February 10. 2022

CLIENT NOTICE:

UPDATES AND IMPROVEMENTS RELATED TO A. CLINICAL URINE DRUG SCREEN and B. BLOOD GLUCOSE-6-PHOSPHATE DEHYDROGENASE AND SERUM/PLASMA/RED BLOOD CELL CHOLINESTERASE TESTING

As part of ongoing efforts to improve our quality of service, LifeLabs Ontario will implement a **new analytical platform for clinical immunoassay-based urine drug screens, and for blood glucose-6-Phosphate dehydrogenase and serum/plasma/red blood cell cholinesterase testing.** **This change will go into effect on February 14. 2022.**

The new analyzers, Siemens Atellica CH 930, have shown similar or improved performance in LifeLabs internal validation. All relevant information related to test menu, reporting changes as well as pre-analytical handling and ordering changes are listed below.

A. CHANGES TO URINE DRUG SCREEN PANEL – CURRENT VS. NEW

The comparison between the current and the new menu and Detected/Not Detected cut-offs is summarized in Table 1. below

Table 1. Urine Drug Screen Panel – Current vs. New (changes highlighted in blue)

Current platform (Siemens ADVIA 2400)			New Platform (Siemens Atellica CH930)		
Analyte	Method/Vendor	Detected/Not Detected Cut Off (ug/L)	Analyte	Method/Vendor	Detected/Not Detected Cut Off **(ng/ml)**
Amphetamines	CEDIA/Thermo	1000	Amphetamines	CEDIA/Thermo	1000
Benzodiazepines	EMIT/Siemens	200	Benzodiazepines	**CEDIA/Thermo**	200
Cocaine metabolite	EMIT/Siemens	150	Cocaine metabolite	EMIT/Siemens	150
Opiates	EMIT/Siemens	300	Opiates	EMIT/Siemens	300
Cannabinoids	EMIT/Siemens	50	Cannabinoids	EMIT/Siemens	50
Oxycodone	DRI/Thermo	100	Oxycodone	**EMIT/Siemens**	100
Methadone Metabolite (EDDP)	CEDIA/Thermo	100	***Methadone Metabolite (EDDP)***	***EDDP - Removed from panel and needs to be ordered separately***	
			Fentanyl	**EIA/ARK**	**1**
			Buprenorphine	**EMIT/Siemens**	**5**

Definitions: EMIT-Enzyme Multiplied Immunoassay Technique, DRI – Diagnostic Reagents Inc. , CEDIA-Cloned Enzyme Donor Immunoassay, EIA-Enzyme Immunoassay

We would like to draw your attention to a few changes in particular:

- Please note addition of two new drugs in the panel – Buprenorphine and Fentanyl.
  - Fentanyl was added because of its increased prevalence in ON unregulated drug supply and associated risks to patients
  - Buprenorphine has seen an increased use in primary care as a safe alternative in opioid replacement therapy
- Please note removal of Methadone Metabolite (EDDP) from the panel
  - EDDP was removed from the panel due to low positivity based on the review of samples submitted over the past two years. We suspect this may be due to many methadone providers ordering urine broad spectrum tox screen instead of urine drug screen. **EDDP is still available to order, but it will have to be specifically requested on the requisition.**

- Units: Results for urine drug screens will be reported in ng/ml instead of ug/L. ng/ml is a standard unit of reporting for urine drug testing. (1 ng/ml = 1 ug/L)

- New Benzodiazepine CEDIA immunoassay with glucuronidase pre-treatment significantly improves detection of commonly prescribed and used benzodiazepines clonazepam and lorazepam in comparison to the current platform.

- Urine ethanol and serum ethanol tests are also moved to the new platforms, but there are no changes to testing methodology, or reporting.
- Due to analytical challenges with the EDDP immunoassay, urine EDDP testing is moved to the LC-MS/MS (liquid chromatography-tandem pass spectrometry) platform. This will be indicated on the report. Apart from this, there are no other changes in reporting.
- Urine Barbiturates screen is referred to another laboratory with no significant changes in reporting.

Improvements to specimen validity testing

- When you order 'pH and creatinine' for specimen validity testing, we will test pH, creatinine, and specific gravity. Depending on the pattern of results, an interpretive comment will be added to indicate the results are consistent with normal, diluted, or potentially adulterated (substituted) sample. Please see table 2 for the full list of interpretive comments.

Table 2. Sample Validity Testing Comments Based on Creatinine, Specific Gravity, and pH Results

Creatinine (mg/dL) Result	Specific Gravity Result	Interpretive Comment
≥20	Any	The creatinine concentration and specific gravity are consistent with expected ranges for normal urine.
≥2 to <20	≥1.0011 to ≤1.0029	The creatinine concentration and specific gravity are consistent with dilute urine.
≥2 to <20	≤1.0010	The creatinine concentration and specific gravity are not consistent with expected ranges for normal urine.
≥2 to <20	≥1.0030	The creatinine concentration and specific gravity are consistent with expected ranges for normal urine.
<2	≤1.0010	The creatinine concentration and specific gravity are consistent with substituted urine.
<2	≥1.0200	The creatinine concentration and specific gravity are consistent with substituted urine.
<2	≥1.0011 to ≤1.0199	The creatinine concentration and specific gravity are not consistent with expected ranges for normal urine.

pH Result	Interpretive Comment
≥5.0 to ≤ 8.5	The pH of the sample is within normal range.
<5.0	The pH of the sample exceeds expected range.
>8.5	The pH of the sample exceeds expected range.

Ordering: clinical urine drug screen panel and/or individual drug tests

- On the OHIP requisition, please write "**Urine Drug Screen (Panel)' under Other category** if you would like to order the panel as described in Table 1.
  NOTE: Urine Drug Screen Panel was historically referred to as Drugs of Abuse (DOA) Screen. Clinical and scientific community has been moving away from the DOA terminology as it carries a negative implicit bias that affects patient care of individuals with substance use disorders.

- If applicable, urine EDDP, urine Barbiturates, and all drugs included in the new urine drug screen panel (Table 1) can also be ordered individually by listing each drug in Other category on the OHIP req.

- Urine ethanol, serum ethanol can be also ordered individually by listing them in the **Othe**r category on the OHIP req

- We will perform specimen validity testing (pH, creatinine, and specific gravity) if it is ordered as **'pH, creatinine'** in Other category on the OHIP req.
  NOTE: Specimen validity testing will be also added by the laboratory should we suspect sample integrity issue based on the sample appearance or results.

Turn Around Time (TAT): TAT remains 1 day for all urine drug screens and for urine and serum ethanol with two exceptions: Urine Barbiturates screen TAT = 6 days; Urine EDDP TAT = 3-5 days.

Important reminder about clinical vs. workplace and medical legal urine drug testing:

- **For testing described above, specimen collection and testing is not completed using chain of custody processes.** Results must be used for medical purposes only.
- If you are interested in workplace or medical/legal drug testing can contact Contract Services at 1-877-990-1575 or ContractServicesON@lifelabs.com

B. CHANGES TO BLOOD GLUCOSE-6-PHOSPHATE DEHYDROGENASE AND RED BLOOD CELL, PLASMA, SERUM CHOLINESTERASE TESTING

Table 3. Blood G-6-PD and Red Blood Cell (RBC), Plasma, Serum Cholinesterase (changes highlighted in blue)

Current platform (Siemens ADVIA 2400)			New Platform (Siemens Atellica CH930)		
Analyte	**Method/Vendor**	**reference intervals (units)**	**Analyte**	**Method/Vendor**	**reference intervals (units)**
Blood Glucose-6-Phosphate Dehydrogenase (G6PD)	Enzymatic/Pointe Scientific	8.5 – 18.8 U/g Hb (at 37ºC)	Blood Glucose-6-Phosphate Dehydrogenase (G6PD)	**Enzymatic/Sentinel**	**6.8 - 15.0 U/g Hb (at 37ºC)**
Serum Cholinesterase	Enzymatic/Roche	2200-6900 (U/L)	Serum Cholinesterase	Enzymatic/Roche	**2100-6400 (U/L)**
Plasma Cholinesterase	Enzymatic/Roche	2600-6900 (U/L)	Plasma Cholinesterase	Enzymatic/Roche	**2500-6400 (U/L)**
Red Blood Cell (RBC) Cholinesterase	Enzymatic/Roche	5300-10000 (U/L)	Red Blood Cell (RBC) Cholinesterase	Enzymatic/Roche	5300-10000 (U/L)

- Please note about 20% difference in the reference range for the new G6PD test – this is due to differences between methods and platforms; the reference interval was adjusted based on the internal validation results. Please interpret results in context of the reference interval provided on the same report.
- Please note minor changes in reference intervals for serum and plasma cholinesterase; the reference intervals were adjusted based on the internal validation. Critical ranges remain unchanged (serum cholinesterase < 1100 U/L, plasma cholinesterase <1500 U/L, and RBC Cholinesterase < 2650 U/L)

Ordering and Sample Handling Requirements: No changes

TAT: 1 day – for G6PD, Serum and Plasma Cholinesterase; **2-3 days – for RBC Cholinesterase**

We are very excited about the new platform and test 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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