

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:

Uvaraj Uddayasankar, PhD FCACB
uvaraj.uddayasankar@LifeLabs.com
T 416-675-4530 Ext. 42211

Kika Veljkovic, PhD FCACB
kika.veljkovic@lifelabs.com
T 416-675-4530 Ext. 42832

Uvaraj Uddayasankar
PhD FCACB
Clinical Biochemist

Kika Veljkovic
PhD FCACB
Discipline Head, High Volume Chemistry

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.