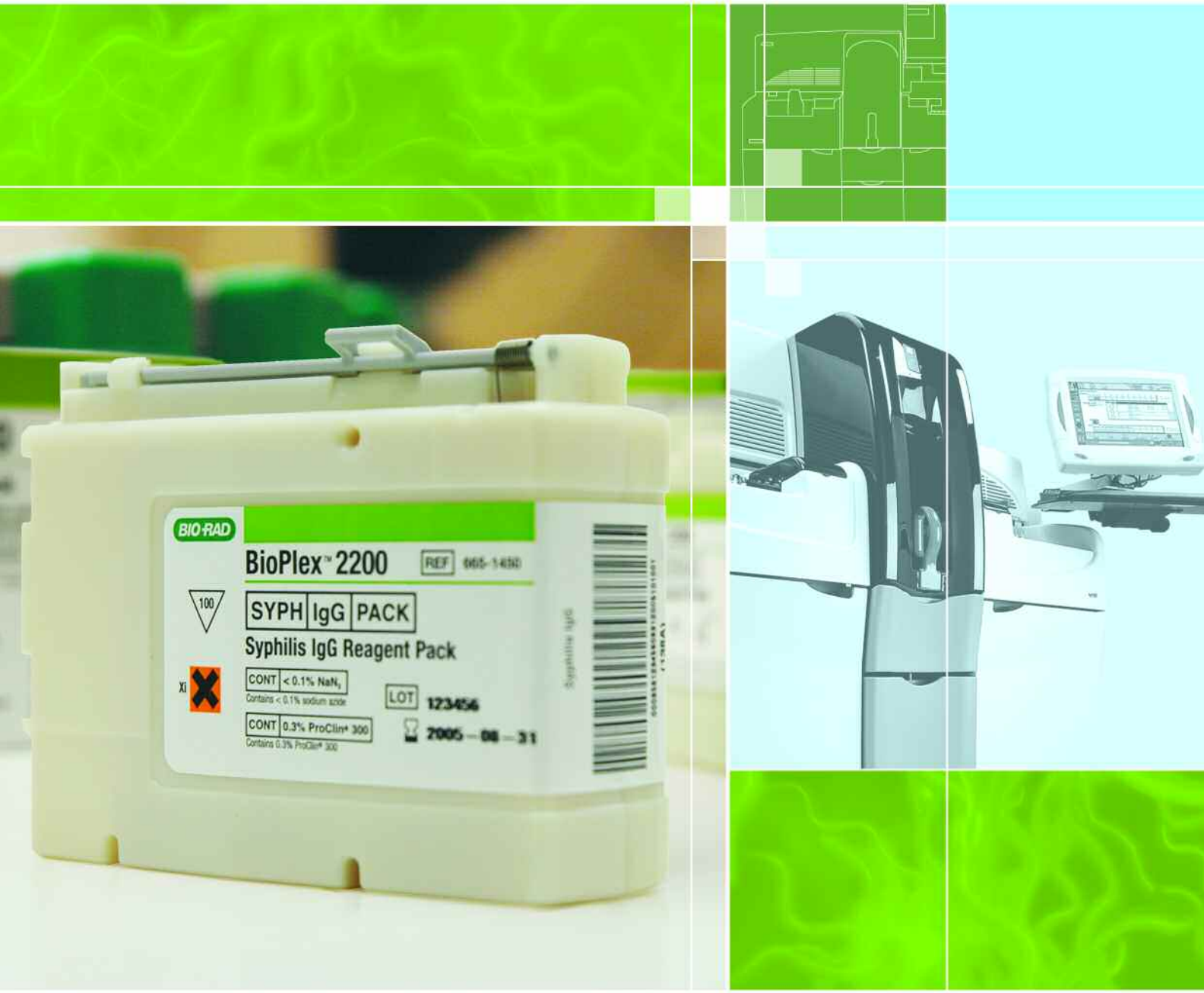


BioPlex™ 2200 Syphilis IgG

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

BIO-RAD

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 rollup 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.

Serum Samples Requested to be Treponemal Positive		BioPlex 2200 Syphilis IgG					
		Reactive	Equivocal	Nonreactive	Total	Positive (+) % Agreement	95% Confidence Interval
Reference Assay Result	Positive	166	0	0	166	100% (166/166)	97.7-100%
	Equivocal	4*	0	0	4		
	Negative	8**	0	5	13		
	Total	178	0	5	183		

* 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.

Serum Samples Requested to be RPR and TPPA Non-Reactive		BioPlex 2200 Syphilis IgG					
		Reactive	Equivocal	Nonreactive	Total	Negative (-) % Agreement	95% Confidence Interval
Reference Assay Result	Positive	0	0	0	0	98.8% (247/250)	96.5-99.6%
	Equivocal	0	0	0	0		
	Negative	3*	0	247	250		
	Total	3	0	247	250		

* Three (3) BioPlex 2200 Syphilis IgG reactive samples were RPR and TPPA nonreactive.

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.

Reactivity in Patients	
BioPlex™ 2200 Syphilis IgG	95.7% (67/70)
Reference Method	90.0% (63/70)

Serum Samples from Patients Medically Diagnosed with Syphilis Infection		BioPlex 2200 Syphilis IgG					
		Reactive	Equivocal	Nonreactive	Total	Positive (+) % Agreement	95% Confidence Interval
Reference Assay Result	Positive	63	0	0	63	100.0% (63/63)	94.2-100%
	Equivocal	1*	0	0	1		
	Negative	3**	0	3	6		
	Total	67	0	3	70		

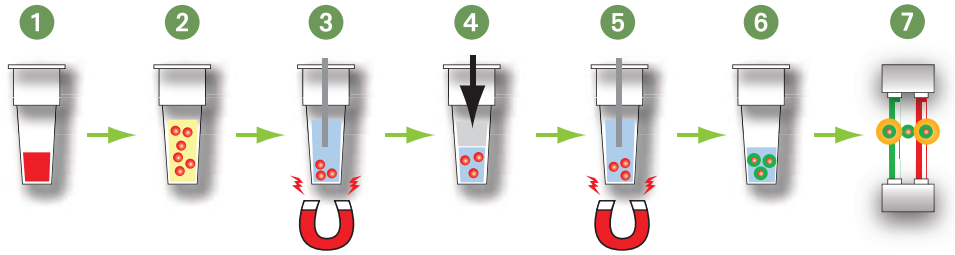
* One (1) sample with BioPlex 2200 Syphilis IgG reactive results was RPR nonreactive, TPPA reactive and treponemal EIA equivocal.
** Three (3) samples with BioPlex 2200 Syphilis IgG reactive results were RPR and TPPA nonreactive.

Precision

Following CLSI EP5-A guidelines, the BioPlex™ 2200 Syphilis IgG kit demonstrated %CV's of under 8.5% for total precision near cut-off 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 Panel Members	Sample N	Grand Mean AI	Within-Run		Between-day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Near Cut-off 1 Tp 15kDa	80	1.0	0.04	3.5%	0.07	7.0%	0.03	3.1%	0.09	8.4%
Near Cut-off 2 Tp 15kDa	80	1.0	0.04	3.8%	0.06	6.5%	0.03	3.3%	0.08	7.8%
Near Cut-off 1 Tp 17kDa	80	1.0	0.03	3.3%	0.07	6.9%	0.03	3.1%	0.08	7.9%
Near Cut-off 2 Tp 17kDa	80	1.0	0.03	3.1%	0.05	5.3%	0.04	4.3%	0.08	7.3%
Near Cut-off 1 Tp 47kDa	80	1.1	0.03	2.4%	0.04	4.3%	0.03	3.0%	0.06	5.7%
Near Cut-off 2 Tp 47kDa	80	1.1	0.04	3.1%	0.05	4.8%	0.03	2.8%	0.07	6.4%

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.

Ordering Information

Catalog No.	Description
BioPlex 2200 Syphilis IgG	
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	
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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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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