BioPlex® 2200 Syphilis IgG Kit

The first and only fully-automated, random access multiplex platform for Syphilis IgG
Like no other

The BioPlex® 2200 Syphilis IgG kit simultaneously detects three of the most clinically relevant antibodies directed against individual recombinant proteins to *Treponema pallidum* in a multiplex format.

The BioPlex® 2200 Syphilis IgG kit is a multiplex flow immunoassay for the qualitative numeric detection of *T. pallidum* IgG antibodies in human serum. The test system, when used in conjunction with non-treponemal based assays, provides serological evidence of infection with *T. pallidum*. This test system is also indicated for use in confirming reactive test results from non-treponemal based screening assays.

The Syphilis IgG kit delivers a composite result for a comprehensive examination of the causative agent. Reportable results include:

- **Syphilis IgG Composite**
  - *T. pallidum* 15kDa**
  - *T. pallidum* 17kDa**
  - *T. pallidum* 47kDa**

* Syphilis IgG Composite is a roll up of the individual results.
** Individual results available outside US only.
Overall Performance

CONCORDANCE: 433 results were obtained from pregnant women to assess positive and negative agreements relative to a reference methodology*. The BioPlex® 2200 Syphilis IgG kit shows excellent correlation with the reference method.

* REFERENCE ASSAY: Combined results from commercially available RPR and TPPA assays. For discrepant results (between RPR and TPPA), a commercial treponemal EIA test was used for final interpretation.

<table>
<thead>
<tr>
<th>Serum Samples Requested to be Treponemal Positive</th>
<th>BioPlex® 2200 Syphilis IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>166</td>
</tr>
<tr>
<td>Equivocal</td>
<td>4</td>
</tr>
<tr>
<td>Negative</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>178</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serum Samples Requested to be RPR and TPPA Non-Reactive</th>
<th>BioPlex® 2200 Syphilis IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0</td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
</tr>
</tbody>
</table>

** Four (4) BioPlex® 2200 Syphilis IgG reactive samples were RPR non-reactive, TPPA reactive, and treponemal EIA equivocal.
** Of eight (8) BioPlex® 2200 Syphilis IgG reactive samples, 7 were RPR non-reactive, TPPA reactive and treponemal EIA negative; and 1 sample was RPR and TPPA non-reactive.

Performance in Medically Diagnosed Patients

COMPARATIVE REACTIVITY: 70 characterized samples from patients medically diagnosed with syphilis infection were tested for positive agreement and reactivity vs. the reference method. The BioPlex® 2200 Syphilis IgG kit demonstrated a higher reactivity rate than the reference method on samples from patients previously diagnosed with syphilis.

<table>
<thead>
<tr>
<th>Reactivity in Patients</th>
<th>BioPlex® 2200 Syphilis IgG</th>
<th>95.7% (67/70)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Method</td>
<td>30.0% (21/70)</td>
<td></td>
</tr>
</tbody>
</table>

** One (1) sample with BioPlex® 2200 Syphilis IgG reactive results was RPR nonreactive, TPPA reactive and treponemal EIA equivocal.
** Three (3) samples with BioPlex® 2200 Syphilis IgG reactive results were RPR and TPPA nonreactive.

Precision

Following CLSI EP5-A guidelines, the BioPlex® 2200 Syphilis IgG kit demonstrated %CV's of under 8.5% for total precision near cutoff levels. The Syphilis IgG kit exhibits market leading performance in precision, particularly when compared to competitive automated products that have average %CV's up to 21%. Our low %CV's can be attributed to a) full automation, b) magnetic bead, heterogenous assay format and c) minimum of 150 measurements per analyte.
Syphilis IgG Assay Procedure

1. Patient sample (5 µL) automatically added to Reaction Vessel
2. Sample diluent & beads (dilution 1:60) added and incubated at 37°C
3. Wash step
4. Conjugate added and incubated at 37°C
5. Wash step
6. Bead resuspended in wash buffer
7. Flow-based, dual laser detection

**Syphilis IgG Reagent Pack**
Contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 patients per pack and up to 100 results per patient.

**Syphilis IgG Calibrator Set**
Calibrators are ready-to-use and pre bar-coded for ease of use.

**Syphilis IgG Control Set**
Quality Controls are ready-to-use and pre bar-coded for ease of use.

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**Ordering Information**

**Catalog No.** | **Description** | **Quantity**
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665-1450 | Syphilis IgG Reagent Pack | 1 pack
663-1400 | Syphilis IgG Calibrator Set | 1 set
663-1420 | Syphilis IgG Calibrator Lot Data CD | 1 CD
663-1430 | Syphilis IgG Control Set | 1 set
663-1440 | Syphilis IgG Control Lot Data CD | 1 CD
665-1460A | Syphilis IgG Instructions for Use Package | 1 package

**BioPlex® 2200 System and Bulk Reagents**

**BioPlex® 2200 System** | 1 system
**Sample Racks** (30 per box) | 1 box
**Sample Tray** | 1 tray
**Instrument Sheath Fluid** (2 per box) | 1 box
**Instrument Wash Buffer** | 1 box
**Reaction Vessels** (1000 per bag) | 1 bag
**Instrument Detector Calibration Pack** | 1 pack
**Instrument Detector Clean Pack** | 1 pack
**Instrument Probe Cleaning Solution** (4 per box) | 1 box

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Bio-Rad Laboratories

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics