BACKGROUND

- Syphilis is a treatable infection caused by the bacteria Treponema pallidum (TP) that is most often spread by sexual contact; however, if left untreated the disease can spread and cause considerable organ damage.\(^1\)
- The number of primary and secondary syphilis cases in the US increased 66.7% from 2011 to 2015.\(^1\)
- Treponemal tests are required to screen and diagnose a syphilis infection.\(^2\)
- Two different algorithms, which combine a treponemal with a nontreponemal test, are used to aid in the diagnosis of syphilis. In recent years, the reverse algorithm has become increasingly utilized compared to the traditional algorithm due to reduced screening labor costs and improved clinical performance.\(^3,4\)

VALUE TO YOUR LAB

The ARCHITECT Syphilis TP assay is a qualitative test for the detection of antibodies (IgG and IgM) directed against TP to aid in the diagnosis of syphilis infection.\(^3,7\)

- Automated Treponemal test that can significantly decrease manual RPR testing labor costs
- Provides objective interpretation of results that can be interfaced with LIS
- Utilizes three recombinant antigens (Tp15, Tp17, and Tp47) on microparticle for improved syphilis detection
- Reverse algorithm can decrease the number of false positives resulting in improved specificity and is also more sensitive than the traditional algorithm for detecting cases of primary and latent syphilis infections

INTENDED USE AND IMPORTANT SAFETY INFORMATION

For In Vitro Diagnostics Use

**Intended Use:** The ARCHITECT Syphilis TP assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibodies (IgG and IgM) directed against Treponema pallidum (TP) in human serum and plasma. The ARCHITECT Syphilis TP assay is intended to be used as an initial diagnostic test or in conjunction with a nontreponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection.

See Important Safety Information on Reverse
### ORDERING INFORMATION

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>LIST NUMBER</th>
<th>CONFIGURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent (tests):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>8D06-31</td>
<td>Each test kit contains: 1 bottle each</td>
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<tr>
<td>500</td>
<td>8D06-41</td>
<td>(microparticles, conjugate, and diluent)</td>
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<tr>
<td>Calibrator</td>
<td>8D06-04</td>
<td>1 Calibrator</td>
</tr>
<tr>
<td>Control</td>
<td>8D06-13</td>
<td>Negative and Positive</td>
</tr>
</tbody>
</table>

### AVAILABILITY ON SYSTEM

ARCHITECT i1000sr, i2000, i2000sr

### REFERENCES:

5. ARCHITECT Syphilis Package Insert GS-6810/R01.

### INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

**Warning:** The ARCHITECT Syphilis TP assay is not intended for use in screening blood, plasma, or tissue donors. The effectiveness of the ARCHITECT Syphilis TP assay for use in screening blood, plasma, or tissue donors has not been established.

**Important Safety Information:** Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in the package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

**Caution:** United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. This product contains human-sourced and/or potentially infectious components and must be handled in accordance with the OSHA Standard on Bloodborne Pathogens.