BioPlex™ 2200 ToRC IgG

The first and only fully-automated, random access, Multiplexed solution for ToRC IgG testing

BIO-RAD

Like no other

The BioPlex™ 2200 ToRC kit simultaneously detects IgG antibodies to *T. gondii*, Rubella, and CMV.

By detecting the most commonly requested infectious disease serology assays, the BioPlex™ 2200 provides laboratories with efficient workflow and faster turnaround time.

The BioPlex™ 2200 ToRC kit reports results for the following:

- Anti-*Toxoplasma gondii* IgG
- Anti-Rubella IgG
- Anti-Cytomegalovirus IgG

Efficiency

High Throughput Capability

Up to 300 results per hour for improved workflow and reduced hands-on time and labor costs.

The Power of One Panel

Consolidating three traditional assays from the ToRCH panel into one test kit gives the opportunity to significantly reduce turnaround and cost per patient result.

Rapid, multi-parameter infectious disease testing, including STAT capabilities, from a single reaction vessel fascilitating workflow efficiency.

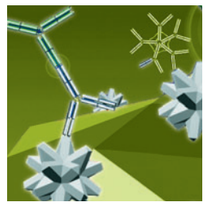
eFlex™ Software

The system features a powerful package of user-friendly software tools that provide optimum flexibility.

Key Features Include:

- "Add-on" new test orders from previously run patient samples
- Creation of custom ToRC IgG panels
- Bi-directional LIS connectivity

Quality



Standardization

The BioPlex™ 2200 ToRC IgG assays are standardized to the applicable World Health Organization (WHO) reference material. The *T. gondii* IgG assay (1st International Standard, 2003) and the Rubella IgG assay (1st International Standard, 1996).

Novel Multiplex Chemistry

Magnetic bead technology enables thorough washing for improved signal to noise ratios and better overall performance compared to homogeneous methods.

Excellent Performance Compared to Other Immunoassay Methods

The BioPlex™ 2200 ToRC kit features the combination of a heterogeneous assay format and a minimum of 150 measurements per analyte per reaction vessel (vs. one photometric or luminometric measurement) for increased precision and lot-to-lot consistency.

Confidence

Full Automation

From primary tube to final result, the BioPlex™ 2200 is the only fully-automated, multiplexed ToRC IgG testing system featuring:

- Completely automated assay procedure minimizing human errors commonly observed with manual sample and reagent handling
- Standardized assay procedure for improved performance
- Multiplex calibration and quality control to reduce cost and improve turnaround time.

Internal Quality Controls

For every sample processed, three internal quality controls are also processed, improving confidence in results and quality assurance:

- Serum Verification Bead (SVB) confirms presence of serum or plasma
- Internal Standard Bead (ISB) standardizes detector performance
- Reagent Blank Bead (RBB) identifies sample problems associated with non-specific binding

Correlation with CDC Evaluation Serum Panels

The Centers for Disease Control (CDC) provided evaluation serum panels for testing of *T. gondii* IgG, Rubella IgG, and CMV IgG. These panels were tested to evaluate performance of the ToRC IgG kit and do not imply an endorsement of the BioPlex™ 2200 ToRC IgG kit by the CDC. (see tables below)

BioPlex™ 2200 Results for CDC *T. gondii* Reference Sera (N=100)

CDC Samples	Reference Result	BioPlex Pos (+)	BioPlex Neg (-)
T. gondii IgG	Pos (+)	70	0
	Neg (-)	0	30

Note: Tested at Bio-Rad Laboratories

BioPlex™ 2200 Results for CDC Rubella IgG Reference Sera (N=100)

CDC Samples	Reference Result	Site 1		Site 2		Site 3	
		BioPlex Pos (+)	BioPlex Neg (-)	BioPlex Pos (+)	BioPlex Neg (-)	BioPlex Pos (+)	BioPlex Neg (-)
Rubella IgG	Pos (+)	82	0	82	0	82	0
	Neg (-)	0	18	0	18	0	18

Note: Tested at 3 clinical evaluation sites

BioPlex™ 2200 Results for CDC CMV IgG Reference Sera (N=100)

CDC Samples	Reference Result	BioPlex Pos (+)	BioPlex Neg (-)
CMV IgG	Pos (+)	66	0
	Neg (-)	0	34

Note: Tested at Bio-Rad Laboratories

Precision

Reproducibility near the cut off (breakpoint) is essential for providing consistent patient results. Two (2) peri-cut off and two low positive samples were tested at three (3) different testing facilities according to the principles described in the Clinical Laboratory Standards Institute (CLSI) guidance EP5-A2 (Vol. 24, No. 25). The standard deviation (SD) and percent coefficient of variation (% CV) were calculated. (see tables below)

Toxoplasma gondii IgG

T. gondii IgG Panel Members	Sample N	Grand Mean IU/mL	Within-Run		Between-Day		Between-Run		Between-Site*		Total*	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Peri-Cut Off 1	60	10	0.65	6.5%	0.40	4.0%	0.00	0.0%	1.13	11.3%	1.36	13.6%
Peri-Cut Off 2	60	13	0.63	4.9%	0.46	3.5%	0.00	0.0%	0.89	6.9%	1.18	9.2%
Low Positive 1	60	15	0.98	6.5%	0.24	1.6%	0.00	0.0%	1.41	9.3%	1.73	11.5%
Low Positive 2	60	15	0.71	4.6%	0.55	3.6%	0.30	1.9%	2.02	13.2%	2.23	14.6%

* Total and Between-site variance includes between lot and between instrument variance

Rubella IgG

Rubella IgG Panel Members	Sample N	Grand Mean IU/mL	Within-Run		Between-Day		Between-Run		Between-Site*		Total*	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Peri-Cut Off 1	60	9	0.45	5.3%	0.00	0.0%	0.25	2.9%	0.30	3.5%	0.59	7.0%
Peri-Cut Off 2	60	11	0.74	6.9%	0.00	0.0%	0.00	0.0%	0.16	1.5%	0.76	7.0%
Low Positive 1	60	16	0.90	5.6%	0.00	0.0%	0.00	0.0%	0.59	3.7%	1.08	6.7%
Low Positive 2	60	13	0.69	5.5%	0.10	0.8%	0.00	0.0%	0.64	5.2%	0.95	7.6%

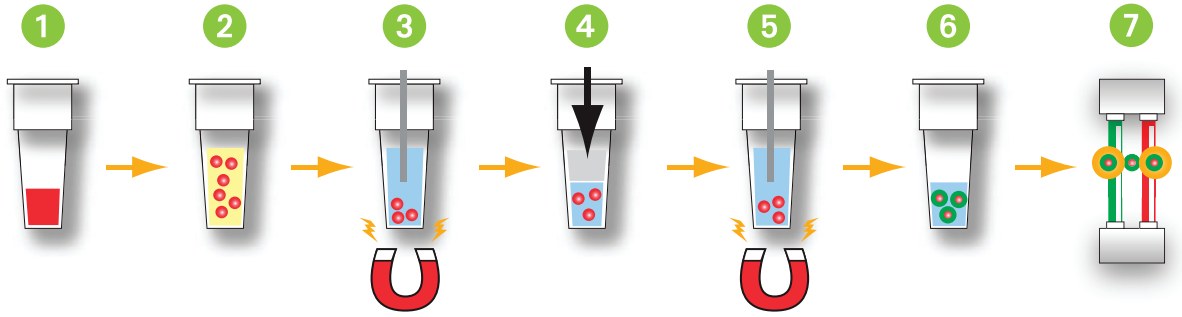
* Total and Between-site variance includes between lot and between instrument variance

Cytomegalovirus (CMV) IgG

CMV IgG Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total*	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Peri-Cut Off 1	60	1.4	0.07	5.3%	0.00	0.0%	0.05	3.4%	0.11	7.8%	0.14	10.0%
Peri-Cut Off 2	60	1.2	0.07	5.8%	0.00	0.0%	0.04	3.1%	0.11	8.9%	0.13	11.1%
Low Positive 1	60	1.9	0.09	4.7%	0.05	2.7%	0.05	2.7%	0.18	9.5%	0.21	11.3%
Low Positive 2	60	1.6	0.09	5.5%	0.00	0.0%	0.04	2.6%	0.15	9.3%	0.18	11.1%

* Total and Between-site variance includes between lot and between instrument variance

ToRC IgG Assay Procedure



1. Patient sample (5 µL) automatically added to reaction vessel
2. Sample diluent & beads 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

ToRC IgG Reagent Pack

Contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples and up to 3 results per sample.

ToRC IgG Calibrator Set

Calibrators are ready-to-use and multiplexed. For *T. gondii* and Rubella, a six-point 4PL fitted curve is used to calculate quantitative results. For CMV, a point-to-point curve fit using four calibrators is used to calculate semi-quantitative results.

ToRC IgG Control Set

Quality Controls are ready-to-use and multiplexed. The set includes a negative control as well as two different levels of multi-analyte postitive controls.

Ordering Information

Catalog No.	Description
BioPlex™ 2200 ToRC IgG	
665-1650	ToRC IgG Reagent Pack.....1 pack
663-1600	ToRC IgG Calibrator Set .....1 set
663-1630	ToRC IgG Control Set .....1 set

BioPlex™ 2200 System and Bulk Reagents	
660-0000	BioPlex™ 2200.....1 instrument
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 Bottles (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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