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 negative or positive, rather than with a numerical value.

<table>
<thead>
<tr>
<th></th>
<th>New method</th>
<th>Old method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test name</td>
<td>No change</td>
<td>Anti-adrenal cortex autoantibodies</td>
</tr>
<tr>
<td>Synonyms</td>
<td>No change</td>
<td>Anti – 21 hydroxylase</td>
</tr>
<tr>
<td>Turnaround time</td>
<td>No change</td>
<td>3 weeks</td>
</tr>
<tr>
<td>*Method type</td>
<td>Qualitative</td>
<td>Quantitative</td>
</tr>
<tr>
<td>*Reference interval</td>
<td>Negative</td>
<td>&lt;5 U/ml</td>
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</tbody>
</table>

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:
Dr. Josh Raizman, Clinical Biochemist, APL North Sector, josh.raizman@aplabs.ca, 780-718-2402

This bulletin has been reviewed and approved by:
Dr. Kareena Schnabl, Interim Section Chief Clinical Biochemistry – APL North Sector
Dr. Michael Mengel, Medical Director – APL North Sector