of Global Infectious Diseases*. 2012; 4:22-5. (4) Nye MB, Schwebke JR, Body BA. Comparison of APTIMA *Trichomonas vaginalis* transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. *American Journal of Obstetrics and Gynecology*. 2009; 200:188.e1-7 (5) Kingston MA, Carlin EM, Bansal D. 'Shelf life' of *Trichomonas vaginalis*. *International Journal of STD's and AIDS*. 2003;14:28-9. (6) 3. BD ProbeTecTM Chlamydia trachomatis/ Neisseria gonorrhoeae/ *Trichomonas vaginalis* (CT/GC/TV) Qx Amplified DNA Assay. Package Insert. 8081408, 2013

By Daniela Leto MD FRCPC
Medical Microbiologist and Infectious Diseases Specialist

Causes of Discrepant Hemoglobin Results

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.

These discrepancies are often a result of pre-examination and/or physiologic variables and are rarely due to analytical or laboratory instrument errors. 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% (4g/L) due to hemo-concentration.
- 2. Time of day differences:** A patient may show daily hemoglobin variation of up to 8% (11g/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 10g/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. Interlaboratory Variation:** Often due to different automated techniques but also due to several other factors, the reproducibility of a single result between laboratories will vary.
- 7. Patient mis-identification:** If a result varies by more than would be expected due to pre-analytical or physiologic variables (e.g.: >15g/L difference), the possibility of patient mis-identification should be considered.

There are many reasons for variant hemoglobin results. 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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1. Jacob G, Raj S, Ketch T, Pavlin B, Biaggioni I, Ertl A, Robertson D. Postural Pseudomanemia: Posture-Dependent Change in Hematocrit. *Mayo Clin Proc.* 2005;80(5):611-614 2. Pocock S, Shby D, Shaper A, Walker M, Broughton P. Diurnal variations in serum biochemical and haematological measurements. *J Clin Pathol.* 1989;42:172-179 3. CLSI/NCCLS. Validation Verification and Quality Assurance of Automated Hematology Analyzers; Approved Standard. CLSI/NCCLS document H26-A2. Wayne, PA: CNLNS; 2010.

By Miranda Wozniak MD FRCPC
Ontario Deputy Medical Director
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Urine Drug Screen Panel and the Urine Broad Spectrum Toxicology (BST) Screen: Frequently Asked Questions

Table 1 summarizes key information about the two main clinical urine drug tests offered by LifeLabs Ontario: urine drug screen panel and urine broad spectrum toxicology (BST) screen.

	Urine Drug Screen Panel	Urine BST Screen
Is test covered by OHIP?	Yes	Yes
How are the tests ordered on the OHIP requisition?	Write urine drug screen under OTHER	Write urine broad spectrum tox screen (BST) under OTHER
What does each test include?	<p>The panel includes screens for: amphetamines, opiates, benzodiazepines, cocaine metabolite, methadone metabolite, oxycodone, THC</p> <p>NOT INCLUDED: barbiturates and urine ethanol</p>	<p>150 drugs in the following categories: amphetamines, opioids (including opiates), benzodiazepines, anti-psychotics, anti-depressants, cannabinoids, other drugs (including cocaine metabolite)</p> <p>New designer drugs are also included such as bath salts, synthetic cannabinoids, fentanyl analogues (i.e. carfentanil).</p> <p>NOT INCLUDED: barbiturates and urine ethanol</p>
Is testing qualitative or quantitative?	<p>Qualitative - exact amounts cannot be determined.</p> <p>If drug is detected above reporting cut off, it is reported as DETECTED, otherwise it is reported as NOT DETECTED.</p>	<p>Qualitative - exact amounts cannot be determined.</p> <p>If drug is detected above reporting cut off, it is reported as DETECTED. Drugs that are NOT DETECTED are not reported.</p>

(Continued)	Urine Drug Screen Panel	Urine BST Screen
What is analytical method used in each test?	Immunoassay which detects either: 1) a drug class (i.e. amphetamines, opiates, benzodiazepines), or 2) specific drugs (i.e. cocaine metabolite, methadone metabolite, oxycodone, THC)	Liquid Chromatography - Tandem Mass Spectrometry (LC-MSMS) Test is considered definitive or confirmatory.
How long are samples saved?	1 month	10 Days
What is the turnaround time?	24 hours from time of collection	5-7 days from time of collection

Top ten FAQs about clinical urine drug testing offered by LifeLabs, Ontario:

1. How do I determine when to order a urine drug screen panel versus BST screen?

The urine drug screen panel is an appropriate test to start with as long as you are aware of the limitations of each of the screens in the panel in order to avoid errors in interpretation. These panels are performed by immunoassay, and thus if the antibody has enough cross-reactivity with a drug or its metabolite, then it will be detected.

BST screening is considered a definitive or confirmatory test. It typically has higher specificity and sensitivity for most drugs. BST screening is usually recommended: a) to confirm or rule out unexpected urine drug screen results; b) when the use of unknown illicit or non-prescribed drugs is suspected; or c) to test for specific drugs that the urine drug screen panel may not detect.

2. Can urine drug screen and BST screen be ordered together on the same sample?

NO: Although both tests are covered by OHIP, urine drug screen panel and BST screen cannot be both ordered on the same sample. Please order either urine drug screen or BST screen. However, if a urine drug screen gives an

unexpected result, the ordering healthcare provider can contact the laboratory to add BST testing to the same sample. Samples are saved for one month.

3. When I order a BST screen do I need to list specific drugs of interest on the requisition?

NO: All drugs included in the BST menu are always tested with each BST screen. Only drugs detected above the reporting cut off will be reported as detected.

4. My patient is prescribed a drug (i.e. hydromorphone) but it was not detected by the urine drug screen for opiates. Does this mean they are not taking the medication?

MAYBE: This could be one of the answers, but other possibilities should be considered first:

- Does the screen have poor cross-reactivity with this drug or even detect it at all? The interpretive comments on the report include information about this type of method limitation.
- Perhaps the urine is dilute? Note that pH and creatinine are not performed automatically. Please order urine pH and/or urine creatinine under OTHER if this testing is desired.

5. Does the amphetamine urine drug screen detect Methylphenidate-based ADHD drugs such as Ritalin or Concerta?

NO: Methylphenidate-based ADHD drugs are not detected by the amphetamine urine drug screen. To screen for Methylphenidate, order the BST screen directly. All drugs included in the BST menu are always tested with each other.

6. Does THC urine drug screen or BST screen detect synthetic cannabinoid Nabilone?

NO: At this time neither urine drug screen nor BST can detect Nabilone.

7. Can benzodiazepine urine drug screen detect all benzodiazepines?

NO: Although the benzodiazepine screen typically cross-reacts well with drugs such as diazepam, temazepam and oxazepam, the screen does not cross-react well with benzodiazepines like lorazepam and clonazepam. The BST screen can detect the majority of commonly prescribed benzodiazepines.

8. Can the opiate urine drug screen panel detect all opioids and opiates?

NO: The opiate screen cross-reacts well with natural opiates such as codeine and morphine; however, its cross-reactivity is poor with semi-synthetic opiates such as hydrocodone, hydromorphone and oxycodone. In addition, opiate screen will not detect any of the synthetic opioids (i.e. fentanyl, tramadol, meperidine), methadone, or buprenorphine. The BST screen can detect the majority of commonly prescribed opiates and opioids.

9. What is Benzoyllecgonine that is reported on BST screen?

Benzoyllecgonine is one of major cocaine metabolites excreted in urine and its detection is consistent with cocaine use.

10. Why is turnaround time 5-7 days for BST, as opposed to 24 hrs for urine drug screen?

Unlike the urine drug screen where a urine sample is tested directly without any pre-treatment, BST testing requires an "extraction" step prior to testing. In addition, BST testing and the interpretation of results takes longer given the complexity of data and the number of drugs included.

Contact us:

Our toxicology laboratory is composed of a variety of personnel with special expertise in this area. Questions or concerns about urine drug screen and BST testing and results comprise a significant number of our calls. We are always interested in discussing cases and results, so please call us when you have a question at 1-877-849-3637.

Our website <http://tests.lifelabs.com/> has information on the tests available and their cut-off limits. Search for: BROAD SPECTRUM TOX SCREEN (BST)

To add a BST screen to a sample with unexpected urine drug screen results, call 416-675-4530 ext. 43339 and speak with a Query Team member.

NOTE that routine results from urine drug screen panels and from BST screens cannot be used for medical legal purposes. For specific requests for medical legal urine drug testing please contact LifeLabs Specialty Services: 1-877-990-1575

By Danijela Konforte PhD, FCACB
Clinical Biochemist

Transferrin Saturation: UIBC discontinued

Effective March 5, 2018, LifeLabs will **discontinued UIBC** testing. Direct measurement of transferrin will now be used in all iron investigations to calculate the “transferrin saturation” (also known as % saturation, %SAT, saturation, saturation index). Measuring transferrin directly will provide more reliable results. TIBC will be calculated from transferrin so that it will still be readily available for those who wish to review it.

See <https://labtestsonline.org/tests/transferrin-and-iron-binding-capacity-tibc-uibc> for a table with more information related to transferrin saturation.

By Patrick St.Louis PhD, FCACB
Chemistry Discipline Head

By Christine Collier PhD, FCACB
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Website Wanderings!

This month we are featuring Lab Tests Online (<https://labtestsonline.org/>), which is an award-winning health information web resource designed for both patients and caregivers.

The “At a Glance” area includes sections on: Why get tested? When to get tested? Sample required? Test preparation needed? While the next sections address: What is being tested? How is it used? When is it ordered?

What does the test result mean? Is there anything else I should know?

Since 2001, laboratory and medical professionals have developed and reviewed the content, including articles on lab tests, conditions/diseases, screening, patient resources, and lab test news. The site is produced by AACC and its impressive list of partners and sponsors. It is now available in 13 different languages on 15 international sites.



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