



# BioPlex™ 2200 Syphilis IgM

The first and only fully-automated, random access, multiplex platform for Syphilis IgM

**BIO-RAD**



# Like no other

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

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 use in conjunction with treponemal and/or non-treponemal based tests as an aid in identification of acute infection with *T. pallidum*.

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

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

\* Syphilis IgM Composite is a rollup of the individual results.

\*\* Individual results available outside US.

# Performance Characteristics

## Specificity

### BioPlex™ 2200 Syphilis IgM

Specificity can be defined as the ability of a test to give a negative result in normal sera from populations that may be tested. The specificity of the BioPlex™ 2200 Syphilis IgM assay on 1247 samples was excellent at 98% or better. Detailed results are shown below.

Population	N	BioPlex™ 2200 Syphilis IgM	95% CI
Unselected pregnant women	497	99.4% (494*/497)	98.2 to 99.8%
Pregnant women with known RPR/TPPA nonreactive results	250	98.0% (245**/250)	95.4 to 99.1%
Patients who had a Syphilis test ordered	500	98.2% (491***/500)	96.6 to 99.1%

\* Two (2) samples were Syphilis IgM reactive, one (1) sample was Syphilis IgM equivocal, and all three (3) samples were RPR/TPPA nonreactive.

\*\* Five (5) samples were Syphilis IgM reactive, all five (5) samples were RPR/TPPA nonreactive.

\*\*\* Eight (8) samples were Syphilis IgM reactive. Of those eight (8) samples, five (5) samples were RPR/TPPA nonreactive, two (2) samples were RPR/TPPA reactive, and one (1) sample was RPR nonreactive/TPPA reactive. One (1) sample was Syphilis IgM equivocal and RPR/TPPA nonreactive.

## Sensitivity

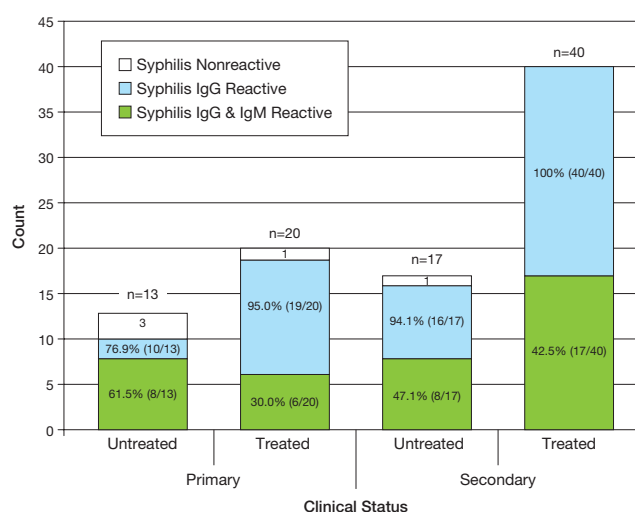
### BioPlex™ 2200 Syphilis IgM

#### Data Summary:

- IgM was positive in 43% (39/90) of patients with primary and secondary syphilis infection, helping distinguish acute (primary and secondary) vs. non-acute disease status.
- IgM and IgG combined were positive in 94%\* (85/90) of patients with primary and secondary syphilis infection.

Please reference the IgM and IgG results, shown in the bar graph to the right.

\* Of the 5 samples nonreactive by BioPlex, 3 out of 5 were also nonreactive for all other testing methods including RPR, TPPA and Western Blot. By excluding these 3 samples, BioPlex assay sensitivity is further improved.



## Precision

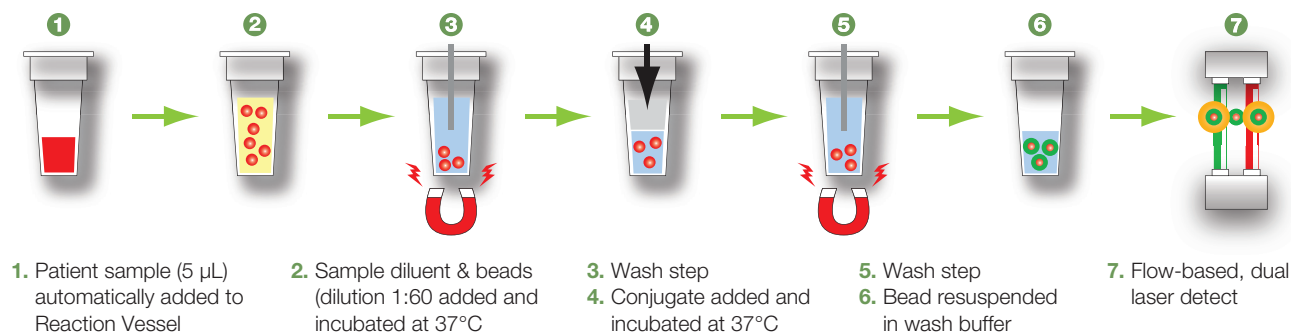
Following CLSI EP%-A2 guidelines, the BioPlex™ 2200 Syphilis IgM kit demonstrated % CV's of under 11%.

### Low % CV's can be attributed to:

- full automation
- magnetic bead, heterogenous assay format
- minimum of 150 measurements per analyte

Syphilis IgM Panel Members	Sample N	Grand Mean AI	Within-Run SD	Within-Run %CV	Between-Day SD	Between-Day %CV	Between-Run SD	Between-Run %CV	Total SD	Total %CV
Near Cutoff 1 – Tp 17kDa	80	1.0	0.05	5.4%	0.03	3.3%	0.03	3.3%	0.07	7.3%
Near Cutoff 2 – Tp 17kDa	80	1.0	0.06	6.4%	0.05	5.8%	0.05	5.8%	0.10	10.6%
Near Cutoff 1 – Tp 47kDa	80	1.0	0.06	6.1%	0.04	4.4%	0.00	0.3%	0.07	7.6%
Near Cutoff 2 – Tp 47kDa	80	1.2	0.08	6.5%	0.03	2.6%	0.03	2.6%	0.09	7.5%

## Syphilis IgM Assay Procedure



### Syphilis IgM 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 IgM Calibrator Set

Calibrators are ready-to-use and pre bar-coded for ease of use.



### Syphilis IgM Control Set

Quality Controls are ready-to-use and pre bar-coded for ease of use.

## Ordering Information

### Catalog No. Description

#### BioPlex® 2200 Syphilis IgM

665-1550	Syphilis IgM Reagent Pack.....	1 pack
663-1500	Syphilis IgM Calibrator Set.....	1 set
663-1520	Syphilis IgM Calibrator Lot Data CD.....	1 CD
663-1530	Syphilis IgM Control Set .....	1 set
663-1540	Syphilis IgM Control Lot Data CD .....	1 CD
665-1560A	Syphilis IgM Instructions for Use Package .....	1 package

#### BioPlex® 2200 System and Bulk Reagents

660-0000	BioPlex® 2200.....	1 system
660-0800	Sample Racks (30 per box) .....	1 box
660-0801	Sample Tray .....	1 tray
660-0817	Instrument Sheath Fluid (2 per box) .....	1 box
660-0818	Instrument Wash Buffer .....	1 box
660-2003	Reaction Vessels (1000 per bag) .....	1 bag
666-0001	Instrument Detector Calibration Pack .....	1 pack
666-0002	Instrument Detector Clean Pack.....	1 pack
666-0003	Instrument Probe Cleaning Solution (4 per box).....	1 box



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