Toxoplasma gondii IgG and IgM Antibody Testing Update

On February 18, 2015 Providence Regional Laboratory Services will begin performing Toxoplasma gondii IgG and Toxoplasma gondii IgM antibody tests at the Regional Core Laboratory utilizing the Beckman Coulter Access chemiluminescent immunoassays. Points to remember:

- Assays from different manufacturers are not standardized and should not be used interchangeably.
- Toxoplasma IgM antibody is not available as a discreetly orderable test because it must be interpreted in conjunction with Toxoplasma IgG antibody.
- For diagnosis of neonatal toxoplasmosis, specimens MUST be sent to the Toxoplasma Serology Laboratory in Palo Alto, CA. Please contact Providence Laboratory Services at 503.215.6660.

Collect:
- 3 mL Serum (Gold Top SST)
  - Preferred volume: 1.0 mL serum
  - Minimum volume: 0.5 mL serum

Stability:
- Refrigerated: 4 days; Frozen: 2 months

Unacceptable:
- EDTA Plasma or Heparinized Plasma

Reported:
- Monday – Friday

EPIC ORDERABLE:
- LAB501 Toxoplasma gondii IgG Antibody
- LAB13075 Toxoplasma gondii IgG/IgM Antibody

Please note the following changes to reference intervals and interpretations:

### Toxoplasma gondii IgG:

<table>
<thead>
<tr>
<th>Old Reference Interval and Interpretive Comment</th>
<th>New Reference Interval and Interpretive Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7.1 AU/mL Not Detected</td>
<td>&lt; 7.5 IU/mL Non-Reactive</td>
</tr>
<tr>
<td>7.2 – 8.7 AU/mL Indeterminate – Repeat testing in 10 – 14 days may be helpful.</td>
<td>7.5 – 10.4 IU/mL Equivocal</td>
</tr>
<tr>
<td>≥ 8.8 AU/mL Detected</td>
<td>&gt; 10.4 IU/mL Reactive</td>
</tr>
</tbody>
</table>

### INTERPRETIVE REPORTS

**OLD:**
The best evidence for current infection is a significant change on two appropriately timed specimens, where both tests are done in the same laboratory at the same time.

**NEW:**
A reactive result is generally indicative of a recent or past exposure to the pathogen, however a non-reactive result does not rule out an acute infection. If exposure to the pathogen is suspected despite an initial non-reactive or equivocal result, a second sample should be collected and tested 2 – 3 weeks later.

The Toxoplasma IgG Antibody result was obtained with the Access Toxo IgG Assay. Despite calibration by means of a reference preparation, values obtained with different manufacturers’ assay methods should not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to the endpoint titer.
### Toxoplasma gondii IgM:

<table>
<thead>
<tr>
<th>Old Reference Interval and Interpretive Comment</th>
<th>New Reference Interval and Interpretive Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7.9 AU/mL Not Detected</td>
<td>&lt; 0.80 S/CO Non-Reactive</td>
</tr>
<tr>
<td>8.0 – 9.9 AU/mL Indeterminate – Repeat testing in 10 – 14 days may be helpful.</td>
<td>0.80 – 0.99 S/CO Grey Zone – Repeat testing in 10 – 20 days is recommended.</td>
</tr>
<tr>
<td>≥ 10.0 AU/mL Detected – Significant level of Toxoplasma gondii IgM antibody detected and may indicate a current or recent infection. However, low levels of IgM antibodies may occasionally persist for more than 12 months post-infection.</td>
<td>&gt; 0.99 S/CO Reactive</td>
</tr>
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</table>

**OLD:**
This test is performed using the DiaSorin LIAISON. As suggested by the DCD, any indeterminate or detected Toxoplasma gondii IgM result should be retested in parallel with a specimen collected 1 - 3 weeks later. Further confirmation may be necessary using a different test from another reference laboratory specializing in toxoplasmosis testing where and IgM ELISA should be ordered. Caution should be exercised in the use of IgM antibody levels in prenatal screening. Any Toxoplasma gondii IgM in pregnant patients that have also been confirmed by a second reference laboratory should be evaluated by amniocentesis and PCR testing for Toxoplasma gondii.

For male and non-pregnant female patients with indeterminate or detected Toxoplasma gondii IgM results, PCR may also be useful if a specimen can be collected from the affected body site. For additional information, refer to the CDC website: www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html

**NEW:**
Toxoplasma IgM Antibody performed using Access Toxo IgM assay. Toxoplasma IgM antibody must be interpreted in conjunction with Toxoplasma IgG antibody results.

As suggested by the CDC, any suspect non-reactive or reactive Toxoplasma gondii IgM result should be retested in parallel with a specimen collected 10-20 days later. Further confirmation may be necessary using a different test from another reference laboratory specializing in toxoplasmosis testing where an IgM ELISA should be ordered. Caution should be exercised in the use of IgM antibody levels in prenatal screening. Any Toxoplasma gondii IgM in pregnant patients that have also been confirmed by a second reference laboratory should be evaluated by amniocentesis and PCR testing for Toxoplasma gondii. To diagnose congenital toxoplasmosis, specimens should be sent directly to the Toxoplasma Serology Laboratory, Palo Alto, CA as recommended by the CDC.

For male and non-pregnant female patients with grey-zone or reactive Toxoplasma IgM results, PCR may also be useful if a specimen can be collected from an affected body site. For additional information, refer to the CDC website: www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html