

INTENDED USE

The BioPlex 2200 HIV Ag-Ab Calibrator Set is intended for the calibration of the BioPlex 2200 HIV Ag-Ab assay.

SUMMARY AND PRINCIPLE

BioPlex 2200 HIV Ag-Ab uses calibrators to assign the relative fluorescence intensity (RFI) corresponding to the cutoff value when determining the presence of HIV-1 and HIV-2 antibodies and HIV-1 antigen in human specimens.

MATERIALS PROVIDED

Reagents:

- HIV-1/HIV-2 Antibody Calibrator: Three (3) vials with 0.8 mL of antibody calibrator containing human antibodies to HIV-1 Group M and HIV-2; purified rabbit antibody to HIV-1 Group O in Tris buffer; protein stabilizer (bovine); and ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (<0.1%) as preservatives. Human plasma used in preparing this calibrator has been inactivated.
- HIV Antigen Calibrator: Three (3) vials with 0.8 mL of antigen calibrator containing purified HIV-1 p24 antigen (from viral lysate inactivated with a chaotropic agent) in Tris Buffer; protein stabilizer (bovine); and ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (<0.1%) as preservatives.

Documents:

- One (1) package insert providing instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

663-3420 – BioPlex 2200 HIV Ag-Ab Calibrator Lot Data CD-ROM.

Note: Printable PDF files for reagent lot specific calibrator 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 Calibrators 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 Calibrators was tested by FDA accepted methods and found nonreactive for Hepatitis B surface antigen (HBsAg) and antibodies to Hepatitis C virus (HCV Ab).
- b. Human source material, containing HIV-1 and HIV-2 human antibody has been heat-treated.
- c. The HIV-1 p24 Antigen Calibrator 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 calibrators.
9. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial(s).
10. The calibrator volume is sufficient for five (5) calibration events performed in triplicate or fifteen (15) individual runs.
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, the calibrators are stable for 30 days (but not beyond the printed expiration date of the calibrators) when stored tightly capped at 2-8°C.

PROCEDURE

- This product should be used in accordance with the instructions accompanying the BioPlex 2200 System and the BioPlex 2200 HIV Ag-Ab Reagent Pack.
- Before sampling, gently mix calibrators to ensure homogeneity.
- If foam or bubbles are observed, centrifuge the calibrators 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 calibrators and return to 2-8°C storage.

LIMITATIONS

This product is intended for use with the BioPlex 2200 Instrument. Any other use has not been characterized.

ASSIGNED VALUES

- The BioPlex 2200 HIV Ag-Ab Calibrator Set includes two (2) vials for determining assay cut-off.
- Assigned values are included as printable PDF files on each BioPlex 2200 HIV Ag-Ab Calibrator Lot Data CD-ROM. Calibrator assignment is established using a master set of calibrators.
- A BioPlex 2200 HIV Ag-Ab Calibrator Lot Data CD-ROM is required in order to load the necessary value assignment data into the instrument. Refer to the BioPlex 2200 System Operation Manual for more information regarding this activity.

IVDFor In Vitro
Diagnostic UseTemperature
LimitConsult
Instructions
for Use**LOT**

Lot Number

Use by
(YYYY-MM-DD)Manufactured
by**REF**Catalog
NumberCaution, consult
accompanying
documents**CAL**

Calibrator 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).

BIO-RAD**Bio-Rad**
Laboratories