

# BioPlex™ 2200 Syphilis IgG and IgM

## Fully-automated, random access, multiplex syphilis testing

The BioPlex™ 2200 Syphilis IgG and IgM kits detect the five most clinically relevant antibodies against individual recombinant proteins to *Treponema pallidum* in a multiplex format.

### Syphilis IgG

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.

#### BioPlex™ 2200 Syphilis IgG:

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

### Syphilis IgM

The BioPlex™ 2200 Syphilis IgM kit is a multiplex flow immunoassay for the qualitative numeric detection of *T. pallidum* IgM antibodies in human serum. The test system can be used in conjunction with a syphilis IgG test as a screen of active or past infection. In addition, the Syphilis IgM kit can be used in conjunction with treponemal and/or non-treponemal tests as an aid in the identification of acute infection with *T. pallidum*.

#### BioPlex™ 2200 Syphilis IgM: (OUS only)

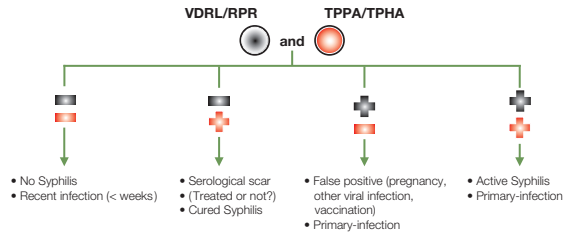
- Syphilis IgM Composite\*
- *T. pallidum* 17kDa\*\*
- *T. pallidum* 47kDa\*\*

\* Syphilis IgG and IgM Composite are a rollup of the individual results.  
\*\* Individual results available outside US.



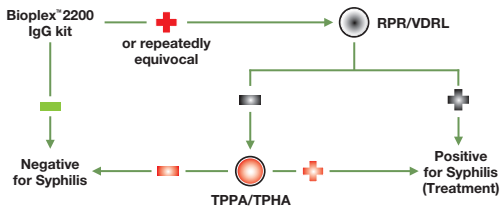
**Traditional Syphilis Algorithm:**

Screen with Reagin test followed by Treponemal based assay confirmation to determine active syphilis infection.



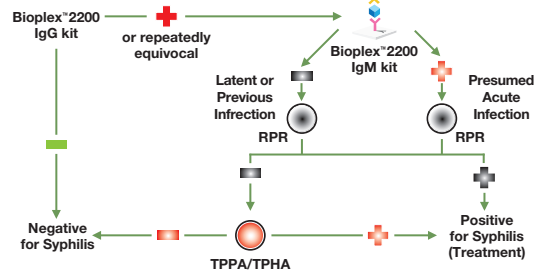
**Alternative high volume algorithm:**

Treponemal based assay (i.e. EIA) as a diagnostic screen followed up by a non-treponemal assay for confirmation (may also include TPPA additional testing for discordant analysis).



**Alternative high volume algorithm:**

with Syphilis IgM to aid in the identification of acute infection.



**Efficiency**

- Fully-automated, random access multiplex assay procedure for Syphilis IgG & IgM testing from primary tube to final result
- Time to first result in approximately 45 minutes
- Ready-to-use multiplexed calibrators and controls
- Curve stability up to 30 days for Syphilis IgG and 21 days for Syphilis IgM

**Quality**

- Excellent Syphilis IgG negative agreement at 98.8% and positive agreement at 100% with RPR and TPPA\*
- Excellent Syphilis IgM\*\* specificity from 98.2-99.4%\*
- Syphilis IgM\*\* positivity in 43% of patients with primary and secondary syphilis infection, distinguishing acute vs. non-acute (primary and secondary) disease status\*
- Excellent lot-to-lot reproducibility with IgG %CV's under 8.5% for total precision near cut-off levels, and IgM %CV's under 11% for total precision near cut-off levels

\* Please refer to Instructions for Use (IFU)  
 \*\* Available OUS only

**Ordering Information**

**Catalog No. Description**

**BioPlex™ 2200 Syphilis IgG**

665-1450	BioPlex™ 2200 Syphilis IgG Reagent Pack .....	1 pack
663-1400	BioPlex™ 2200 Syphilis IgG Calibrator Set .....	1 set
663-1430	BioPlex™ 2200 Syphilis IgG Control Set .....	1 set

**BioPlex™ 2200 Syphilis IgM**

665-1550	BioPlex™ 2200 Syphilis IgM Reagent Pack .....	1 pack
663-1500	BioPlex™ 2200 Syphilis IgM Calibrator Set .....	1 set
663-1530	BioPlex™ 2200 Syphilis IgM Control Set .....	1 set



**Bio-Rad Laboratories**

*For further information, please contact the Bio-Rad office nearest you or visit our website at [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics)*

*Clinical Diagnostics Group*

**Website** [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics) **U.S.** 1-800-2BIO-RAD **Australia** 61-2-9914-2800 **Austria** 43-1-877-8901 **Belgium** 32-9-385-5511 **Brazil** 5521-3237-9400 **Canada** 1-514-334-4372 **China** 86-21-64260808 **Czech Republic** 420-241-430-532 **Denmark** +45-4452-1000 **Finland** 358-9-804-22-00 **France** 33-1-47-95-60-00 **Germany** +49-(0)89-318-840 **Greece** 30-210-7774396 **Hong Kong** 852-2789-3300 **Hungary** +36-1-459-6100 **India** 91-124-4029300 **Israel** 972-3-9636050 **Italy** +39-02-216091 **Japan** 81-3-6361-7070 **Korea** 82-2-3473-4460 **Mexico** 52(55)5200-0520 **The Netherlands** +31-318-540666 **New Zealand** 64-9-415-2280 **Norway** 47-23-38-41-30 **Poland** 48-22-3319999 **Portugal** 351-21-472-7700 **Russia** 7-495-721-14-04 **Singapore** 65-6415-3188 **South Africa** 27-11-442-85-08 **Spain** 34-91-590-5200 **Sweden** 46-8-555-127-00 **Switzerland** 41-61-717-95-55 **Thailand** 662-651-8311 **United Kingdom** +44-(0)20-8328-2000