December 2018

CLIENT NOTICE

CHANGES TO TESTING OF SERUM 17-HYDROXYPROGESTERONE AND ANDROSTENEDIONE

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LifeLabs is pleased to announce changes to testing of serum 17-hydroxyprogesterone and Androstenedione that will take effect on December 17. 2018.

A.Serum 17- hydroxyprogesterone (17-OHP)

Sample Collection Requirements

17-OHP requires RED TOP collection tube instead of SST. Samples must be separated from cells immediately after clotting and stored and shipped refrigerated.

If androstenedione and 17-OHP are ordered on the same patient, only a single collection tube will be needed.

New Testing Methodology

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) method will replace current radioimmunoassay (RIA) as a testing method for 17-OHP. Switching to the LC-MS/MS method means improvement in analytical specificity and sensitivity, and you can expect 50-60% lower results compared to current RIA method.

Improvement in TAT:
In addition to analytical improvements to 17-OHP testing, there will be significant decrease of our current 14 days turnaround time to 7 business days.

New Reference Interval

17-OHP Reference Interval will change with implementation of new methodology.

	AGE	RANGE (nmol/L)
Female	<14 days	< 4.9
	14 days - <1yr	< 3.5
	1yr - <12 yr	< 1.2
	12yr - <14 yr	< 2.1
	14yr - <16 yr	< 4.3
	16yr - <19 yr	< 4.0
	19yr and older:	
	Follicular	<5.6
	Midcycle	<6.8
	Luteal	<8.6
	Post-Menopausal	<1.4
Male	<14 days	< 4.9
	14 days - <1yr	< 3.5
	1yr - <12 yr	< 1.2
	12yr - <14 yr	< 2.1
	14yr - <16 yr	< 4.3
	16yr - <19 yr	< 4.0
	19yr and older	< 6.0

B. Serum Androstenedione

Sample collection requirements.

As before, Androstenedione requires RED TOP collection tube. Samples must be separated from cells immediately after clotting and stored and shipped refrigerated.

If androstenedione and 17-OHP are ordered on the same patient, only a single collection tube will be needed.

No change in testing methodology.

Androstenedione will continue to be tested by LC-MS/MS method.

Improvement in TAT:

Androstenedione will now be analyzed in-house. As such, current turnaround time of 14 days will be decreased to 7 business days. A quicker turnaround time will provide our clients with faster access to results and allow for medical decisions to be made sooner.

Minor changes to the reference interval

There will be only minor changes in reference intervals for adult males and post-menopausal women. Reference intervals for all other partitions will remain the same as before.

	AGE	RANGE (nmol/L)
Female	<14 days	< 2.6
	14days - <1yr	0.1 - 2.1
	1yr - <6yr	0.1 - 0.6
	6yr - <10yr	0.2 - 0.9
	10yr - <12yr	<2.6
	12yr - <15yr	0.7 - 6.0
	15yr - <19yr	0.5 - 6.5
	19yr and older:	
	Follicular	1.2 - 8.7
	Midcycle	2.1- 10.0
	Luteal	1.1 - 8.2
	Post-Menopausal	0.4 - 2.9
Male	<14 days	<2.6
	14days - <1yr	0.1 - 2.1
	1yr - <6yr	0.1 - 0.6
	6yr - <10yr	0.2 - 0.9
	10yr - <12yr	<2.6
	12yr - <15yr	0.5 - 1.2
	15yr - <19yr	0.9 - 3.6
	19yr and older	0.8-3.1

Both 17-OHP and androstenedione LC-MS/MS testing methods were developed by LifeLabs. Performance characteristics of each test have been fully validated and the

tests have been designated fit for use in routine patient testing. The tests have not been submitted to Health Canada for evaluation, and as in-house validated tests, do not require Health Canada approval for diagnostics use.

The development of these new methodologies demonstrates our continued commitment to improving quality of testing, and to help build a healthier Canada.

If you have any questions, please feel free to contact our Customer Care Centre at 1-877-849-3637.