

Laboratory Bulletin

Leaders in Laboratory Medicine

Date: February 10, 2020

To: All Zones

From: Alberta Precision Laboratories (APL) – North Sector, University of Alberta Hospital

(UAH)

Re: Changes to anti-adrenal cortex autoantibody (21-hydroxylase antibody) testing

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Key Message:

• Effective Thursday February 20, 2020, a new method for anti-adrenal cortex (21-hydroxylase antibody) testing has been implemented at UAH, the only site in Alberta that offers this test.

 Results are now qualitative and will be reported as either <u>negative or positive</u>, rather than with a numerical value.

| | New method | Old method |
|---------------------|-------------|------------------------------------|
| Test name | No change | Anti-adrenal cortex autoantibodies |
| Synonyms | No change | Anti – 21 hydroxylase |
| Turnaround time | No change | 3 weeks |
| *Method type | Qualitative | Quantitative |
| *Reference interval | Negative | <5 U/ml |

Why this is important:

- The manufacturer recently discontinued its radioimmunoassay (RIA) kits and replaced it with enzyme-linked immunosorbent assays (ELISA) kits.
- Although there is good concordance between new and old kits, the new kit is designed only for qualitative reporting and is unable to report similar quantitative values as its predicate.
- 21-hydroxylase antibodies are useful in identification of underlying cause of adrenal insufficiency and aiding in risk prediction of autoimmune adrenal failure when there is a high index of suspicion.
- Clinical studies by the manufacturer demonstrated a sensitivity of 87% in detecting autoimmune adrenal disease in patients with or without autoimmune polyglandular syndrome.

Action Required:

- Be aware that results will now be reported as either negative or positive.
- False positives and false negative results can still occur with the new method, therefore, the test should always be used in conjunction with other clinical and laboratory findings, is not a population screening tests or a substitute for stimulation testing required to diagnose adrenal insufficiency.

Inquiries and feedback may be directed to:

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This bulletin has been reviewed and approved by:

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