

BioPlex 2200 Syphilis Total & RPR Assay

Simultaneous detection and differentiation of Treponemal and non-Treponemal antibodies

BIO-RAD

Redefine your workflow.

The BioPlex 2200 Syphilis Total & RPR Assay is the only automated dual treponemal/non-treponemal immunoassay test that offers laboratories a global one-step testing solution for Syphilis. The BioPlex 2200 Syphilis Total & RPR Assay is intended for the qualitative detection of total (IgG/IgM) antibodies to *Treponema pallidum* and the qualitative detection and/or titer determination of non-treponemal reagin antibodies in human serum or plasma.

The BioPlex 2200 Syphilis Total & RPR Assay offers a one-step universal testing method

Reportable results include:

- Syphilis Total (IgG/IgM)
- Qualitative RPR (Rapid Plasma Reagin)
- Onboard RPR titer determination (1:4, 1:8, 1:16, 1:32, 1:64)

Productivity

Reduced hands-on time and labor savings and higher total throughput, up to 200 results per hour.



Consolidation

Dual non-treponemal/treponemal assay to streamline your syphilis testing algorithm. Detect, diagnose and monitor.



Performance

Improved sensitivity and specificity including differentiation of current and/or past infection.



Accuracy

Excellent precision, objective RPR result reporting.



Performance

Test Ordered Samples

A total of 210 syphilis test ordered prospective samples and 278 retrospective RPR/VDRL positive samples were evaluated by the BioPlex 2200 Syphilis Total & RPR Assay. The BioPlex 2200 Syphilis Total & RPR Assay shows excellent agreement with the reference methods.*

BioPlex Syphilis Total					
Population	N	Positive Agreement	95% CI	Negative Agreement	95% CI
Test Ordered	210	96.4% (27/28)	82.3%– 99.4%	98.9% (180/182)	95.9%-99.5%
Retrospective RPR/VDRL positive	278	100% (260/260)	98.5%-100%	-	-

* Reference Syphilis Total Result: Combined results from commercially available Syphilis Total, RPR and TPPA assays.

BioPlex RPR					
Population	N	Positive Agreement	95% CI	Negative Agreement	95% CI
Test Ordered	210	94.7% (18/19)	75.4%– 99.1%	99.5% (190/191)	97.1%-99.9%
Retrospective RPR/VDRL positive	278	94.4% (253/268)	91.0%-96.6%	-	-

* Reference RPR Result: Commercially available RPR assay.

Performance in Medically Diagnosed Patients

118 characterized samples from patients medically diagnosed with syphilis infection were tested for positive agreement versus the reference result. Both the Syphilis Total and the RPR show excellent correlation with clinical samples with a positive agreement of 99.1% and 100% respectively.

BioPlex Syphilis Total				BioPlex RPR	
Population	N	Positive Agreement	95% CI	Positive Agreement	95% CI
Samples from patients medically diagnosed with syphilis infection	118	99.1% (110/111)	95.1%-100.0%	100% (92/92)	96.1%-100%

Precision

Following EP5-A3 the BioPlex 2200 Syphilis Total & RPR Assay demonstrated %CV's for total precision near the cutoff of 4.8% and 9.3% respectively for the Syphilis Total and RPR.

Syphilis Total Panel Members	Sample N	Mean (AI)	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	80	0.3	0.03	N.A	0.00	N.A	0.03	N.A	0.04	N.A
High Negative	80	0.5	0.04	6.5%	0.02	3.5%	0.03	5.6%	0.05	9.3%
Near Cutoff	80	0.9	0.03	3.3%	0.02	2.2%	0.02	2.7%	0.04	4.8%
Low Positive	80	1.5	0.06	3.7%	0.02	1.0%	0.12	7.8%	0.13	8.7%
Mid Positive	80	1.8	0.08	4.3%	0.00	0.0%	0.19	10.3%	0.20	11.2%
High Positive	80	3.2	0.08	2.5%	0.04	1.4%	0.09	2.9%	0.13	4.1%
Positive Control	80	2.6	0.13	4.7%	0.01	0.4%	0.05	1.8%	0.13	5.1%

RPR Panel Members	Sample N	Mean (AI)	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	80	0.2	0.03	N.A	0.02	N.A	0.04	N.A	0.05	N.A
High Negative	80	0.7	0.04	6.6%	0.06	9.0%	0.05	7.3%	0.09	13.4%
Near Cutoff	80	0.9	0.04	4.2%	0.06	6.5%	0.05	5.1%	0.09	9.3%
Near Cutoff/Low Positive	80	1.0	0.05	4.7%	0.08	7.5%	0.08	7.8%	0.12	11.8%
Mid Positive	80	1.9	0.10	5.2%	0.10	5.3%	0.08	4.2%	0.16	8.6%
High Positive	80	3.4	0.09	2.6%	0.16	4.8%	0.12	3.5%	0.22	6.5%
Positive Control	80	2.0	0.05	2.4%	0.11	5.4%	0.08	4.0%	0.14	7.1%

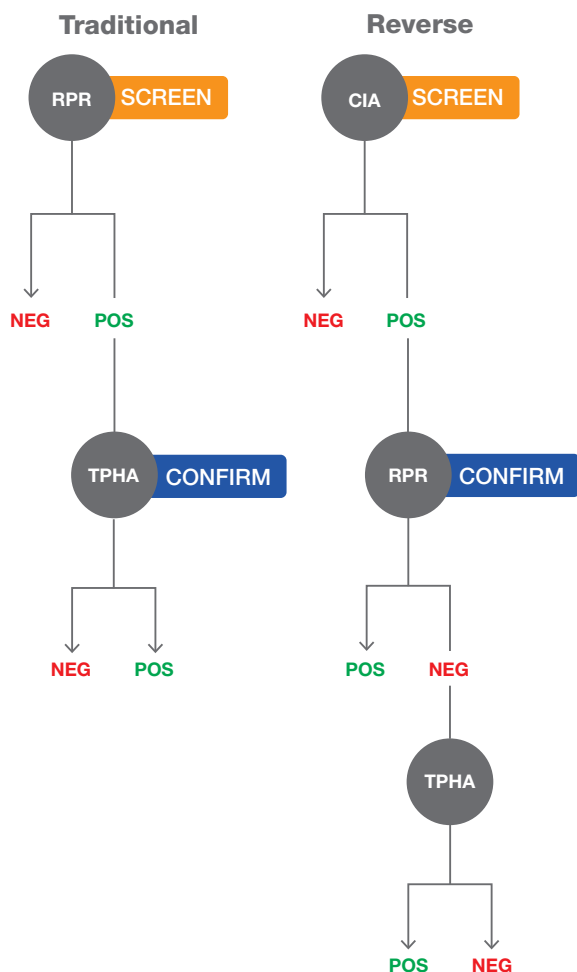
Seroconversion Panel - Sera Care PSS901

The BioPlex Syphilis Total assay detects infection up to 2 weeks earlier (PSS901-5) than all the treponemal reference methods.

Panel	Bleed Day	BioPlex Syphilis Total	Reference Syphilis IgM	Reference Syphilis IgG	Reference Syphilis Total	Reference TPPA	BioPlex RPR	Reference Manual RPR
PSS901-01	0	0.2	0.42	0.15	Neg	Neg	0.9	Neg
PSS901-02	5	0.2	0.45	0.12	Neg	Neg	0.3	Neg
PSS901-03	10	0.2	0.41	0.12	Neg	Neg	0.6	Neg
PSS901-04	13	0.2	0.40	0.13	Neg	Neg	0.5	Neg
PSS901-05	31	1.5	0.68	0.16	Neg	Neg	1.8	POS
PSS901-06	45	6.2	1.17	0.50	POS	POS	>10.0	POS
PSS901-07	48	>8.0	1.26	0.80	POS	POS	>10.0	POS
PSS901-08	52	>8.0	1.51	0.98	POS	POS	>10.0	POS
PSS901-09	59	>8.0	1.87	1.32	POS	POS	>10.0	POS

Simplify your testing with the BioPlex 2200 Syphilis Total & RPR Assay.

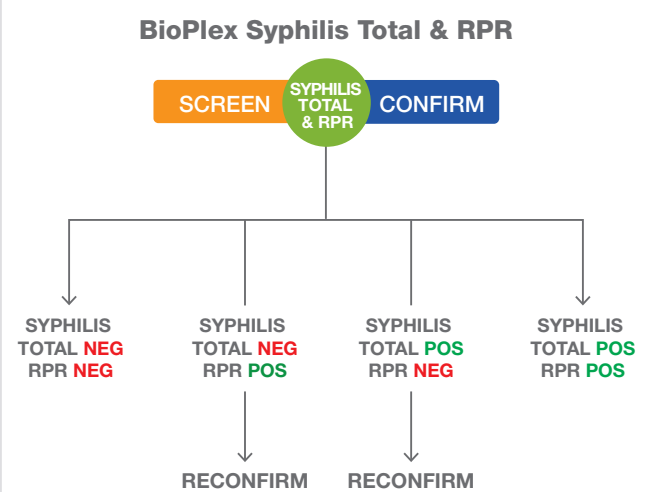
Traditional and Reverse Syphilis Algorithms



Challenges

- Longer turn-around time for final result
- Need to maintain at least 2 different methods/assays
- Manual RPR testing and result reporting

Load and walk away with the BioPlex 2200 Syphilis Total & RPR Assay



Features

- Dual non-treponemal/treponemal assay
- Automated RPR
- Onboard titer/dilutions (1:4, 1:8, 1:16, 1:32, 1:64)
- Up to 200 results per hour
- Excellent precision
- Ready to use reagents
- 30 day calibration curve stability

Benefits

- Accurate, consistent and objective RPR result reporting
- Full traceability
- Better patient management

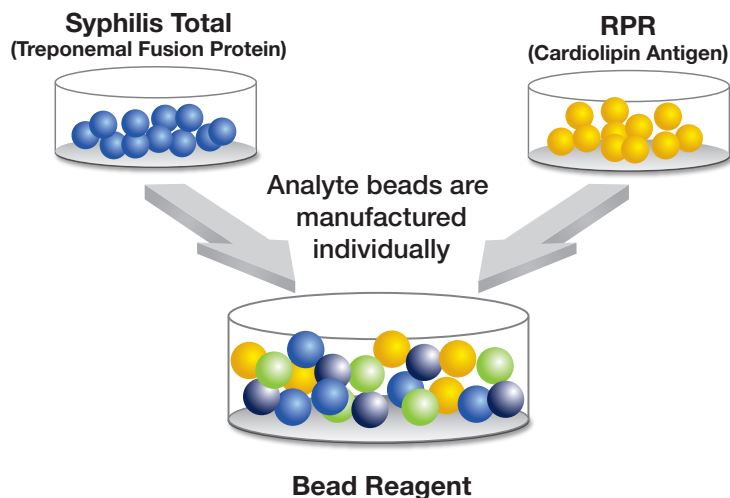
Assay Principle

The BioPlex 2200 Syphilis Total & RPR Assay is dual treponemal/non-treponemal assay. The bead reagent is a mixture of 2 distinct populations of dyed microparticle beads in addition to two internal quality beads.

INTERNAL QC BEADS

- Internal Standard Bead (ISB)
- Serum Verification Bead (SVB)

Beads are combined into a single **Bead Reagent** for multiplex analysis.



Syphilis Total & RPR Reagent Pack

Contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples per pack and up to 200 results



Syphilis Total & RPR Calibrator Set

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



Syphilis Total & RPR Control Set

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

Ordering Information

Catalog #	Description	
12000650	BioPlex 2200 Syphilis Total & RPR Reagent Pack.....	1 pack
12000651	BioPlex 2200 Syphilis Total & RPR Calibrator Set	1 set
12000653	BioPlex 2200 Syphilis Total & RPR Control Set.....	2 sets

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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

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