BIO-RAD

REF 663-3435

BioPlex® 2200 HIV Ag-Ab Control Set

IVD

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 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.

Documents:

- One (1) package insert providing instructions for use.
- One (1) assignment of values sheet.

OPTIONAL MATERIALS NOT PROVIDED

663-3440 – BioPlex 2200 HIV Ag-Ab Control Lot Data CD-ROM.

Note: Printable PDF files for reagent lot specific control assigned values are included.

WARNINGS / PRECAUTIONS:

1. For professional use only.
2. WARNING: This product is preserved with ≤ 0.3% ProClin 300, a biocidal preservative that is irritating to eyes and skin, may be detrimental if enough is ingested, and may cause sensitization by skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

H317	May cause an allergic skin reaction.
P280	Wear protective gloves/protective clothing/eye protection/face protection
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Dispose of contents and container in accordance with local, regional, national, and international regulations.

3. This product contains human blood components. No test method can offer complete assurance that infectious agents are absent. In accordance with Good Laboratory Practice (GLP), all human source material should be considered potentially infectious for Hepatitis B (HBV), Hepatitis C (HCV), HIV-1, HIV-2, and all other infectious agents; therefore, handle the BioPlex 2200 HIV Ag-Ab kit Controls with the same precautions used with patient specimens. All human blood derivatives, reagents, and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for bloodborne pathogens as defined by OSHA Biosafety Level 2 guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, WHO Laboratory Biosafety Manual and/or local, regional, and national regulations. The following information relates to the human blood derivatives found in this kit:

   a. Each unit of human plasma used in the manufacture of the BioPlex 2200 HIV Ag-Ab Positive Controls was tested by FDA accepted methods and found nonreactive for Hepatitis B surface antigen (HBsAg) and antibodies to Hepatitis C virus (HCV Ab).
   b. 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).
   c. Human source material, containing HIV-1 and HIV-2 human antibody has been heat-treated.
   d. The HIV-1 p24 Antigen Positive Control has been inactivated using a chaotropic agent.
4. This product should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate personal protective equipment, including lab coat, eye/face protection, and disposable gloves (synthetic, non-latex gloves are recommended) while handling all reagents and samples and while operating the BioPlex 2200 System. Wash hands thoroughly after performing the test.
5. Clean up all spills immediately and thoroughly. Decontaminate the area for any spills involving biohazardous materials with an effective disinfectant. Dispose of all wastes in accordance with applicable national and/or local regulations.
6. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.
7. Safety Data Sheets are available at www.bio-rad.com and on request.
8. Do not interchange vial caps, which may lead to cross contamination of controls.
9. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial(s).
10. The control volume in each vial is sufficient for 32 assays.
11. Do not use product beyond the printed expiration date.

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.

For In Vitro Diagnostic Use | Temperature Limit | Consult Instructions for Use | Lot Number | Use By (YYYY-MM-DD) | Manufactured By | Catalog Number | Caution, consult accompanying documents | Control Level

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).

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