



# BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgG, IgM and IgA Kits

**Unparalleled automation for the simultaneous detection of multiple APS antibodies.**

The first and only fully-automated, random access, multiplex platform that offers the highest throughput testing for the accurate and timely diagnosis of primary and secondary Antiphospholipid Syndrome (APS).

The combination of multiplex technology, excellent diagnostic accuracy and seamless automation make the BioPlex® 2200 System a useful and practical tool for the laboratory diagnosis of APS.

**BIO-RAD**



# Like no other

The BioPlex® 2200 System offers the highest throughput for consolidated testing of the first-line serological assays, as recommended in the laboratory criteria for diagnosis of APS<sup>1</sup> – anti-Cardiolipin (aCL) IgG and IgM and anti-Beta 2 Glycoprotein I (aβ2GPI) IgG and IgM.

This high level of automation provides the flexibility and improved workflow to consolidate testing of second-line assays that are frequently detected in specific patient subgroups<sup>1</sup> – aCL IgA and aβ2GPI IgA.

Generating a full profile of clinically relevant APS antibodies facilitates identification of patients with multiple APS autoantibody positivity which is associated with a higher risk of thrombosis.<sup>1</sup>

## BioPlex® 2200 APLS kits report results for the following analytes:

- APLS IgG Kit
  - aCL IgG
  - aβ2GPI IgG
- APLS IgM Kit
  - aCL IgM
  - aβ2GPI IgM
- APLS IgA Kit
  - aCL IgA
  - aβ2GPI IgA

# Excellent Diagnostic Accuracy

## Minimize misdiagnosis of APS and inappropriate anti-coagulation treatment

- BioPlex® 2200 APLS IgG, IgM and IgA assays demonstrate a specificity of  $\geq 96\%$  (range 96% - 99%)
- Assay cutoff set at the 99th percentile of a healthy, normal population (as recommended by Miyakis et al.<sup>1</sup>), providing a low incidence of false positive results

Assay	Clinical Cohort	BioPlex® 2200 System		Predicate EIA	
		Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
aCL IgG	302 APS, 202 non-APS Disease Controls, 300 Healthy Blood Donors	65.7%	<b>98.5%</b>	69.6%	89.1%
aβ2GPI IgG		65.0%	<b>99.0%</b>	66.8%	99.0%
aCL IgM	199 APS, 346 Non-APS Disease Controls	33.7%	<b>96.8%</b>	40.2%	92.8%
aβ2GPI IgM		40.2%	<b>96.0%</b>	35.7%	96.5%
aCL IgA	302 APS, 202 Non-APS Disease Controls, 300 Healthy Blood Donors	55.3%	<b>96.5%</b>	23.5%	97.0%
aβ2GPI IgA		52.0%	<b>97.0%</b>	68.9%	87.1%

# Reliable Results

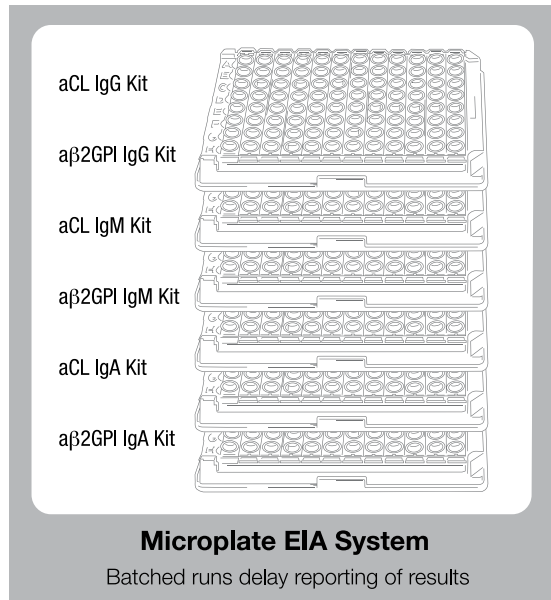
## Increased confidence in results with extensive quality assurance and consistent lot-to-lot reproducibility

- 3 internal quality control beads are processed with each sample ensuring integrity of the assay system and improving confidence in results
  - Serum Verification Bead (SVB) – confirms presence of serum or plasma
  - Internal Standard Bead (ISB) – standardizes detector performance
  - Reagent Blank Bead (RBB) – identifies sample problems association with non-specific binding
- Multiple measurements per analyte (at least 150) provide excellent precision with low %CV's ranging from 1.8% to 10.7%

BioPlex® 2200 APLS	Within-Run % CV	Between-Run % CV	Total % CV
aCL IgG	1.4 – 6.3%	0.0 – 4.5%	2.4 – 6.8%
aβ2GPI IgG	1.3 – 6.3%	0.0 – 4.8%	1.8 – 6.4%
aCL IgM	3.5 – 8.1%	0.0 – 7.1%	5.7 – 10.7%
aβ2GPI IgM	4.7 – 8.3%	0.0 – 6.5%	5.7 – 10.1%
aCL IgA	2.2 – 6.4%	0.0 – 3.9%	2.9 – 7.5%
aβ2GPI IgA	2.2 – 6.0%	0.0 – 2.9%	2.5 – 6.0%

# Enhanced Efficiency and Workflow

**The BioPlex® 2200 APLS test system provides improved results reporting and lean laboratory workflow**



**vs.**



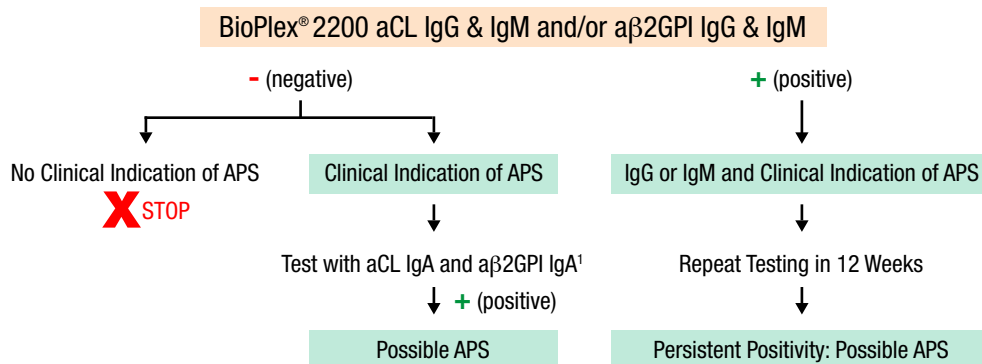
## Experience the benefits of multiplex testing

- Improve workflow with simultaneous detection of multiple antibodies
- Reduce reagent kit inventory with 2 analytes per kit
- Provide more test results with less sample volume using one small 5 µL sample per kit

## Realize the benefits of full automation and random access

- Eliminate batch runs with random access capabilities on the BioPlex® 2200 System
- Achieve faster turnaround time with up to 200 results per hour
- Eliminate the need for daily calibration with a 30-day calibration curve
- Improve laboratory efficiency with on-board refrigerated reagents
- Perform immediate sample processing with serum or plasma tube types

# Customize Your APS Algorithm with the BioPlex® 2200 Test Menu



- Increase the amount of patient information rapidly available to the clinician by parallel detection of aCL and aβ2GPI antibodies
- Facilitate identification of patients with a higher risk of thrombosis through multi-marker positivity

## BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgG, IgM and IgA Kits



### APLS IgG, IgM and IgA Reagent Packs

Each reagent pack contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples and up to 2 results per sample.



### APLS IgG, IgM and IgA Calibrator Sets

Calibrators are ready to use. A point-to-point curve fit, using four calibrators (two calibrators for APLS IgA), is used to calculate semi-quantitative results.



### APLS IgG, IgM and IgA Control Sets

Quality Controls are ready to use. Each bi-level set includes a negative control as well as a positive control for each aCL and aβ2GPI analyte.

1. Miyakis S. et al. International Consensus Statement On An Update of the Classification Criteria for Definite Antiphospholipid Syndrome (APS). J Thromb Haemost. 2006;4: 295-306.



# Experience better laboratory workflow & optimal performance with BioPlex® 2200 APLS assays



## Ordering Information

665-1950	BioPlex® 2200 APLS IgG Reagent Pack, 100 Samples . . . . .	1 pack
663-1900	BioPlex® 2200 APLS IgG Calibrator Set. . . . .	1 set
663-1930	BioPlex® 2200 APLS IgG Control Set . . . . .	2 sets
665-2050	BioPlex® 2200 APLS IgM Reagent Pack, 100 Samples . . . . .	1 pack
663-2000	BioPlex® 2200 APLS IgM Calibrator Set . . . . .	1 set
663-2030	BioPlex® 2200 APLS IgM Control Set . . . . .	2 sets
665-2150	BioPlex® 2200 APLS IgA Reagent Pack, 100 Samples . . . . .	1 pack
663-2100	BioPlex® 2200 APLS IgA Calibrator Set . . . . .	1 set
663-2130	BioPlex® 2200 APLS IgA 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](http://www.bio-rad.com/diagnostics)*

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