INTENDED USE
BioPlex 2200 HIV Ag-Ab Control Set is intended for use as an assayed quality control to monitor the performance of the BioPlex 2200 Instrument and BioPlex 2200 HIV Ag-Ab assay in the clinical laboratory. The performance of the BioPlex 2200 HIV Ag-Ab Control Set has not been established with any other HIV antibody or antigen assays.

SUMMARY AND PRINCIPLE
Quality control materials provide an objective assessment of the precision and accuracy of test methods. They are an integral part of good laboratory practices.

MATERIALS PROVIDED

Reagents:
- HIV-1 Ag-Ab Negative Control - Three (3) vials with 1.5 mL of negative control containing processed human plasma with ProClin 300 (≤0.3%), sodium benzoate (≤0.1%), sodium azide (<0.1%), ProClin 950 (≤0.16%) and gentamicin sulfate (≤0.005%) as preservatives.
- HIV-1 Antigen Positive Control - Three (3) vials with 1.5 mL of antigen positive control containing purified HIV-1 antigen (from viral lysate inactivated with a chaotropic agent) in Tris Base; protein stabilizer (bovine); and ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (<0.1%) as preservatives.
- HIV-1/HIV-2 Antibody Positive Control - Three (3) vials with 1.5 mL of antibody positive control containing human antibody to HIV-1 Group M and HIV-2; purified rabbit antibody to HIV-1 Group O; processed human plasma; and ProClin 300 (≤0.3%), sodium benzoate (≤0.1%), sodium azide (<0.1%), ProClin 950 (≤0.16%) and gentamicin sulfate (≤0.005%) as preservatives. Human plasma used to manufacture this control has been inactivated.
- HIV Control, Negative (Human Plasma) - Three (3) vials with 1.5 mL of negative control containing processed human plasma used to manufacture this control has been inactivated using a chaotropic agent.
- HIV-1 p24 Antigen Positive Control has been inactivated using a chaotropic agent.
- HIV-1 and HIV-2 human antibody has been heat-treated.
- The human source material used in the preparation of the Negative Control was also tested by FDA accepted methods and found nonreactive for human immunodeficiency virus (HIV-1 and HIV-2).
- The Human source material, containing HIV-1 and HIV-2 human antibody has been heat-treated.
- The HIV-1 p24 Antigen Positive Control has been inactivated using a chaotropic agent.

STORAGE AND STABILITY
This product is stable until the expiration date when stored unopened at 2-8°C. Once opened, all controls are stable for 60 days (but not beyond the printed expiration date of the controls) when stored tightly capped at 2-8°C.

PROCEDURE
- This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the BioPlex 2200 Instrument and the BioPlex 2200 HIV Ag-Ab Reagent Pack.
- Before sampling, gently mix to ensure homogeneity.
- If foam or bubbles are observed, centrifuge controls at 10,000 RCF (relative centrifugal force) for 5 minutes. Ensure that all bubbles are removed prior to use.
- After each use, promptly cap the controls and return to 2-8°C storage.
LIMITATIONS
1. The BioPlex 2200 HIV Ag-Ab Control Set is intended for use with the BioPlex 2200 HIV Ag-Ab assay performed on the BioPlex 2200 Instrument. Any other use has not been characterized.
2. This product is intended to monitor for substantial reagent failure.

ASSIGNMENT OF VALUES
The BioPlex 2200 HIV Ag-Ab Control Set includes a Negative Control as well as two different Positive Controls - one Control containing antibodies to HIV-1 (Groups M and O) and HIV-2, and one Control containing HIV-1 p24 antigen. The Positive Controls are manufactured to give REACTIVE results for antibodies to HIV-1 (Groups M and O) and HIV-2, as well as HIV-1 p24 antigen. The Negative Control is manufactured to give Non-Reactive results, with values below the cut-off for both HIV-1/-2 antibodies and HIV-1 p24 antigen.

Control value assignment is established using a master set of calibrators and multiple lots of BioPlex 2200 HIV Ag-Ab reagent packs on multiple BioPlex 2200 systems. A BioPlex 2200 HIV Ag-Ab Control Lot Data CD-ROM is available to load the necessary value assignment data into the Instrument. Refer to the BioPlex 2200 System Operation Manual for more information regarding this activity.

TECHNICAL INFORMATION CONTACT:
Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. Call toll free 1-800-2-BIORAD (224-6723).

Bio-Rad Laboratories