In the February 11, 2011 Morbidity and Mortality Weekly Report (MMWR), the CDC recommends that laboratories using the reverse algorithm for syphilis screening (treponemal screen followed by non-treponemal secondary test) perform a third level of testing by Treponema pallidum-particle agglutination (TP-PA) for those samples that test positive by the treponemal screening immunoassay but non-reactive by the non-treponemal RPR (syphilis reagin test). Effective April 13, 2011, Laboratory Alliance will modify our testing algorithm to comply with the CDC recommendation.

In September 2007, Laboratory Alliance implemented the DiaSorin Liaison chemiluminescent immunoassay for Treponema IgG/IgM as the initial syphilis test (screen). The DiaSorin Liaison Treponema IgG/IgM assay is a very sensitive and specific test that detects both recent (IgM+) and past infections (IgG+) but cannot distinguish between the different antibody classes. Recall that in contrast to non-treponemal tests, antigen-specific treponemal tests remain positive after treatment, often for life, and therefore, cannot be used alone for determining response to therapy. Therefore, any sample testing positive or borderline with the Treponema IgG/IgM assay is followed up with a secondary non-treponemal syphilis reagin test (RPR), titred as necessary. Additional treponemal tests may be useful if initial and secondary test results are inconsistent with the patient's clinical history. We have been using separate treponemal tests for IgG and IgM antibodies to Treponema pallidum as our third level of testing.

Beginning April 13, 2011, we will discontinue the separate tests for syphilis IgG and IgM antibodies and instead provide testing using the TP-PA assay as the third level of testing when the initial treponemal and secondary non-treponemal test results are discordant.

The following table may be useful in the interpretation of results.

<table>
<thead>
<tr>
<th>Treponema IgG/IgM Assay</th>
<th>Reagin Syphilis (RPR)</th>
<th>TP-PA</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative (non-reactive)</td>
<td>Not Done</td>
<td>Not Done</td>
<td>No serological evidence of infection with Treponema pallidum. Incubating or early primary syphilis cannot be excluded.</td>
</tr>
<tr>
<td>Positive (reactive)</td>
<td>Non-Reactive</td>
<td>Positive</td>
<td>Syphilis (past or present). Clinician should evaluate patient, determine whether treated for syphilis in the past, assess risk of infection and administer therapy according to CDC guidelines</td>
</tr>
<tr>
<td>Positive</td>
<td>Non-Reactive</td>
<td>Negative</td>
<td>Syphilis unlikely. Clinician should repeat RPR testing in several weeks if patient is at risk for syphilis.</td>
</tr>
<tr>
<td>Positive (reactive)</td>
<td>Reactive</td>
<td>Not done</td>
<td>Presumptive evidence of current infection (or inadequately treated infection, persistent infection or reinfection).</td>
</tr>
</tbody>
</table>

1304 Buckley Road • Syracuse, New York 13212-4302 • 315.453.7200
www.laboratoryalliance.com
Test Code: TREP (TREPC for cord blood)

Method: Chemiluminescent Immunoassay

Specimen Requirements: One SST tube; 1.0 mL serum minimum

Unacceptable: Plasma, other body fluids

Stability: Refrigerated 7 days

Storage and Transport: Refrigerated

Schedule of Testing: Daily

Notes: If Treponema IgG/IgM is positive or borderline, a secondary test will be performed. If the secondary test is also reactive, a titer will be performed. If the secondary test is non-reactive, a third test will be performed.

If cord blood is tested and is positive or borderline, no further testing is performed. Instead, the laboratory will contact the ordering location to collect maternal and baby serum for testing. To avoid delays, please submit maternal serum instead of cord blood for testing.

CPT Code: 86781

Billing Code: 2010174

For More Information:
If you have any questions or concerns regarding this modified algorithm, please contact Ms. Cheryl Haskins, Chemistry Manager, at 410-7014.

Reference:

4/7/2011, cmh