

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)

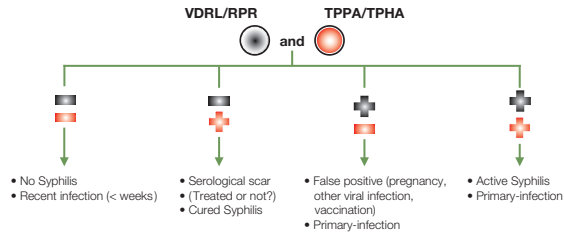
- Syphilis IgM Composite*
- *T. pallidum* 17kDa**
- *T. pallidum* 47kDa**

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



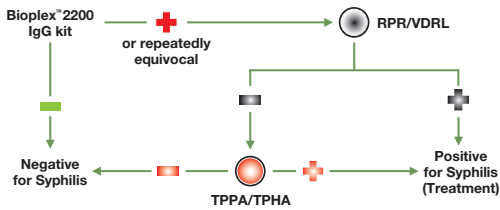
Traditional Syphilis Algorithm:

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



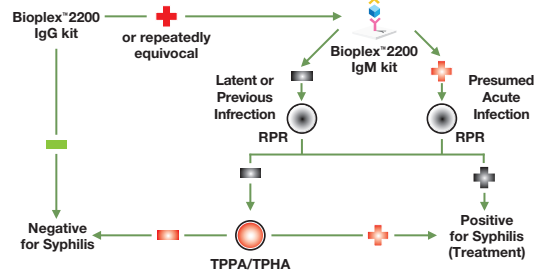
Alternative high volume algorithm:

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

Clinical Diagnostics Group

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