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.
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