Legacy Laboratory Services

Legacy Lab Alert
An Important Update from Legacy Laboratory Services

**Update: Cardiolipin Antibodies**

**Effective October 22, 2019,** Legacy Laboratory Services will change methodology for measuring Cardiolipin Antibodies from the INOVA Enzyme-Linked Immunoassay to the INOVA Chemiluminescent Immunoassay as performed on the Bioflash analyzer. Reference ranges and units will also change. Quantitative values between the ELISA and Chemiluminescent methods should thus not be compared for clinical purposes. Qualitative results between the two methods are comparable, as was demonstrated for clinically defined specimens. Changes are summarized in Table 1.

Table 1: Significant changes are indicated in red font.

<table>
<thead>
<tr>
<th>Name</th>
<th><strong>NEW (Starts October 22, 2019)</strong></th>
<th><strong>Current (Prior to October 22, 2019)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test and Mnemonic</strong></td>
<td>Test</td>
<td>Mnemonic</td>
</tr>
<tr>
<td>Cardiolipin Antibodies, IgA</td>
<td>CARD A</td>
<td></td>
</tr>
<tr>
<td>Cardiolipin Antibodies, IgG, IgM</td>
<td>CARD GM</td>
<td></td>
</tr>
<tr>
<td>Cardiolipin Ab, IgG, IgM, IgA</td>
<td>CARD GMA</td>
<td></td>
</tr>
<tr>
<td>Collect</td>
<td>Serum, one 5.0 mL Gold (SST) or 7.0 mL red top tube</td>
<td>Serum, one gold (SST) top tube</td>
</tr>
<tr>
<td>Handling</td>
<td>Allow serum to clot completely at room temperature. Separate serum from cells ASAP.</td>
<td>Centrifuge and separate the serum from the clot within 2 hours. Pour into a plastic tube.</td>
</tr>
<tr>
<td>Preferred Volume</td>
<td>1.0 mL serum</td>
<td>2.0 mL</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>0.5 mL serum (whole blood 1.2 mL minimum draw)</td>
<td>1.0 mL (2.5 mL minimum whole blood draw)</td>
</tr>
<tr>
<td>Transport</td>
<td>Frozen</td>
<td>Frozen</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Plasma. Microbiologically contaminated, heat treated, specimens containing visible particulates, grossly hemolyzed, and grossly lipemic specimens.</td>
<td>Plasma or heat inactivated samples</td>
</tr>
<tr>
<td>Name</td>
<td>NEW (Starts October 22, 2019)</td>
<td>Current (Prior to October 22, 2019)</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td><strong>Test Name</strong></td>
<td><strong>Test Name</strong></td>
<td></td>
</tr>
<tr>
<td>Stability</td>
<td>AFTER SEPARATION FROM CELLS: Ambient (18-26°C): 8 hours; Refrigerated (2-8°C): 48 hours; Frozen (at or below -20°C): 2 months</td>
<td>AFTER SEPARATION FROM CELLS: Ambient (20-25°C): 8 hours; Refrigerated (2-8°C): 48 hours; Frozen (at or below -20°C): 2 months</td>
</tr>
</tbody>
</table>
| Cardiolipin IgA Antibody: | IgG | Negative: 0-14 GPL  
Borderline: 15-19 GPL  
Moderate Positive 20-80 GPL  
High Positive >80 GPL |
| 0 – 19 CU Negative  
>=20 CU Positive | IgM | Negative 0-11 MPL  
Borderline 12-19 MPL  
Moderate Positive 20-80 MPL  
High Positive >80 MPL |
| Cardiolipin IgG Antibody: | IgA | Negative 0-14 APL  
Borderline 15-19 APL  
Moderate Positive 20-80 APL  
High Positive >80 APL |
| 0 – 19 CU Negative  
20 – 94 CU Low Positive  
>= 95 CU Moderately to High Positive | | |
| Cardiolipin IgM Antibody: | | |
| 0 – 19 CU Negative  
20 – 30 CU Low Positive  
>= 31 CU Moderately to High Positive | | |
| Presence of antiphospholipid antibody syndrome should be considered if cardiolipin IgG and/or IgM antibody is present at moderate or above level on two or more occasions, at least 12 weeks apart. (Miyakis et al. (2005) Journal of Thrombosis and Haemostasis 4, 295-306.) Laboratory results must be correlated with clinical picture of the patient before making the diagnosis. | | |

**Reference Ranges**

- **IgG**:  
  - Negative: 0-14 GPL  
  - Borderline: 15-19 GPL  
  - Moderate Positive: 20-80 GPL  
  - High Positive: >80 GPL

- **IgM**:  
  - Negative: 0-11 MPL  
  - Borderline: 12-19 MPL  
  - Moderate Positive: 20-80 MPL  
  - High Positive: >80 MPL

- **IgA**:  
  - Negative: 0-14 APL  
  - Borderline: 15-19 APL  
  - Moderate Positive: 20-80 APL  
  - High Positive: >80 APL

**Performed**

- Monday, Friday

**Reported**

- 2-5 days

**Method**

- Chemiluminescent Immunoassay

For additional information, please contact your account representative, client services or consult our website.  
Legacy Laboratory Client Services: 503-413-1234, 877-270-5566  
Legacy Laboratory Services website: [www.legacyhealth.org/labservices](http://www.legacyhealth.org/labservices)