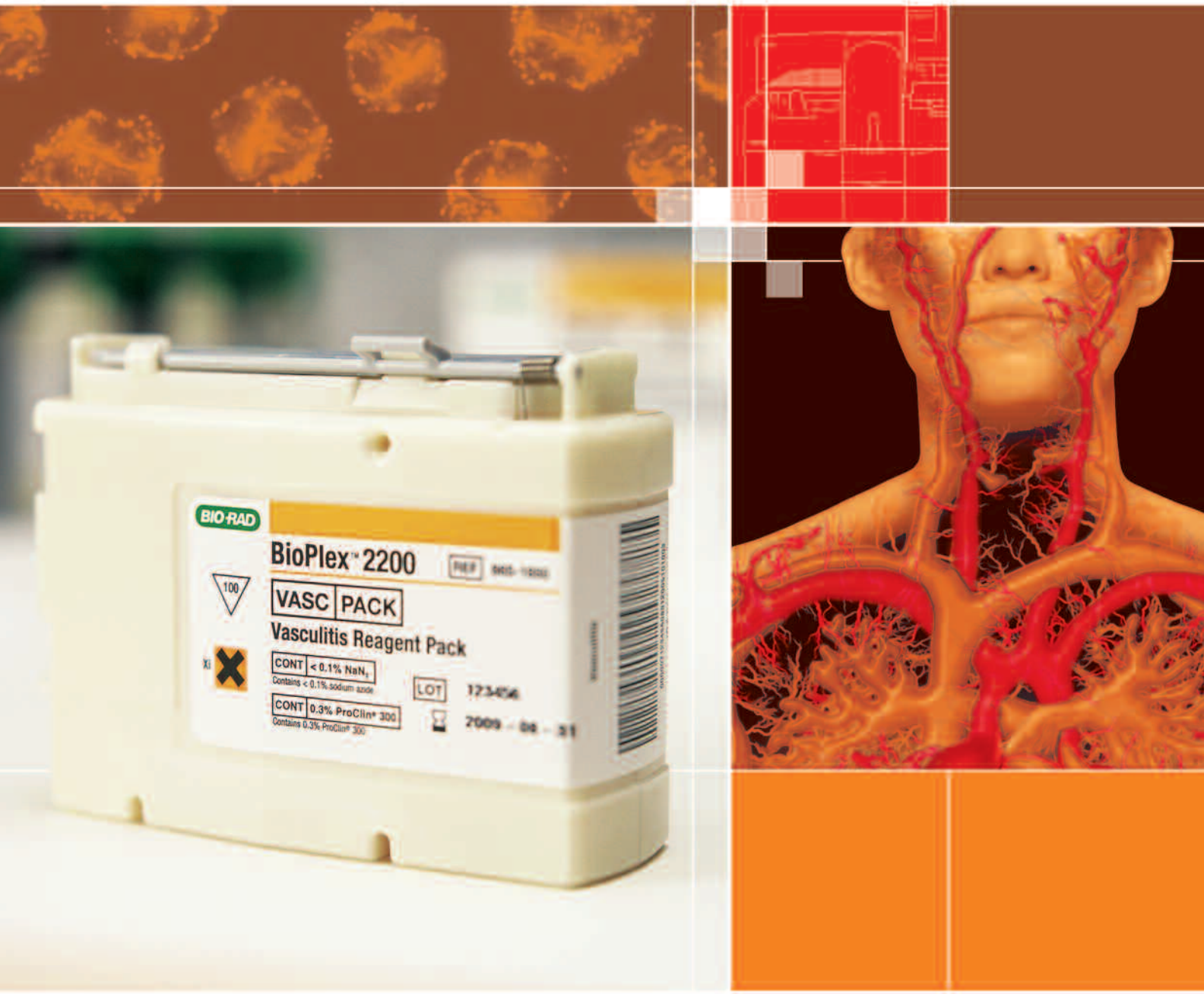


BioPlex™ 2200 Vasculitis

The first and only fully-automated, random access multiplexed solution for vasculitis testing

BIO-RAD

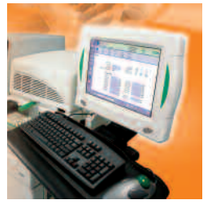
Like no other

The BioPlex™ 2200 Vasculitis kit simultaneously detects the three most clinically relevant antibodies.

By detecting the most clinically relevant vasculitis antibodies, the BioPlex™ 2200 Vasculitis kit provides laboratories with more diagnostically useful information for enhanced patient management with highly reproducible results and faster turnaround time.

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

- Anti-MPO
- Anti-PR3
- Anti-GBM



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 single-analyte tests into one test panel significantly reduces turnaround time and reduces the cost per patient result.

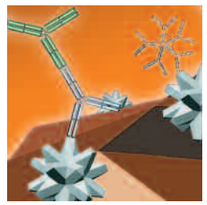
Rapid, multi-parameter antibody profiling including STAT capabilities from a single reaction vessel facilitating disease differentiation and treatment.

eFlex™ Software

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

Key Features Include:

- "Add-on" of new test orders from previously run patient samples
- Creation of custom Vasculitis panels
- Flexible setup options to create custom result
- Bi-directional LIS connectivity



Quality

Antibodies of Clinical Significance

By targeting the most clinically relevant and prevalent antibodies associated with systemic small vessel vasculitis, the BioPlex™ 2200 Vasculitis kit improves clinical specificity, thus reducing the number of false positive results.

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 Traditional EIA and ANCA IFA Methods

The BioPlex™ 2200 Vasculitis kit features the combination of a heterogeneous assay format and a minimum of 150 measurements per analyte per reaction vessel (vs. one photometric EIA measurement) for excellent and consistent lot-to-lot results.

Confidence

Full Automation

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

- Completely automated assay procedure minimizing human errors commonly observed with manual sample and reagent handling
- Standardized assay procedure for improved performance
- Objective results, thus eliminating subjectivity associated with IFA methods

Internal Quality Controls

For every sample processed, three internal quality controls are also processed, improving confidence in results and as an aid in diagnosis:

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

Comparison with EIA Methods

Positive % Agreement

		BioPlex™ 2200 Vasculitis Anti-MPO Result		BioPlex™ 2200 Vasculitis Anti-PR3 Result		BioPlex™ 2200 Vasculitis Anti-GBM Result	
		Positive % Agreement	Overall % Agreement	Positive % Agreement	Overall % Agreement	Positive % Agreement	Overall % Agreement
EIA Result	Retrospective Samples Positive for Anti-MPO, Anti-PR3 and Anti-GBM	93.9% (92/98)	93.0% (93/100)*	100% (79/79)	83.0% (83/100)†	88.9% (16/18)‡	92.6% (25/27)

* One (1) anti-MPO EIA equivocal result is included in the Overall Agreement.
† Ten (10 anti-PR3 EIA equivocal results are included in the Overall Agreement.
‡ Two (2) of the sixteen (16) BioPlex 2200 anti-GBM positive results were weak positive by anti-GBM EIA.
‡ One (1) of the two (2) BioPlex 2200 anti-GBM negative results was a weak positive by anti-GBM EIA

227 retrospective samples positive for anti-MPO (N=100), anti-PR3 (N=100) and anti-GBM (N=27) were tested with the BioPlex™ 2200 Vasculitis kit and the corresponding commercially available microplate EIA methods. The positive % agreement and overall % agreement between the two methods for each analyte are referenced in the table above. The BioPlex™ 2200 Vasculitis kit demonstrated **good positive % agreement** with commercially available EIA assays for each analyte.

Negative % Agreement

		BioPlex™ 2200 Vasculitis Anti-MPO Result		BioPlex™ 2200 Vasculitis Anti-PR3 Result		BioPlex™ 2200 Vasculitis Anti-GBM Result	
		Negative % Agreement	Overall % Agreement	Negative % Agreement	Overall % Agreement	Negative % Agreement	Overall % Agreement
EIA Result	Normal Blood Donors	100% (293/293)	100% (293/293)	100% (293/293)	100% (293/293)	99.3% (289/291)	98.6% (289/293)
	Unselected Patient Samples*	97.6% (284/291)	96.3% (289/300)	99.0% (292/295)	99.0% (297/300)	99.7% (298/299)	99.3% (298/300)

*Previously tested with Vasculitis tests

293 samples from normal blood donors and 300 samples from unselected patient samples previously tested with vasculitis tests were tested with the BioPlex™ 2200 Vasculitis kit and the corresponding commercially available microplate EIA methods. The negative % agreement and overall % agreement between the two methods for each analyte are referenced in the table above. The BioPlex™ 2200 Vasculitis kit demonstrated **excellent negative % agreement** with commercially available EIA assays for each analyte.

Positive % Agreement

		BioPlex™ 2200 Anti-MPO Result	
		Positive % Agreement	Overall % Agreement
pANCA IFA Result	Retrospective Samples Positive for Anti-MPO	93.3% (83/89)	84.0% (84/100)

		BioPlex™ 2200 Anti-PR3 Result	
		Positive % Agreement	Overall % Agreement
cANCA IFA Result	Retrospective Samples Positive for Anti-PR3	94.9% (93/98)	93.0% (93/100)

200 retrospective positive samples (100 anti-MPO and 100 anti-PR3) were evaluated by a commercially available ANCA IFA method using ethanol-fixed slides. The positive % agreement and overall % agreement between the two methods are referenced in the adjacent tables. The BioPlex™ 2200 Vasculitis kit demonstrated **good positive % agreement** with the ANCA IFA method.

BioPlex™ 2200 Vasculitis vs. EIA Methods

	Combined BioPlex™ 2200 Anti-MPO/Anti-PR3 Results		Combined Anti-MPO/Anti-PR3 EIA Results	
	Positive % Agreement	Overall % Agreement	Positive % Agreement	Overall % Agreement
Combined p-/c-ANCA IFA Results	94.1% (176/187)	88.5% (177/200)	88.2% (165/187)	83.0% (166/200)

For the 200 retrospective positive samples described above, a combined positive agreement of 94.1% was observed between BioPlex™ 2200 Vasculitis anti-MPO/anti-PR3 and ANCA IFA results, compared to a combined positive agreement of 88.2% between anti-MPO/anti-PR3 EIA and ANCA IFA results. Also, a combined overall agreement with ANCA IFA results of 88.5% and 83.0% was observed between BioPlex™ 2200 and EIA results, respectively. Overall, the BioPlex™ 2200 Vasculitis kit demonstrated better concordance with ANCA IFA than the corresponding EIA methods.

Reproducibility

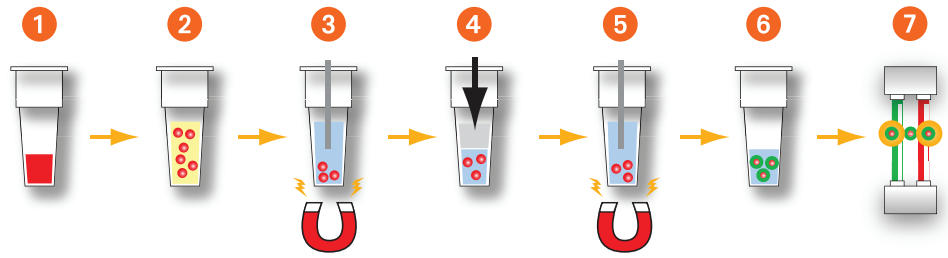
Positive Control	Sample (N)	Grand Mean AI	Within-Run		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV
Anti-MPO	36	2.9	0.198	6.8%	0.000	0.0%	0.223	7.7%
Anti-PR3	36	2.3	0.134	5.8%	0.000	0.0%	0.167	7.3%
Anti-GBM	36	2.8	0.139	4.9%	0.000	0.0%	0.153	5.4%

Following CLSI (formerly NCCLS) EP5-A2 guidelines and ISO/TR 22971:2005, two (2) US testing sites and an internal site performed reproducibility testing using the BioPlex™ 2200 Vasculitis positive control for 3 days with a total of 36 replicates. The overall performance demonstrated **excellent reproducibility** ranging from 0.0% - 7.7%.

The low %CV's on the BioPlex™ 2200 Vasculitis kit can be attributed to:

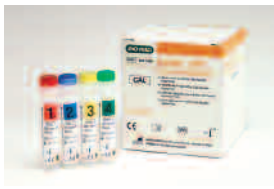
- Full automation
- Magnetic bead, heterogeneous assay format
- A minimum of 150 measurements per analyte per reaction vessel (up to 3 times more than other multiplex methods)

Vasculitis Assay Procedure

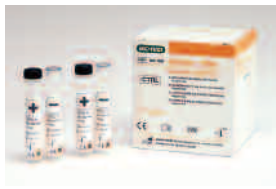


1. Patient sample (5 µL) automatically added to reaction vessel
2. Sample diluent & beads (dilution 1:20) added and incubated at 37°C
3. Wash step
4. Conjugate added and incubated at 37°C
5. Wash step
6. Bead resuspended in wash buffer
7. Flow-based, dual laser detection

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



Vasculitis Calibrator Set
Calibrators are ready-to-use and multiplexed. A point-to-point curve fit, using four calibrators, is used to calculate semi-quantitative results.



Vasculitis Control Set
Quality Controls are ready-to-use and multiplexed. The set includes a negative control as well as a multi-analyte positive control containing antibodies present for analytes within the Reagent Pack.

Ordering Information

Catalog No.	Description
BioPlex™ 2200 Vasculitis	
665-1850	Vasculitis Reagent Pack .....1 pack
663-1800	Vasculitis Calibrator Set.....1 set
663-1830	Vasculitis 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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Clinical Diagnostics Group

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