# BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgM 510(k) Summary

Bio-Rad Laboratories hereby submits this 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This summary of 510(k) safety and effectiveness information provides detail as a basis for a determination of substantial equivalence for the BioPlex® 2200 APLS IgM kit.

**510(k) Number:**
K130528

**Summary Preparation Date:**
October 18, 2013

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**Applicant:**
Bio-Rad Laboratories

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**Purpose for Submission:**
New Device

**Measurand:**
IgM antibodies to Cardiolipin (CL)
IgM antibodies to Beta-2-Glycoprotien I (β2GPI)

**Type of Test:**
Semi-Quantitative multiplexed flow, bead-based immunoassay

**Proprietary and Established Names:**
BioPlex® 2200 APLS IgM kit
BioPlex® 2200 APLS IgM Calibrator Set
BioPlex® 2200 APLS IgM Control Set

**Regulatory Information:**

1. Regulation section:
   21 CFR §866.5660 – Multiple autoantibodies immunological test system
   21 CFR §862.1150 – Calibrator
   21 CFR §862.1660 – Quality Control Material (assayed and unassayed)

2. Classification:
   Class II (Assays, Calibrator)
   Class I (Controls)

3. Product code:
   MID, System Test, Anti-Cardiolipin Immunological
   MSV, Antibodies, β2- Glycoprotein I (β2-GPI)
   JIX, Calibrator, Multi-Analyte Mixture
   JJX, Single (specified) Analyte Controls (Assayed and Unassayed)

4. Panel:
   Immunology (82) (Assays)
   Chemistry (75) (Controls)

**Intended Use:**

1. Intended use(s):

   The BioPlex®2200 Antiphospholipid Syndrome (APLS) IgM kit is a multiplex flow immunoassay intended for the semi-quantitative detection of IgM antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (β2GPI) in human serum and plasma (lithium heparin, sodium heparin, and sodium citrate). In conjunction with clinical findings, the test system is used as an aid in the diagnosis of primary Antiphospholipid Syndrome (APS) and those secondary to systemic lupus erythematosus (SLE) or SLE-like disorders.

   The BioPlex 2200 APLS IgM kit is intended for use with the Bio-Rad BioPlex 2200 System.

   The BioPlex 2200 Antiphospholipid Syndrome (APLS) IgM Calibrator Set is intended for the calibration of the corresponding BioPlex 2200 APLS IgM Reagent Pack.

   The BioPlex 2200 Antiphospholipid Syndrome (APLS) IgM Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and the corresponding BioPlex 2200 APLS IgM Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 APLS IgM Control Set has not been established with any other Antiphospholipid assay.

2. Indication(s) for use:
Same as Intended Use

3. Special conditions for use statement(s):
For prescription use only

4. Special instrument requirements:
Bio-Rad BioPlex® 2200 System

**Device Description:**

BioPlex® 2200 APLS IgM kit includes the following components:

- One (1) 10 mL vial of Bead Set containing two different populations of dyed beads coated with Cardiolipin (CL) and Beta-2-Glycoprotein I (ß2GPI), an Internal Standard bead (ISB), a Serum Verification bead (SVB), and a Reagent Blank bead (RBB) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with glycerol and protein stabilizers (porcine), and ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives.
- One (1) 5 mL vial of Conjugate containing phycoerythrin conjugated murine monoclonal anti-human IgM and phycoerythrin conjugated murine monoclonal anti-human FXIII in MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with protein stabilizers (bovine), and ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives.
- One (1) 10 mL vial of Sample Diluent containing buffer with protein stabilizers (bovine and murine), and ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives.

BioPlex® 2200 APLS IgM Calibrator set contains seven 0.5 mL vials of human antibodies to CL or ß2GPI in a human serum matrix made from defibrinated plasma with ProClin 300 (≤ 0.3%), sodium benzoate (< 0.1%) and sodium azide (< 0.1%) as preservatives.

BioPlex® 2200 APLS IgM Control set contains four 1.5-mL vials of Positive controls of human antibodies to CL or ß2GPI and two vials of Negative Controls in a human serum matrix made from defibrinated plasma; and, in a human serum matrix made from defibrinated plasma with ProClin 300 (≤ 0.3%), sodium benzoate (≤ 0.1%) and sodium azide (< 0.1%) as preservatives.

Additional materials required but not supplied include BioPlex® 2200 Sheath Fluid containing Phosphate Buffered Saline (PBS) with ProClin® 300 (0.03%) and sodium azide (<0.1%) as preservatives; and BioPlex® 2200 Wash Solution containing Phosphate Buffered Saline (PBS) and Tween 20 with ProClin® 300 (<0.03%) and sodium azide (<0.1%) as preservatives.

**Substantial Equivalence Information:**

1. Predicate device name(s):
   HemosIL AcuStar anti-Cardiolipin IgM, k092181
   HemosIL AcuStar anti-β2 Glycoprotein-I IgM, k091556

2. Comparison with predicate:

| Similarities | | | |
|---|---|---|---|
| Item | Device: BioPlex 2200 APLS IgM Kit | Predicate: HemosIL Acustar anti-Cardiolipin IgM Kit | Predicate: HemosIL Acustar anti-ß2GPI IgM Kit |
| Intended Use | Semi-quantitative detection of IgM antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (ß2GPI) in human serum and plasma as an aid in the diagnosis of primary Antiphospholipid Syndrome (APS) and those secondary to systemic lupus erythematosus (SLE) or SLE-like disorders | Semi-quantitative measurement of anti-Cardiolipin (aCL) IgM antibodies in human citrated plasma or serum on the ACL AcuStar, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) | Semi-quantitative measurement of Anti-ß2 Glycoprotein-I (Anti-ß2GPI) IgM antibodies in human plasma or serum on the ACL AcuStar, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) |
| Sample Type | Serum or plasma (lithium heparin, sodium heparin, and sodium citrate) | Serum or citrated plasma | Serum or citrated plasma |
| Assay Type | Semi-quantitative | Same | Same |
| Analyte Detected | Human IgM antibodies to Cardiolipin | Same | Not Applicable |
| | Human IgM antibodies to ß2GPI | Not Applicable | Same |
| Capture Antigen | Cardiolipin | Same | Not Applicable |
| | Human β2GPI | ß2GPI | Same |
| Controls | Two Levels | Same | Same |

| Differences | | | |
|---|---|---|---|
| Item | Device:<br>BioPlex 2200 APLS IgM Kit | Predicate:<br>HemosIL Acustar anti-Cardiolipin IgM Kit | Predicate:<br>HemosIL Acustar anti-ß2GPI IgM Kit |
| Assay Technology | Automated multiplex flow immunoassay | Two-step chemiluminescent immunoassay | Two-step chemiluminescent immunoassay |
| Conjugate Antibody | Phycoerythrin conjugated murine monoclonal anti-human IgM | Isoluminol-labeled anti-human IgM antibody | Isoluminol-labeled anti-human IgM antibody |
| Signal Detection | Fluorescence | Chemiluminescent | Chemiluminescent |
| Solid Phase | Antigen-coated paramagnetic microbead reagent | Antigen-coated magnetic particles | Antigen-coated magnetic particles |
| Calibrator(s) | 4 calibrator levels (sold separately) | Two calibrator levels (included in test kit) | Two calibrator levels (included in test kit) |
| Control | One negative and one positive control (Sold separately) | One low and one high control (Sold separately) | One low and one high controls (Sold separately) |
| Assay range | Anti-Cardiolipin:<br>0.2 – 112 MPL-U/mL | 1.0 – 15480 U/mL | Not Applicable |
| | Anti-Beta-2-Glycoprotein:<br>0.2 – 112 U/mL | Not Applicable | 1.1 – 16820 U/mL |
| Quantitation | Results are determined from a standard calibration curve utilizing a point-to-point curve fitting. | Assay utilizes a stored Master 4 Parameter Logistic Curve (4PLC) fit adjusted with two lot dependent calibrator levels | Assay utilizes a stored Master 4 Parameter Logistic Curve (4PLC) fit adjusted with two lot dependent calibrator levels |
| Instrumentation | Bio-Rad BioPlex 2200 system | HemosIL AcuStar | HemosIL AcuStar |

**Standard/Guidance Document Referenced (if applicable):**

CEN 13640:2002, Stability Testing of In Vitro Diagnostic Reagents

EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition.

EP06-A, Evaluation of Linearity of Quantitative Measurement, Approved Guideline, Second Edition.

EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline, Second Edition

EP09-A2IR, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Second Edition (Interim Revision) (used for matrix comparison).

EP12-A2, User Protocol for Evaluation of Qualitative test Performance, Approved Guideline, Second Edition.
EP14-A2, Evaluation of Matrix Effects, Approved Guideline, Second Edition
EP15-A2, User Verification of Performance for Precision and Trueness, Approved Guideline, Second Edition.
EP17-A, Protocols for Determination of Limits of Detection and Limits of Quantification. Approved Guideline.

**Test Principle:**

**L. Test Principle:**

The BioPlex® 2200 APLS IgM kit uses multiplex flow immunoassay, a methodology similar to traditional EIA; however, this method permits simultaneous detection and identification of many antibodies in a single tube. In the BioPlex APLS assays, two different populations of dyed beads are coated with antigens. One bead population is coated with β2-glycoprotein I and a second population is coated with both Cardiolipin and β2-glycoprotein I. Three additional populations of fluorescent beads function as assay controls. The system combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel and incubates the mixture at 37°C. After a wash cycle to remove unbound antibody, the secondary conjugate containing either phycoerythrin conjugated murine monoclonal anti-human IgM and phycoerythrin conjugated murine monoclonal anti-human FXIII antibody (a control) is added and the mixture is incubated at 37°C. Excess conjugate is removed in another wash cycle and the beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached phycoerythrin. Raw data are calculated in relative fluorescence intensity (RFI).
Three additional dyed beads, Internal Standard Bead (ISB), Serum Verification Bead (SVB), and a Reagent Blank Bead (RBB) are present in each reaction mixture to verify detector response, the addition of serum to the reaction vessel, and the absence of significant non-specific binding in serum or plasma, respectively.

The anti-phospholipid assays are calibrated using a set of calibrators supplied separately by Bio-Rad Laboratories. Results are calculated for both of the antibodies and are compared against their own respective cut-off. For anti-β2-glycoprotein I, the results are provided in units/mL (U/mL). The results are similar except that the unit is MPL-U/mL for the IgM assay. The negative/positive assay cutoff for two analytes (anti-β2-glycoprotein I and anti-Cardiolipin IgM) of the BioPlex® 2200 APLS IgM kit is 20 units.

**Performance Characteristics (if/when applicable):**

1. Analytical performance:

   a. *Precision/Reproducibility:*
   Precision testing of the BioPlex® 2200 APLS IgM kit on the BioPlex® 2200 instrument was performed in accordance with CLSI EP5-A2. Two serum and heparnized plasma panels consisting of samples spanning the measuring range were assayed in replicate twice daily over 20 days (n=80) except for the mid negative samples were run over 10 days (n=40). One positive and one negative

control were included. The data were analyzed for within-run, between-run, between-day, and total precision and the mean, standard deviation and percent coefficient of variation are summarized below:

**BioPlex® 2200 APLS IgM – Anti-Cardiolipin: Serum Samples**

| Precision Sample | N | Mean MPL-U/mL | Within Run | | Between Run | | Between Day | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Mid Negative | 40 | 6.1 | 0.2 | 3.0% | 0.1 | 1.6% | 0.1 | 1.5% | 0.2 | 3.7% |
| Mid Negative | 40 | 6.9 | 0.2 | 2.8% | 0.1 | 1.6% | 0.0 | 0.0% | 0.2 | 3.2% |
| Mid Negative | 40 | 9.1 | 0.3 | 2.8% | 0.2 | 2.1% | 0.0 | 0.0% | 0.3 | 3.5% |
| Mid Negative | 40 | 10.7 | 0.4 | 3.3% | 0.1 | 1.1% | 0.1 | 1.0% | 0.4 | 3.6% |
| Negative Near Cutoff | 80 | 14.5 | 0.8 | 5.3% | 0.5 | 3.6% | 0.6 | 3.8% | 1.1 | 7.4% |
| Negative Near Cutoff | 80 | 15.6 | 0.9 | 6.0% | 0.2 | 1.1% | 0.1 | 0.4% | 1.0 | 6.1% |
| Near Cut-Off | 80 | 17.5 | 1.1 | 6.3% | 0.2 | 1.0% | 0.8 | 4.5% | 1.4 | 7.9% |
| Near Cut-Off | 80 | 19.6 | 1.3 | 6.4% | 0.4 | 2.1% | 0.9 | 4.3% | 1.6 | 8.0% |
| Low Positive | 80 | 22.6 | 1.0 | 4.5% | 0.8 | 3.5% | 1.0 | 4.6% | 1.7 | 7.3% |
| Low Positive | 80 | 22.7 | 1.3 | 5.7% | 0.8 | 3.4% | 1.1 | 4.8% | 1.9 | 8.2% |
| High Positive | 80 | 73.6 | 5.5 | 7.5% | 1.5 | 2.1% | 1.8 | 2.4% | 6.0 | 8.1% |
| High Positive | 80 | 79.1 | 3.7 | 4.7% | 0.0 | 0.0% | 2.1 | 2.7% | 4.3 | 5.4% |
| Pos. Control | 80 | 62.9 | 2.3 | 3.7% | 1.9 | 3.0% | 1.2 | 2.0% | 3.2 | 5.2% |

**BioPlex® 2200 APLS IgM – Anti-Cardiolipin: Heparin Sample**

| Precision Sample | N | Mean MPL-U/mL | Within Run | | Between Run | | Between Day | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Mid Negative | 40 | 6.8 | 0.2 | 2.7% | 0.1 | 2.1% | 0.0 | 0.7% | 0.2 | 3.4% |
| Mid Negative | 40 | 7.4 | 0.2 | 3.0% | 0.1 | 1.3% | 0.1 | 1.4% | 0.3 | 3.6% |
| Mid Negative | 40 | 10.4 | 0.3 | 3.1% | 0.3 | 2.5% | 0.0 | 0.0% | 0.4 | 4.0% |
| Mid Negative | 40 | 10.7 | 0.3 | 2.8% | 0.0 | 0.0% | 0.2 | 2.1% | 0.4 | 3.5% |
| Negative Near Cutoff | 80 | 13.6 | 0.6 | 4.6% | 0.2 | 1.6% | 0.4 | 3.2% | 0.8 | 5.8% |
| Negative Near Cutoff | 80 | 14.0 | 0.8 | 5.4% | 0.2 | 1.3% | 0.6 | 4.4% | 1.0 | 7.1% |
| Near Cut-Off | 80 | 18.2 | 1.0 | 5.3% | 0.7 | 3.9% | 0.2 | 1.1% | 1.2 | 6.7% |
| Near Cut-Off | 80 | 19.0 | 1.3 | 6.9% | 0.3 | 1.3% | 0.6 | 3.0% | 1.4 | 7.6% |
| Low Positive | 80 | 21.5 | 1.3 | 6.1% | 0.4 | 1.8% | 0.0 | 0.0% | 1.4 | 6.3% |
| Low Positive | 80 | 23.4 | 0.8 | 3.4% | 0.7 | 2.8% | 0.9 | 3.9% | 1.4 | 5.9% |
| High Positive | 80 | 72.7 | 3.2 | 4.4% | 1.4 | 1.9% | 2.1 | 2.9% | 4.1 | 5.6% |
| High Positive | 80 | 72.8 | 2.8 | 3.8% | 2.2 | 3.1% | 0.0 | 0.0% | 3.6 | 4.9% |

**BioPlex® 2200 APLS IgM – Anti- ß2GPI: Serum Samples**

| Precision Sample | N | Mean U/mL | Within Run | | Between Run | | Between Day | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Mid Negative | 40 | 8.8 | 0.3 | 3.0% | 0.1 | 0.7% | 0.0 | 0.0% | 0.3 | 3.1% |
| Mid Negative | 40 | 9.0 | 0.3 | 3.1% | 0.3 | 2.8% | 0.0 | 0.0% | 0.4 | 4.2% |
| Mid Negative | 40 | 12.8 | 0.5 | 3.5% | 0.4 | 2.9% | 0.0 | 0.0% | 0.6 | 4.6% |
| Mid Negative | 40 | 15.4 | 0.6 | 4.1% | 0.2 | 1.2% | 0.3 | 1.7% | 0.7 | 4.6% |
| Negative Near Cutoff | 80 | 17.4 | 0.6 | 3.3% | 0.2 | 1.3% | 0.1 | 0.7% | 0.6 | 3.7% |
| Negative Near Cutoff | 80 | 17.7 | 0.7 | 3.8% | 0.4 | 2.1% | 0.4 | 2.1% | 0.9 | 4.8% |
| Near Cut-Off | 80 | 20.6 | 0.9 | 4.2% | 0.0 | 0.0% | 0.5 | 2.6% | 1.0 | 4.9% |
| Near Cut-Off | 80 | 21.4 | 0.8 | 3.6% | 0.4 | 2.0% | 0.6 | 2.7% | 1.1 | 4.9% |
| Low Positive | 80 | 23.5 | 0.7 | 3.1% | 0.7 | 2.7% | 0.7 | 2.9% | 1.2 | 5.1% |
| Low Positive | 80 | 23.5 | 0.9 | 3.9% | 0.5 | 2.0% | 0.9 | 3.7% | 1.4 | 5.8% |
| High Positive | 80 | 79.5 | 5.7 | 7.2% | 2.5 | 3.2% | 1.1 | 1.4% | 6.3 | 8.0% |
| High Positive | 80 | 85.5 | 3.9 | 4.6% | 0.0 | 0.0% | 2.0 | 2.4% | 4.4 | 5.2% |
| Pos. Control | 80 | 52.1 | 2.3 | 4.4% | 1.7 | 3.2% | 1.4 | 2.7% | 3.2 | 6.0% |

**BioPlex® 2200 APLS IgM – Anti- ß2GPI: Heparin Samples**

| Precision Sample | N | Mean U/mL | Within Run | | Between Run | | Between Day | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Mid Negative | 40 | 8.4 | 0.3 | 3.1% | 0.2 | 1.8% | 0.0 | 0.3% | 0.3 | 3.7% |
| Mid Negative | 40 | 8.6 | 0.3 | 3.3% | 0.1 | 1.5% | 0.1 | 1.0% | 0.3 | 3.8% |
| Mid Negative | 40 | 12.2 | 0.5 | 3.7% | 0.3 | 2.7% | 0.0 | 0.0% | 0.6 | 4.6% |
| Mid Negative | 40 | 13.1 | 0.4 | 2.8% | 0.0 | 0.0% | 0.2 | 1.5% | 0.4 | 3.2% |
| Negative Near Cutoff | 80 | 16.8 | 0.5 | 3.0% | 0.2 | 1.4% | 0.4 | 2.5% | 0.7 | 4.2% |
| Negative Near Cutoff | 80 | 17.0 | 0.7 | 3.9% | 0.0 | 0.0% | 0.5 | 2.7% | 0.8 | 4.7% |
| Near Cut-Off | 80 | 20.3 | 0.6 | 3.0% | 0.6 | 2.9% | 0.0 | 0.2% | 0.9 | 4.2% |
| Near Cut-Off | 80 | 20.9 | 0.8 | 3.9% | 0.0 | 0.0% | 0.5 | 2.3% | 0.9 | 4.5% |
| Low Positive | 80 | 23.3 | 0.9 | 3.9% | 0.3 | 1.1% | 0.0 | 0.0% | 1.0 | 4.1% |
| Low Positive | 80 | 24.0 | 0.6 | 2.4% | 0.4 | 1.7% | 0.6 | 2.6% | 0.9 | 3.9% |
| High Positive | 80 | 78.6 | 2.9 | 3.7% | 2.3 | 2.9% | 0.0 | 0.0% | 3.7 | 4.7% |
| High Positive | 80 | 79.0 | 3.5 | 4.5% | 1.5 | 1.9% | 1.4 | 1.8% | 4.1 | 5.2% |

CLSI EP15-A2 Reproducibility

Precision and reproducibility was also evaluated in accordance with CLSI EP15-A2 guideline "User Verification of Performance for Precision and Trueness, Vol 25, No 17".

A different serum panel consisting of samples spanning the measuring range were assayed in 4 replicates per run, one run per day over 5 days (n=20). One positive and one negative control were included. The data were analyzed for within-run, between run (day), and total precision and the mean U/mL, standard deviation and percent coefficient of variation are summarized below:

**BioPlex® 2200 APLS IgM – Anti- Cardiolipin: Serum Samples**

| Panel Member | N | Mean | Within Run | | Between Run | | Total | |
|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV |
| Negative 1 | 20 | 12.2 | 0.42 | 3.5 % | 0.55 | 4.5 % | 0.69 | 5.7 % |
| Negative 2 | 20 | 14.7 | 0.87 | 5.9 % | 1.01 | 6.9 % | 1.34 | 9.1 % |
| Near Cutoff 1 | 20 | 17.8 | 1.43 | 8.0 % | 1.26 | 7.1 % | 1.91 | 10.7 % |
| Near Cutoff 2 | 20 | 19.6 | 0.90 | 4.6 % | 0.77 | 3.9 % | 1.18 | 6.0 % |
| Low positive 1 | 20 | 35.0 | 2.84 | 8.1 % | 1.02 | 2.9 % | 3.01 | 8.6 % |
| Low positive 2 | 20 | 41.1 | 2.50 | 6.1 % | 1.45 | 3.5 % | 2.89 | 7.0 % |
| High Positive 1 | 20 | 64.6 | 3.43 | 5.3 % | 2.30 | 3.6 % | 4.13 | 6.4 % |
| High Positive 2 | 20 | 73.9 | 5.71 | 7.7 % | 0.00 | 0.0 % | 5.71 | 7.7 % |
| Negative Control | 20 | <0.2 | N/A | | | | | |
| Positive Control | 20 | 43.7 | 2.67 | 6.1 % | 0.00 | 0.0 % | 2.67 | 6.1 % |

**BioPlex® 2200 APLS IgM – Anti- ß2GPI: Serum Samples**

| Panel Member | N | Mean | Within run | | Between Run | | Total | |
|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV |
| Negative 1 | 20 | 12.2 | 0.58 | 4.7 % | 0.73 | 5.9 % | 0.93 | 7.6 % |
| Negative 2 | 20 | 17.5 | 0.85 | 4.9 % | 0.62 | 3.6 % | 1.05 | 6.0 % |
| Near Cutoff 1 | 20 | 18.5 | 1.11 | 6.0 % | 1.07 | 5.8 % | 1.54 | 8.3 % |
| Near Cutoff 2 | 20 | 22.2 | 1.73 | 7.8 % | 1.44 | 6.5 % | 2.25 | 10.1 % |
| Low positive 1 | 20 | 52.8 | 4.36 | 8.3 % | 0.00 | 0.0 % | 4.36 | 8.3 % |
| Low positive 2 | 20 | 53.4 | 3.16 | 5.9 % | 1.62 | 3.0 % | 3.55 | 6.7 % |
| High Positive 1 | 20 | 92.9 | 6.74 | 7.3 % | 0.00 | 0.0 % | 6.74 | 7.3 % |
| High Positive 2 | 20 | 96.2 | 5.30 | 5.5 % | 1.52 | 1.6 % | 5.51 | 5.7 % |
| Negative Control | 20 | <0.2 | N/A | | | | | |
| Positive Control | 20 | 55.6 | 3.24 | 5.8 % | 0.00 | 0.0 % | 3.24 | 5.8 % |

Lot-to-lot Reproducibility

The lot-to-lot reproducibility study was conducted to evaluate the variation among the lots of the reagent kit. Serum samples spanning the assay range were tested with three reagent lots on three BioPlex 2200 instruments in replicates of 10 for two runs.

Each lot mean (MPL-U/mL for aCL IgM and U /mL for aß2GPI IgM) was calculated using data 60 points for each patient serum sample (ten replicates, three instruments, two runs per instrument). The lot to lot grand mean (U/mL), standard deviation and %CV were calculated for each of the samples.

**Anti- Cardiolipin** IgM: Lot-to-Lot Reproducibility

| Accession | Mean MPL-U/mL | # Runs per Day | # Days | Within Run | | Between Run | | Between Instrument | | Between Lot | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| APSQSM03 | 15.0 | 1 | 2 | 0.42 | 2.8 | 0.42 | 2.8 | 0.00 | 0.0 | 0.59 | 3.9 | 0.84 | 5.6 |
| APSQSM04 | 14.6 | 1 | 2 | 0.46 | 3.1 | 0.59 | 4.0 | 0.00 | 0.0 | 1.55 | 10.6 | 1.72 | 11.8 |
| APSQSM06 | 23.6 | 1 | 2 | 0.73 | 3.1 | 0.78 | 3.3 | 0.00 | 0.0 | 1.31 | 5.6 | 1.69 | 7.2 |
| APSQSM07 | 26.2 | 1 | 2 | 0.86 | 3.3 | 0.60 | 2.3 | 0.00 | 0.0 | 1.50 | 5.7 | 1.83 | 7.0 |
| APSQSM14 | 91.9 | 1 | 2 | 3.40 | 3.7 | 2.63 | 2.9 | 0.00 | 0.0 | 2.73 | 3.0 | 5.09 | 5.5 |

**Anti- ß2GPI** IgM: Lot-to-Lot Reproducibility

| Accession | Mean U/mL | # Runs per Day | # Days | Within Run | | Between Run | | Between Instrument | | Between Lot | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| APSQSM03 | 16.5 | 1 | 2 | 0.51 | 3.1 | 0.38 | 2.3 | 0.00 | 0.0 | 0.92 | 5.6 | 1.12 | 6.8 |
| APSQSM04 | 18.6 | 1 | 2 | 0.65 | 3.5 | 0.74 | 4.0 | 0.00 | 0.0 | 2.44 | 13.1 | 2.63 | 14.1 |
| APSQSM06 | 22.9 | 1 | 2 | 0.72 | 3.2 | 0.56 | 2.5 | 0.00 | 0.0 | 1.40 | 6.1 | 1.67 | 7.3 |
| APSQSM07 | 26.6 | 1 | 2 | 0.92 | 3.5 | 0.69 | 2.6 | 0.00 | 0.0 | 2.11 | 7.9 | 2.41 | 9.1 |
| APSQSM14 | 98.0 | 1 | 2 | 3.88 | 4.0 | 3.03 | 3.1 | 0.00 | 0.0 | 10.01 | 10.2 | 11.16 | 11.4 |

*b. Linearity/assay reportable range:*

Six aCL and aβ2GPI IgM positive patient samples were tested to demonstrate linearity. These samples were diluted with immunodepleted serum according to CLSI EP06-A. Each sample and dilution was evaluated in replicates of four using one APLS IgM lot on one instrument. Linear and polynomial regression analysis of APLS IgM recovery *vs.* sample dilution was performed to determine if the dilution curves exhibit statistically significant non-linear regression based on the CLSI guideline EP06-A.

The regression parameters (slope, intercept and r2) of the observed values vs. predicted values are show below.

| APLS IgM Assays | Sample | Conc. | Slope | Intercept | $r^2$ | Dilution range |
|---|---|---|---|---|---|---|
| Anti-Cardiolipin IgM (MPL-U/mL) | 1 | 49.5 | 1.0000 | -0.0010 | 0.9931 | 0.6 – 49.5 |
| | 2 | 57.4 | 1.0005 | -0.0117 | 0.9914 | 0.1 – 57.4 |
| | 3 | 54.1 | 0.9992 | 0.0184 | 0.9915 | 0.1 – 54.1 |
| | 4 | 93.9 | 0.9999 | 0.0174 | 0.9954 | 0.1 – 93.9 |
| | 5 | 92.3 | 0.9995 | 0.0203 | 0.9985 | 0.1 – 92.3 |
| | 6 | 100.0 | 0.9998 | 0.0226 | 0.9925 | 0.6 – 100.0 |
| Anti-β2GPI IgM (U/mL) | 1 | 54.2 | 0.9996 | 0.0099 | 0.9942 | 0.6 – 54.2 |
| | 2 | 49.9 | 1.0009 | -0.0319 | 0.9933 | 0.1 – 49.9 |
| | 3 | 53.1 | 0.9996 | 0.0089 | 0.9952 | 0.1 – 53.1 |
| | 4 | 92.5 | 0.9996 | 0.0167 | 0.9978 | 0.6 – 92.5 |
| | 5 | 111.1 | 0.9998 | 0.0258 | 0.9980 | 0.1 – 111.1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 6 | 100.3 | 1.0003 | -0.0275 | 0.9985 | 0.2 – 100.3 |

| BioPlex 2200 APLS IgM Assay | Assay reportable range |
|---|---|
| Anti-Cardiolipin IgM | 0.2 to 112 MPL-U/mL |
| Anti-β2GPI IgM | 0.2 to 112 U/mL |

Over-Range (OR) results may be generated for values greater than the reportable measuring range and results are reported as > 112 MPL-U/mL for aCL and > 112 U/mL for aβ2GPI IgM.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:
There is no international or certified reference material available for anti-CL and anti-β2GPI IgM. The calibrators are assigned relative arbitrary units (MPL-U/mL for aCL and U/mL for aβ2GPI).

Value Assignment:
The calibrators are manufactured independently from the controls, and are stabilized with ≤0.3% ProClin® 300, ≤0.1% sodium benzoate, and <0.1% sodium azide. Calibrator assignment is established for matched lots of BioPlex® 2200 APLS IgM kit and calibrators using a master set of calibrators as reference and replicate analyses on multiple BioPlex® 2200 instruments. The BioPlex® 2200 APLS IgM Reagent Kit is calibrated using a set of four (4) distinct calibrators for anti-Cardiolipin and anti-β2GPI IgM, which are used to establish points of reference for determining the presence of anti-Cardiolipin or anti-β2GPI IgM in human specimens.

The negative control has been tested to give results with values below the cut-off for each assay. The positive control is prepared by blending human disease state serum with negative serum matrix and is manufactured to give results with values above the assay cut-off. The positive controls are manufactured to give positive results, with values above the cut-off for each specific analyte. The negative control is manufactured to give negative results, with values below the cut-off for each specific analyte.

Stability:
Stability studies have been performed to support the following claims:

Calibrator and Control:
BioPlex® 2200 APLS IgM Control and Calibrator Sets: Calibrator Open Vial Stability (2 to 8°C), 30 days from first opening; Control Open Vial Stability (2 to 8°C), 60 days from first opening; Onboard Calibration Curve Stability, 30 days; Calibrators and Controls Real Time Stability (2 to 8°C), 24 months; labeled as until expiration date; Calibrators and Controls Accelerated Stability (2 to 8°C),

2.5 years predicted. Calibrators and Controls freeze-thaw (-20°C or -70°C), 5-freeze thaw cycles.

Kit Stability:
BioPlex® 2200 APLS IgM Kit: Real Time (unopened) Kit Stability, 24 months or until the date of expiration when stored unopened on the instrument or at 2 to 8°C; The Open kit claim is 60 days.

Sample Stability:
Sample stability studies were also performed: Sample stability fresh (2 to 8°C), 7 days; Sample stability frozen (-20 or -70°C), 24 months; Sample Freeze-thaw (-20 or -70°C), up to 3-freeze thaw cycles acceptable.

*d. Detection limit:*

The results of LoQ, LoD and LoB are summarized in the table below

| BioPlex® 2200 APLS IgM Assay | LoQ | LoD | LoB |
|---|---|---|---|
| Anti-Cardiolipin IgM (MPL-U/mL) | 0.2 | 0.13 | 0.0974 |
| Anti-β2GPI IgM (U/mL) | 0.2 | 0.13 | 0.1044 |

*e. Analytical specificity:*
An interfering substances study was conducted to evaluate the potential interference of specific endogenous and exogenous substances with the BioPlex® 2200 APLS IgM kit according to CLSI EP7-A2.
No interference was observed with any of the substances tested. The substances and the maximum levels tested are shown in the table below:

| **Substance** | **Concentration** |
|---|---|
| Hemoglobin | ≤500 mg/dL |
| Bilirubin (unconjugated) | ≤20 mg/dL |
| Bilirubin (conjugated) | ≤30 mg/dL |
| Triglycerides | ≤3300 mg/dL |
| Total Protein | ≤12 g/dL |
| Cholesterol | ≤500 mg/dL |
| Red Blood Cells | ≤0.4% (v/v) |
| Gamma-Globulin | ≤6 g/dL |
| Beta-Carotene | ≤0.6 mg/dL |
| Ascorbic Acid | ≤3 mg/dL |
| Heparin Lithium | ≤ 8000 units/dL |
| Heparin Sodium | ≤ 8000 units/dL |
| Sodium Citrate | ≤ 1000 mg/dL |

Cross-Reactivity:
A cross-reactivity study was performed to determine if samples from individuals with various disease states and other potentially interfering factors interfere with

test results from the BioPlex® 2200 APLS IgM kit. Samples from individuals with known disease states for potential cross reactivity listed in the table below were evaluated with the BioPlex® 2200 APLS IgM kit. The table below shows the number (N) of samples containing potential cross reactants as disease state evaluated by the BioPlex® APLS IgM kit. The cross reactivity was obtained as the positivity rate from the ratio of the number of samples scored positive by the BioPlex® APLS IgM assays to the total number of cross reactant samples evaluated.

| Cross Reactive Disease State | N | BioPlex 2200 APLS IgM | | | |
|---|---|---|---|---|---|
| | | Anti-CL IgM | | Anti-β2GPI IgM | |
| | | Pos (+) | % Positivity | Pos (+) | % Positivity |
| Systemic Lupus Erythematosus | 34 | 2 | 5.9% | 2 | 5.9% |
| Scleroderma | 20 | 3 | 15.0% | 3 | 15.0% |
| Sjogrens | 22 | 0 | 0% | 0 | 0% |
| Crohn's Disease | 21 | 2 | 9.5% | 2 | 9.5% |
| Ulcerative Colitis | 20 | 1 | 5.0% | 1 | 5.0% |
| Rheumatoid Arthritis | 12 | 1 | 8.3% | 1 | 8.3% |
| Syphilis | 15 | 0 | 0% | 0 | 0% |

High dose hook effect:
Not Applicable

*f. Assay cut-off:*

The cutoff value and assignment of the calibrators are determined by performing concordance testing and Receiver Operator Characteristic (ROC) analysis using the clinical diagnosis as the standard. The study to determine the APLS IgM assay cutoff is comprised of two sample groups – one clinical cohort has 103 samples from patients diagnosed as primary or secondary APS and 123 from non-APS or other rheumatic disease control donors. It was later confirmed by testing 208 samples from apparently healthy donors.

The cut-off was established to achieve a clinical specificity of 99% while accepting the resultant clinical sensitivity. The criteria for choosing a cutoff at the

99th percentile of a normal healthy population is derived from the "International Consensus Statement on an Update of the Classification Criteria for Definite Antiphospholipid Syndrome (APS)", *Journal of Thrombosis and Haemostasis (2006)4, 295-306.*

A cutoff of 20.0 MPL-U/mL for anti-CL IgM and 20 U/mL for anti- β2GPI IgM was established by optimizing for clinical specificity.

2. Comparison studies:

*a. Method comparison with predicate device:*
The performance of the BioPlex® 2200 APLS IgM kit was evaluated including 199 patients diagnosed with primary or secondary APS, 346 patients with other rheumatic or non-APS disease. Results in the measuring range and 10% of diluted total samples of both the new and the predicate immunoassays are compared. Results are summarized in the tables below:

BioPlex 2200 APLS IgM

| Diagnosed Primary and Secondary APS Patients and Non-APS Disease Patients | | Predicate IgM Kit (aCL: 1.0 – 15480 U/mL; aβ2GPI:1.1 – 16820 U/mL) | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| **aCL IgM (0.2 -112 MPL-U/mL)** | Positive | 77 | 1 | 78 |
| | Negative | 28 | 403 | 431 |
| | Total | 105 | 404 | 509 |
| **aβ2GPI IgM (0.2 – 112 U/mL)** | Positive | 79 | 15 | 94 |
| | Negative | 4 | 233 | 237 |
| | Total | 83 | 248 | 331 |

aCL IgM Positive Agreement (95% CI) = 73.3% (77/105) (64.2 – 80.9%)
aCL IgM Negative Agreement (95% CI) = 99.8% (403/404) (98.6 – 100%)
aCL IgM Total Agreement (95% CI) = 94.3% (480/509) (91.9 – 96.0%)
aβ2GPI IgM Positive Agreement (95% CI) = 95.2% (79/83) (88.3 – 98.1%)
aβ2GPI IgM Negative Agreement (95% CI) = 94.0% (233/248) (90.3 – 96.3%)
aβ2GPI IgM Total Agreement (95% CI) = 94.3% (312/331) (91.2 – 96.3%)

*b. Matrix comparison:*
Testing for matrix effects was conducted using 38 matched sets of serum, heparin, and citrate plasma samples drawn from the same donor in accordance with CLSI EP9-A2. The samples were spiked with aCL IgM or aβ2GPI IgM positive sera as necessary in order to assemble a panel of samples to cover the measuring range of the assay. All samples were evaluated in replicates of two. Plasma values were compared to matched serum values. Anticoagulants were

considered non-interfering if the linear regression of aCL IgM or aβ2GPI IgM values from matched serum *versus* plasma samples has a slope of 1.00 ± 0.2, a y-intercept of 0.0 ± 6.0 and a correlation coefficient (r) between 0.980 and 1.000. The regression correlation parameters for the slopes, intercepts and correlation coefficient (r) are summarized below.

| Comparison | N | BioPlex® APLS Assay | Slope (95% CI) | Intercept (95% CI) | r |
|---|---|---|---|---|---|
| Lithium Heparin vs. Serum | 38 | aCL IgM | 1.0106 (0.9808, 1.0405) | -0.3053 (-2.0421, 1.4315) | 0.9962 |
| | | aβ2GPI IgM | 0.9991 (0.9682, 1.0301) | 0.3054 (-1.5299, 2.1405) | 0.9958 |
| Sodium Heparin vs. Serum | 38 | aCL IgM | 1.0369 (0.9786, 1.0953) | -0.6412 (-4.0349, 2.7525) | 0.9864 |
| | | aβ2GPI IgM | 1.0271 (0.9750, 1.0779) | -0.2328 (-3.3212, 2.8555) | 0.9889 |
| Sodium Citrate vs. Serum | 38 | aCL IgM | 1.0494 (1.0190, 1.0779) | -0.9676 (-2.7381, 0.8029) | 0.9963 |
| | | aβ2GPI IgM | 1.0354 (1.0082, 1.0627) | -0.4738 (-2.0890, 1.1414) | 0.9970 |

3. Clinical studies:

*a. Clinical Sensitivity and specificity:*

The clinical studies involved testing 545 specimens including 199 diagnosed primary or secondary APS patients and 346 non-APS disease control patients. The BioPlex® 2200 APLS IgM sensitivity and specificity are shown below:

BioPlex 2200 APLS IgM

| Clinical Sensitivity and Specificity | | Clinical Diagnosis | | |
|---|---|---|---|---|
| | | Diagnosed with Primary or Secondary APS | Non-APS Disease Controls | Total |
| **aCL IgM** | Positive | 67 | 11 | 78 |
| | Negative | 132 | 335 | 467 |
| | Total | 199 | 346 | 545 |
| **aβ2GPI IgM** | Positive | 80 | 14 | 94 |
| | Negative | 119 | 332 | 451 |
| | Total | 199 | 346 | 545 |

aCL IgM Sensitivity (95% CI) = 33.7% (67/199) (27.5 – 40.5%)
aCL IgM Specificity (95% CI) = 96.8% (335/346) (94.4 – 98.2%)

aβ2GPI IgM Sensitivity (95% CI) = 40.2% (80/199) (33.6 – 47.1%)
aβ2GPI IgM Specificity (95% CI) = 96.0% (332/346) (93.3 – 97.6%)

The number of samples positive of the BioPlex APLS IgM assay in each of disease category are shown below.

| Disease Category | Number Enrolled | aCL IgM | aβ2GPI IgM |
|---|---|---|---|
| Apparently Healthy Subject | 300 | 7 | 3 |
| Primary APS (PAPS) | 123 | 43 | 50 |
| Secondary APS (SAPS) | 76 | 24 | 30 |
| Syphilis | 15 | 0 | 0 |
| Systemic Lupus Erythematosus | 101 | 4 | 5 |
| Rheumatoid Arthritis | 90 | 3 | 4 |
| Crohn's Disease | 21 | 1 | 1 |
| CREST | 3 | 0 | 0 |
| Fibromyalgia | 19 | 0 | 0 |
| Gout | 14 | 0 | 0 |
| Inflammatory Arthritis | 4 | 0 | 0 |
| Osteoarthritis | 11 | 1 | 1 |
| Scleroderma | 24 | 1 | 3 |
| Sjogrens | 21 | 1 | 0 |
| Ulcerative Colitis | 18 | 0 | 0 |
| Wegeners Granulomatosis | 5 | 0 | 0 |

c. Other clinical supportive data (when a. and b. are not applicable):

Refer to Method Comparison

4. Clinical cut-off:
See Assay Cutoff

5. Expected values/Reference range:
Three hundred samples from apparently healthy donors including 132 males ranging in age from 7 to 85 and 168 females ranging in age from 14 to 83 were tested with BioPlex® 2200 APLS IgM kit. The number of positive and mean value of the BioPlex® APLS IgM results is shown below.

| Assay | N (%Positive) | Mean | 99th Percentile |
|---|---|---|---|
| aCL IgM | 7 (2.3%) | 3.0 MPL-U/mL | 27.9 MPL-U/mL |
| aβ2GPI IgM | 3 (1.0%) | 2.5 U/mL | 19.4 U/mL |

Each laboratory should establish its own reference range pertinent to their specific patient populations.

**Instrument Name:**
The BioPlex 2200 System, software version 4.0 has been cleared in k103834.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2013

BIO-RAD LABORATORIES
DR. JUANG WANG
REGULATORY AFFAIRS REPRESENTATIVE
5500 E. 2ND STREET
BENICIA CA 94510

Re: K130528
Trade/Device Name: BioPlex 2200 APLS IgM kit,
BioPlex 2200 APLS IgM Calibrator Set,
BioPlex 2200 APLS IgM Control Set
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: II
Product Code: MID, MSV, JIX, JJX
Dated: October 01, 2013
Received: October 10, 2013

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K130528

Device Name
BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgM Kit

Indications for Use *(Describe)*
The BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgM kit is a multiplex flow immunoassay intended for the semi-quantitative detection of IgM antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (ß2GPI) in human serum and plasma (lithium heparin, sodium heparin, and sodium citrate). In conjunction with other clinical findings, the test system is used as an aid in the diagnosis of primary Antiphospholipid Syndrome (APS) and those secondary to systemic lupus erythematosus (SLE) or SLE-like disorders.

The BioPlex 2200 APLS IgM kit is intended for use with the Bio-Rad BioPlex 2200 System

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K130528

Device Name
BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgM Control Set

Indications for Use *(Describe)*
The BioPlex 2200 Antiphospholipid Syndrome (APLS) IgM Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and the corresponding BioPlex 2200 APLS IgM Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 APLS IgM Control Set has not been established with any other Antiphospholipid assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K130528

Device Name
BioPlex® 2200 Antiphospholipid Syndrome (APLS) IgM Calibrator Set

Indications for Use *(Describe)*
The BioPlex 2200 APLS IgM Calibrator Set is intended for the calibration of the corresponding BioPlex 2200 APLS IgM Reagent Pack.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S