



The next generation in HIV testing

**Have it all with the BioPlex® 2200 HIV Ag-Ab Test
Detect. Differentiate. Diagnose earlier.**

The 5th generation assay design simultaneously detects and reports:

- HIV Ag-Ab overall result
with
- HIV-1 p24 Ag
- HIV-1 Ab (groups M & O)
- HIV-2 Ab

Approved for organ donor screening

Excellent overall performance:

- Best analytical sensitivity for HIV testing:
HIV-1 p24 Ag LOD = 0.33 IU/mL or 5.2 pg/mL
- Excellent reproducibility: Total CV's of 4.5 - 11.7%
- High specificity: Low risk populations - 99.86%
- Differentiates between HIV-1 and HIV-2 Ab:
100% capability rate for HIV-1, 94% for HIV-2

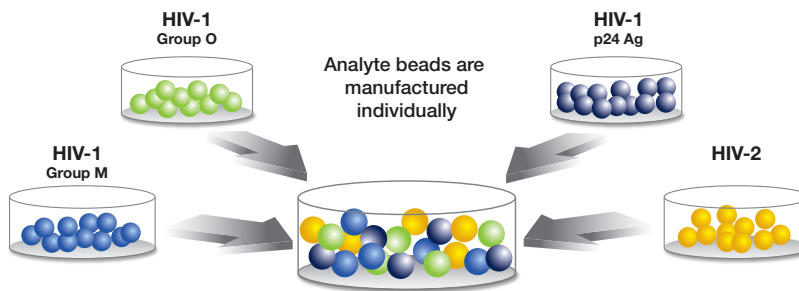
Helps guide supplemental testing

BIO-RAD

BioPlex® 2200 HIV Ag-Ab Test System

Assay Principle

The 5th generation assay design allows for the simultaneous detection and identification of multiple HIV analytes. The bead reagent consists of a mixture of four distinct populations of dyed microparticle beads, in addition to three internal quality beads that assure quality results.



Beads are combined into single "Bead Reagent" for multiplex analysis

Panel	Bleed Day	Reference 4th Gen Test	BioPlex® HIV-1 p24 Ag	BioPlex® HIV-1 Ab	NAT Roche Amplicor
12008-01	0	0.08	0.03	0.01	ND
12008-02	2	0.14	0.04	0.01	ND
12008-03	7	0.09	0.04	0.01	ND
12008-04	9	0.11	0.04	0.00	400
12008-05	14	0.10	0.07	0.01	ND
12008-06	16	0.10	0.04	0.01	ND
12008-07	21	0.13	0.07	0.00	2000
12008-08	23	0.53	2.03	0.01	44700
12008-09	28	50.26	181.76	0.01	>750000
12008-10	33	167.70	>200	2.20	>750000
12008-11	35	53.66	68.64	18.68	>750000
12008-12	40	28.35	2.11	35.00	143000
12008-13	42	30.20	0.55	34.63	ND

Seroconversion Data- Zeptomatrix Panel 12008

The BioPlex® 2200 HIV Ag-Ab assay de-tects infection one bleed earlier (12008-08) than the reference method and detects antibody within 10 days of antigen detection.

Ordering Information

Catalog No.	Description	
665-3455	BioPlex® 2200 HIV Ag-Ab Reagent Kit, 200 samples (US / Canada).....	1 Pack
663-3405	BioPlex® 2200 Calibrator Set, HIV Ag-Ab (US / Canada).....	3 Sets
663-3435	BioPlex® 2200 Control Set, HIV Ag-Ab (US / Canada)	3 Sets

INTENDED USE: The BioPlex® 2200 HIV Ag-Ab assay is a multiplex flow immunoassay intended for the simultaneous qualitative detection and differentiation of the individual analytes HIV-1 p24 antigen, HIV-1 (groups M and O) antibodies, and HIV-2 antibodies in human serum or plasma (fresh or frozen K2 EDTA, K3 EDTA, lithium heparin, sodium heparin; fresh citrate). This kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2, including acute (primary) HIV-1 infection. The assay may also be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in pediatric subjects as young as two years of age, and pregnant women.

The BioPlex® 2200 HIV Ag-Ab assay is also intended for use in testing plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating.

The BioPlex® 2200 HIV Ag-Ab assay is not intended for use in screening blood or plasma donors, as the effectiveness of this test for use in the screening of these donors has not been established. However, in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical, this assay can be used as a blood donor screening assay. The BioPlex® 2200 HIV Ag-Ab assay is intended for use with the BioPlex® 2200 System.

Warning: FDA has approved this test for use with serum and plasma specimens only. Use of this test kit with specimens other than those specifically approved for use with this test kit may result in inaccurate test results. This test is not intended for use in children younger than 2 years of age.

CAUTION: United States federal law restricts this device to sale by or on the order of a physician, or to a clinical laboratory.



Bio-Rad
Laboratories

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics

Clinical
Diagnostics Group

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