The Next Generation in HIV Testing

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

Technical Assay Specifications (US Only)

BIO-RAD

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BioPlex 2200 HIV Testing

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 assay 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.

BioPlex is a registered trademark of Bio-Rad Laboratories, Inc. in various jurisdictions.

Key Attributes / Differentiators

"5th Generation" HIV Ag-Ab Assay Design

- Simultaneously detects and reports:
  HIV-1 p24 Ag, HIV-1 Ab & HIV-2 Ab

Market Leading Performance

- Best Analytical Sensitivity on the market for HIV-1 p24 Ag:
  Limit of Detection (LOD) = 0.33 IU/mL (WHO Standard) and 5.2 pg/mL (French Standard)
- Seroconversion Panels:
  Detection earlier in 7 of 42 panels, when compared to leading 4th generation assays.
- High Reproducibility:
  Total CV's of 4.5 – 11.7%
- High Specificity:
  Low Risk Population – 99.86%

Differentiates Between HIV-1 and HIV-2 Ab

- 100% capability rate for HIV-1
- 94.0% capability rate for HIV-2

Approved for Organ Donor Screening

- 100% Sensitivity and Specificity

Helps Guide Supplemental Testing

- Knowing which analytes are detected can help identify which supplemental testing to perform.

Long Specimen Stability

- Up to FOUR days at room temperature and seven days at 2-8°C.

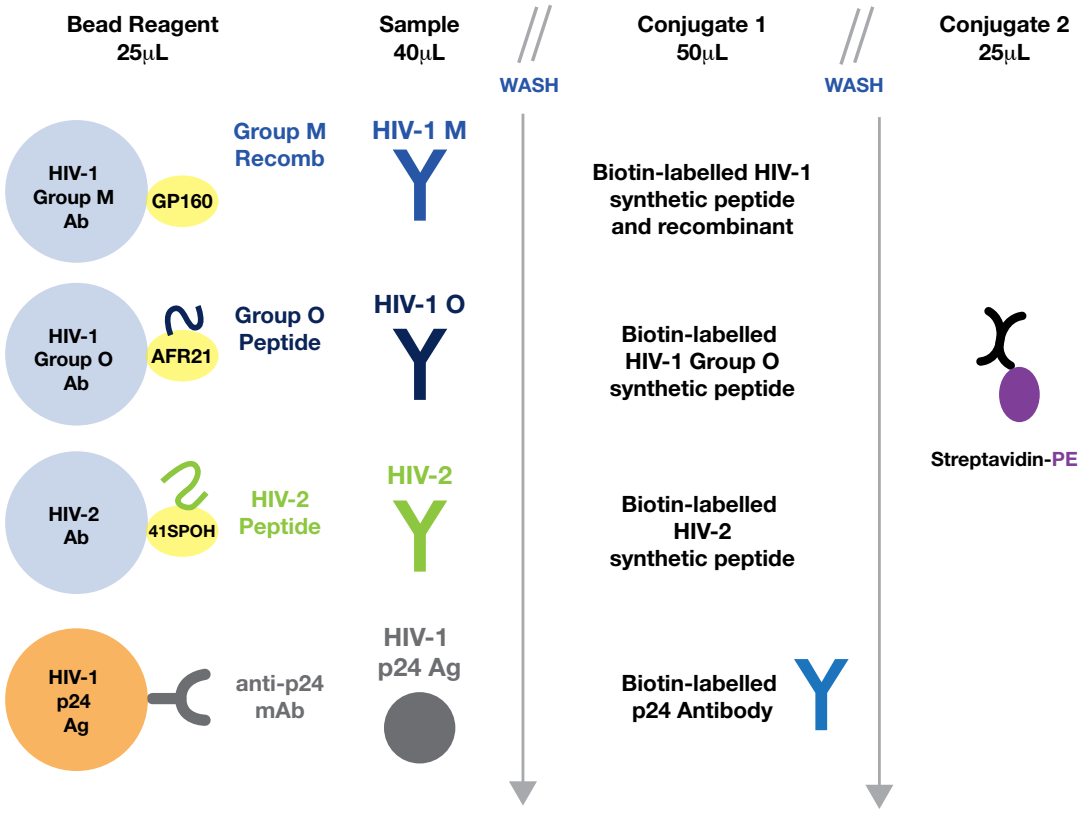
Validated Sample Matrices

- Serum or plasma
  K2 or K3 EDTA, Lithium Heparin, Sodium Heparin and Fresh Sodium Citrate.
- Plasma for organ donor screening.

Assay Design

The BioPlex 2200 HIV Ag-Ab Assay is a multiplex flow immunoassay that incorporates highly conserved recombinant and synthetic peptide sequences representing HIV-1 (groups M and O) and HIV-2, as well as a monoclonal antibody specific for HIV-1 p24 antigen. The assay's design allows for the simultaneous detection, identification and separate reporting of multiple HIV analytes. It has the capability to differentiate HIV-1 p24 antigen separately to help identify acute infections, as well as differentiate between HIV-1 and HIV-2 reactivity.

This information can be useful in selecting additional, more specific supplemental tests to verify specimens reactive with the HIV Ag-Ab Assay. Supplemental tests may include nucleic acid amplification test (NAAT), HIV-1/ HIV-2 differentiation assays, Western Blot, or immunofluorescence procedures.

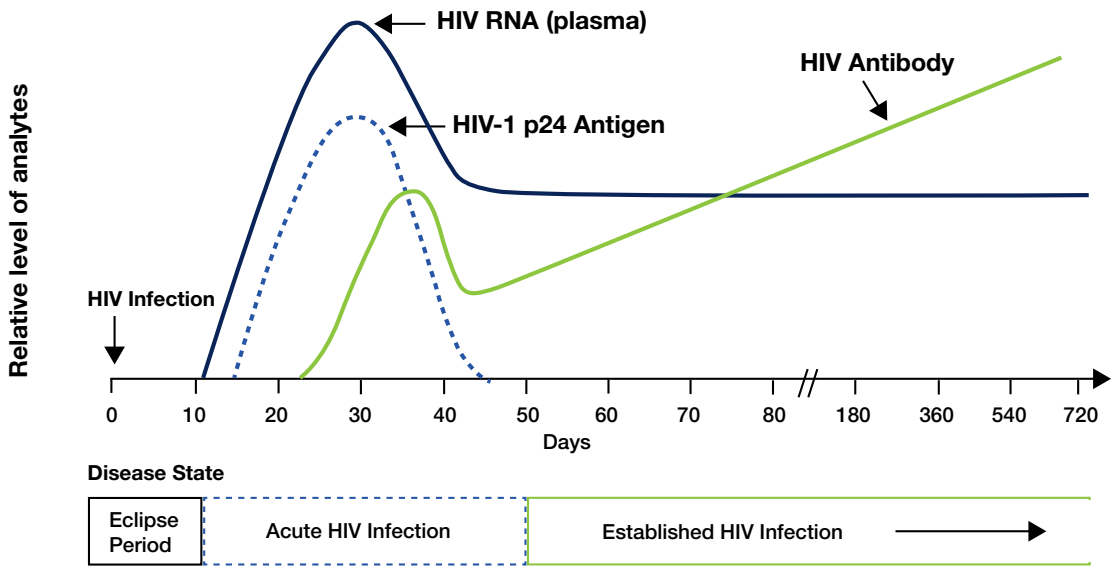


In addition, each test includes a series of Quality Assurance Beads to help ensure consistent and reliable results. They include 1) Signal Normalization Bead (SNB) to normalize RFI values, 2) Internal Standard Bead (ISB) to monitor detector fluctuations, and 3) Serum Verification Bead (SVB) to verify the addition of serum or plasma to the reaction vessel.

HIV Background

Two major types of HIV have been identified: HIV-1 and HIV-2. HIV-1 is responsible for most HIV infections throughout the world. HIV-2 is found primarily in West Africa; however, cases of HIV-2 infection have been identified in the United States. HIV-1 and HIV-2 are similar, but distinct viruses. HIV-2 patients do not effectively respond to HIV-1 therapies and are often diagnosed after immunologic deterioration. The ability to diagnose HIV infection early and differentiate between types of infection is important in the care of individuals as both viruses cause the same symptoms, but they progress at different rates.

HIV antigens and antibodies appear and are detectable at different stages of the infection. Early in the infection, HIV-1 antigen can be detected prior to the development of detectable levels of HIV-1 antibodies. Acute HIV-1 infection is identified when the blood specimen is positive for HIV-1 p24 antigen but is negative for HIV-1 and HIV-2 antibodies.



The BioPlex 2200 HIV Ag-Ab Assay allows results of antigen and antibody detection to be reported separately. In addition to distinguishing between established HIV-1 and HIV-2 infection, reporting of distinct results helps differentiate between acute and established HIV infection.

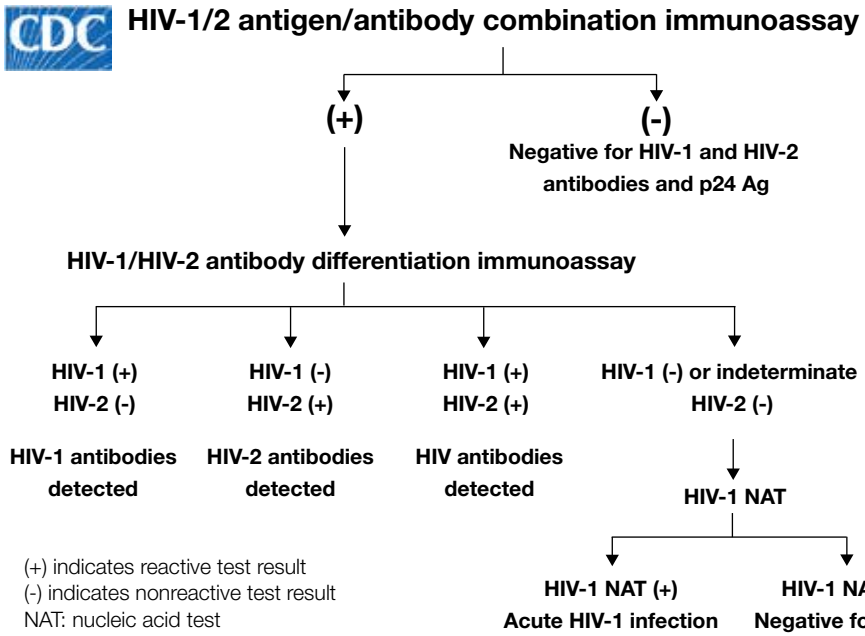
The first 6 months after infection, virus levels are higher and the risk of transmission is greatest.

Early treatment of these patients and outreach to those they may have infected reduces the risk of further transmission.

Evidence that starting HIV treatment early lowers the risk of developing AIDS or other serious illness.

US HIV Testing Algorithm

Algorithms are used to help guide Clinicians in selecting the correct tests to accurately identify patients infected with HIV. The following is the recommended HIV Testing Algorithm published by CDC in 2014 in their document: *Laboratory Testing for the Diagnosis of HIV-Updated Recommendations*. The BioPlex 2200 HIV Ag-Ab Assay can be used as part of the initial step in the algorithm (antigen/antibody combination immunoassay). Additionally the Bio-Rad Geenius™ HIV-1/2 Supplemental Assay can be used in the second step of the algorithm (antibody differentiation immunoassay).



Interpretation of Results

When testing with the BioPlex 2200 HIV Ag-Ab Assay, an overall HIV Ag-Ab Assay result will be reported by the BioPlex 2200 System along with the individual HIV analyte results (HIV-1 Ab, HIV-2 Ab, and HIV-1 p24 Ag). The overall HIV Ag-Ab Assay result uses the highest index of the individual assays and determines an overall interpretation based on that index.

For an overall HIV Ag-Ab result that has an interpretation of Non-Reactive, the Final Interpretation is Non-Reactive for HIV as per the table below. The individual analytes associated with that overall HIV Ag-Ab result will also be Non-Reactive and do not need to be reported individually.

For an overall HIV Ag-Ab result that has an interpretation of REACTIVE, the Final Interpretation is REACTIVE as per the table below. All of the individual analytes associated with that interpretation should be reported, along with the Final Interpretation of REACTIVE for HIV Ag-Ab.

Index (IDX)	Retest	Summary of All Results	Final Interpretation
< 1.00 for all analytes	No	All analytes have IDX < 1.00	Non-Reactive for HIV
≥ 1.00 for at least one analyte	Yes - In Duplicate	No analytes have 2 or more IDX results ≥ 1.00	Non-Reactive for HIV
		At least one analyte has 2 or more IDX results ≥1.00†	REACTIVE for HIV Ag-Ab with REACTIVE for HIV-1 Ag* and/or REACTIVE for HIV-1 Ab and/or REACTIVE for HIV-2 Ab or REACTIVE, Undifferentiated for HIV-1 and HIV-2 Abs**

† The final HIV result is based on the number of analytes that are repeatedly reactive. The order in which reactive and/or non-reactive results occur in replicate testing does not affect the final result.

** Results are not reportable for HIV-1 Ag if the HIV-1 Ag Index is ≥ 1.00 and the index for HIV-1 Ab or HIV-2 Ab is ≥ 100.*

*** If 2 of 3 results are REACTIVE, Undifferentiated for HIV-1 Ab and HIV-2 Ab, the final result is REACTIVE, Undifferentiated. If 2 of 3 results are specific for an HIV Ab type, that specific HIV type is reported as HIV REACTIVE.*

Note: When testing with the HIV Ag-Ab Assay, all of the individual HIV analytes (HIV-1 Ab, HIV-2 Ab, and HIV-1 p24 Ag) must be reported.

The final HIV interpretation result is based on the number of analytes that are repeatedly reactive

The final overall HIV Ag-Ab result is determined based on the final result for each individual analyte. If any of the analytes has 2 or more replicates that are REACTIVE, the final overall HIV Ag-Ab result is also REACTIVE (See example in Table 1). If different analytes are reactive in replicate testing, and no individual analytes are repeatedly reactive, the final overall HIV Ag-Ab result is non-reactive (See example in Table 2).

Table 1

Analyte	Initial result	Repeat 1 Result	Repeat 2 Result	Final Interpre-tation
HIV-1 Ag	R	R	NR	R
HIV-1 Ab	NR	NR	NR	NR
HIV-2 Ab	NR	NR	NR	NR
HIV Ag-Ab	R	R	NR	R

Note: In this example, HIV-1 Ag is repeatedly REACTIVE and therefore the final HIV Ag-Ab result is REACTIVE.

Table 2

Analyte	Initial result	Repeat 1 Result	Repeat 2 Result	Final Interpre-tation
HIV-1 Ag	R	NR	NR	NR
HIV-1 Ab	NR	R	NR	NR
HIV-2 Ab	NR	NR	NR	NR
HIV Ag-Ab	R	R	NR	NR

Note: In this example, the overall HIV Ag-Ab shows two individual REACTIVE results; however, no analyte has two or more replicates that are REACTIVE, and therefore the final result is Non-Reactive.

A result that is non-reactive for HIV Ag-Ab is non-reactive for all individual HIV analytes

The Interpretation of Results section of the IFU states, under Data Analysis, "When testing with the BioPlex 2200 HIV Ag-Ab Assay, results for all of the individual HIV analytes (HIV-1 Ab, HIV-2 Ab, and HIV-1 p24 Ag) must be reported." When a result is reported as Non-Reactive for HIV Ag-Ab, the result is inclusive, and by default includes results of all of the individual analytes even if they are not each stated separately. Thus, the different analytes associated with that overall HIV Ag-Ab nonreactive result **do not need to be reported individually**.

Special Case: HIV-1 p24 Ag Results

When HIV-1 Ab and/or HIV-2 antibody levels are very high, the antibody may interfere with HIV-1 p24 Ag results. Therefore the output of the system will not contain HIV-1 p24 Ag results when:

- Index for HIV-1 Ab or HIV-2 Ab is at least 100, AND
- HIV-1 p24 Ag Index is at least 1.00

The system output for the HIV-1 p24 Ag results for these specimens will be: **"Not reportable due to high HIV Ab level,"** without Indices.

Patient Sample Summary Report Examples

Test	Value	Result	Result Date/Time	Status
HIV Ag-Ab		**(258416/13000)**	4/22/2016 4:32:04 PM	1 of 1
HIV Ag-Ab	133.09 IDX	REACTIVE		Released
HIV-1 Ab	133.09 IDX	REACTIVE		Released
HIV-1 Ag		*Not reportable due to high HIV Ab level*		Released
HIV-2 Ab	0.71 IDX	Non-Reactive		Released

Test	Value	Result	Result Date/Time	Status
HIV Ag-Ab		**(258416/11000)**	5/13/2016 5:52:21 PM	1 of 1
HIV Ag-Ab	103.68 IDX	REACTIVE		Released
HIV-1 Ab	0.32 IDX	Non-Reactive		Released
HIV-1 Ag		*Not reportable due to high HIV Ab level*		Released
HIV-2 Ab	103.68 IDX	REACTIVE		Released

Special Case: HIV-1 and HIV-2 Ab Results

Some specimens that are reactive for HIV-1 antibody can cross-react with HIV-2 antigens, causing results on the HIV-2 beads to be reactive. Likewise, some specimens reactive for HIV-2 antibody can cross-react with HIV-1 antigens causing results on the HIV-1 beads to be reactive. Therefore, the system output for specimens with Indices of at least 1.00 for both HIV-1 Ab and HIV-2 Ab is as follows:

- If the HIV-1 Ab Index is at least 5-fold the HIV-2 Ab Index, the system output for HIV-1 Ab is REACTIVE with its Index. The HIV-2 Ab result output will be **"Non-Reactive,"** without Indices.

- If the HIV-2 Ab Index is at least 5-fold the HIV-1 Ab Index, the system output for HIV-2 Ab is REACTIVE with its Index. The HIV-1 Ab result output will be **"Non-Reactive,"** without Indices.
- If the HIV-1 Ab and HIV-2 Ab Indices have less than a 5-fold difference, the system output for both HIV-1 Ab and HIV-2 Ab will be **"REACTIVE, Undifferentiated,"** with Indices.

Patient Sample Summary Report Examples

Test	Value	Result	Result Date/Time	Status
HIV Ag-Ab		**(258416/13000)**	4/22/2016 4:32:10 PM	1 of 1
HIV Ag-Ab	169.92 IDX	**REACTIVE**		Released
HIV-1 Ab		Non-Reactive		Released
HIV-1 Ag	0.26 IDX	Non-Reactive		Released
HIV-2 Ab	169.92 IDX	**REACTIVE**		Released

Test	Value	Result	Result Date/Time	Status
HIV Ag-Ab		**(258416/13000)**	4/22/2016 4:31:14 PM	1 of 1
HIV Ag-Ab	2.14 IDX	**REACTIVE**		Released
HIV-1 Ab	2.10 IDX	**REACTIVE, Undifferentiated**		Released
HIV-1 Ag	0.03 IDX	Non-Reactive		Released
HIV-2 Ab	2.14 IDX	**REACTIVE, Undifferentiated**		Released

Specimen Type

Serum or plasma (K2 EDTA, K3 EDTA, lithium heparin, sodium heparin) specimens, either fresh or frozen, may be used in the test. Serum separator tubes and plasma preparation tubes with lithium heparin may also be used. Fresh samples that have been collected in sodium citrate may also be used. Do not use samples collected in sodium citrate that have been previously frozen, as false positive results may occur. The following specimen tube types may be used with the HIV Ag-Ab Assay:

Specimen Type	Anticoagulant	Glass	Plastic
Serum	None	X	X
Serum - SST*	None	X	X
Plasma	Dipotassium (K2) and Tripotassium (K3) EDTA		X
Plasma	Na Citrate (Do not use frozen sodium citrate samples)		X
Plasma	Na Heparin		X
Plasma - PST**	Li Heparin		X

** Serum Separator Tube*
***Plasma Separator Tube*

Avoid hemolysis. Samples collected into anticoagulant tubes should be processed according to the manufacturer's direction for centrifugation and removal of the plasma from the cells. False positive results may occur if the plasma remains with the cells for > 24 hours.

Specimen Stability

Samples may be stored for up to **4 days at room temperature** or 7 days at 2-8°C, including the time that samples are in transit. For longer storage of samples, keep at -20°C or colder. Up to **4 freeze / thaw cycles** are acceptable.

Specimen Preparation

Ensure specimens are thoroughly mixed and homogenous. Centrifuge specimens to remove bubbles, foam, or gross particulate matter. For frozen samples perform the following steps:

- Thaw samples completely.
- Mix thoroughly by inverting 10 times or by vortexing. Continue to mix until samples are visibly homogeneous.
- Centrifuge at > 10,000 relative centrifugal force for 10 minutes.
- Avoid multiple freeze/thaw cycles (up to 4 cycles are acceptable).

Note: For repeat testing, it is recommended to centrifuge sample per instructions above.

Product Information

HIV Ag-Ab Assay Components Required

Catalog Number	Description	Packaging
665-3455	BioPlex 2200 HIV Ag-Ab Reagent Pack, 200 tests	1 Pack
663-3405	BioPlex 2200 Calibrator Set, HIV Ag-Ab	1 Box, 3 Sets
663-3435	BioPlex 2200 Control Set, HIV Ag-Ab	1 Box, 3 Sets
663-3420	CD, BioPlex 2200 Calibrator Value Assignment, HIV Ag-Ab	1 CD
663-3440	CD, BioPlex 2200 Control Value Assignment, HIV Ag-Ab	1 CD
12001443 (US only)	BioPlex 2200 HIV Ag-Ab Instructions for Use (IFU) Package (Includes Assay Protocol File CD)	1 Set

Note: The BioPlex 2200 HIV Ag-Ab Assay requires system software version 4.3 or higher

Other Related HIV Ag-Ab Components

Catalog Number	Description	Packaging
12000449	BPX Sample/Reagent Probe, Stainless Steel	1 Each
660-0306*	BPX HIV Manual Pack Piercer (MPP)	1 Each
12000544	Minimum Sample Volume Guide for HIV	1 Each
LB001328	Sub Notification: HIV Ag-Ab Carryover Procedure	1 Each

** Included in every reagent pack; can be ordered separately*

Other System Components Required

Catalog Number	Description	Packaging
660-0817	BPX Sheath Fluid	1 Box, 2 Sets
660-0818	BPX Wash Buffer	1 Box, 1 Set
666-0001	BPX Detector Calibration Pack	1 Pack
666-0002	BPX Detector Clean Pack	1 Pack
660-2003	BPX Reaction Vessels, 1000 tests	1 Bag

Performance Characteristics

See the BioPlex 2200 HIV Ag-Ab Assay Instructions for Use (IFU) for specific performance characteristics.

Product Features

Feature	Description
Sample Volume	40 µL
Time to First Result (TTFR)	64 minutes
Throughput	84 samples / hour
Methodology	Multiplex Flow Immunoassay
Sample Type	Human serum or plasma (see Specimen Type section)
Reagent Preparation	N/A – all ready to use; includes reagents, calibrators and controls
Reagent Storage	2-8°C
Reagent Open Pack Stability	60 days
Reagent Shelf Life	24 months from manufacture
Calibration Frequency	30 days
Calibrator Open Vial Stability	30 days; 3 hours room temperature
Control Frequency	24 hours and after each calibration event
Control Open Vial Stability	60 days; 3 hours room temperature
QC Bracketing	N/A – pack validation
HIV-1 p24 Limit of Detection	0.33 IU/mL (WHO Standard) and 5.2 pg/mL (French Standard)

Quality Control

The BioPlex 2200 HIV Ag-Ab Control Set must be run at least once every 24 hours, and after each calibration event. The HIV Ag-Ab Control Set includes a Negative Control and two Positive Controls in plasma or synthetic matrix containing HIV-1 and HIV-2 antibodies or antigen for HIV-1.

Positive Controls are manufactured to give reactive results (i.e., values above the cut-off for each specific bead). The Negative Control is manufactured to give non-reactive results (i.e., values below the cut-off for all beads). The Negative Control must have a non-reactive result, and the Positive Controls must have reactive results for the HIV-1 p24 antigen, HIV-1 antibody (groups M and O), and HIV-2 antibody, as appropriate.

Values for a given lot of Controls are loaded into the system database via the provided media or by manual input. After identifying the control via the barcoded vial, the system compares the control results to the expected lot-specific control values stored in the system database. Failure to obtain the appropriate values for controls will invalidate the assay and indicates procedural error, improper sample handling, or deterioration of reagents.

Follow accreditation or government regulations for quality control frequency. Additional controls may be tested in accordance with the laboratory's quality control policy. If a control result is out of its specified range, any test results generated since the last acceptable control results must be evaluated to determine if test results may have been affected adversely. Results that have been affected adversely are invalid, and these samples must be retested.

External Quality Controls may also be used to independently monitor system performance and chart trends (Levy-Jennings). The system has the ability to track performance via L-J Charts and set QC Rules (e.g. 1-2s rule), as well as connect to Bio-Rad Laboratories **Unity Interlab QCNet** program for peer comparisons.

Bio-Rad Laboratories Recommended External HIV Quality Controls

Catalog Number	Description	Alternative Class
00100C	VIROTROL I, anti-HIV-1, Single Level (1 x 5mL)	F
00105C	VIROTROL HIV-2, anti-HIV-2, Single Level (1 x 5mL)	A or B
00108A	VIROTROL HIV-1 Ag, HIV-1 Antigen, Single Level (1 x 5mL)	-
00106	VIROCLEAR, Non-Reactive, Single Level (1 x 5mL)	-

Proficiency Testing

The following proficiency testing is recommended for use with the BioPlex 2200 HIV Ag-Ab Assay:

The College of American Pathologist (CAP) – Viral Markers Survey

Test	Description	Manufacturer Code
VM1	Anti-HIV-1 Screening Anti-HIV-1/2 Combination Assay Anti-HIV-2	3288
VM3	HIV-1 p24 Antigen	3288
VM6	Anti-HIV-1/2 Ab, HIV-1 p24 Ag Combination Assay	3288

LOINC and SNOMED Test Codes

The BioPlex 2200 HIV Ag-Ab Assay is used as an initial test in a HIV diagnostic testing algorithm. It is possible a laboratory might perform all three tests of the algorithm (see US HIV Testing Algorithm), or one laboratory may conduct the initial test and send the specimen to a referral laboratory to complete the remaining parts of the testing sequence (i.e., the supplemental test and NAT). The following recommendations are for use with Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).

LOINC Codes – Qualitative [Presence]

Assay / Test Result	LOINC Code & Short Name	LOINC Long Name	Possible Values
BioPlex 2200 HIV Ag-Ab (order code)	**85037-0** HIV-1 & 2 Ab & HIV-1 p24 Ag panel	HIV-1 and 2 Ab and HIV-1 p24 Ag panel - Serum or Plasma by Immunoassay	See 4 children reportable codes: (56888-1, 29893-5, 18396-2, 30361-0)
HIV Ag-Ab (overall result interpretation)	**56888-1** HIV-1+2 Ab+HIV-1 p24 Ag	HIV-1+2 Ab+HIV1 p24 Ag [Presence] in Serum or Plasma by Immunoassay	1. Reactive 2. Non-Reactive
HIV-1 Ab (result)	**29893-5** HIV-1 Ab	HIV-1 Ab [Presence] in Serum or Plasma by Immunoassay	1. Reactive 2. Reactive, Undifferentiated 3. Non-Reactive
HIV-1 Ag (result)	**18396-2** HIV-1 p24 Ag	HIV-1 p24 Ag [Presence] in Serum or Plasma by Immunoassay	1. Reactive 2. Non-Reactive 3. Not reportable due to high HIV Ab level
HIV-2 Ab (result)	**30361-0** HIV-2 Ab	HIV-2 Ab [Presence] in Serum or Plasma by Immunoassay	1. Reactive 2. Reactive, Undifferentiated 3. Non-Reactive

Reference website: ***loinc.org***

LOINC to SNOMED Mapping

Assay / Test Result	LOINC Code & Short Name	Possible Values and SNOMED Codes
HIV Ag-Ab (overall result interpretation)	**56888-1** HIV-1+2 Ab+HIV-1 p24 Ag	1. Reactive (112141006) 2. Non-Reactive (131194007)
HIV-1 Ab	**29893-5** HIV-1 Ab	1. Reactive (112141006) 2. Reactive, Undifferentiated (PLR475) 3. Non-Reactive (131194007)
HIV-1 Ag	**18396-2** HIV-1 p24 Ag	1. Reactive (112141006) 2. Non-Reactive (131194007) 3. Not reportable due to high HIV Ab level (PLR474)
HIV-2 Ab	**30361-0** HIV-2 Ab	1. Reactive (112141006) 2. Reactive, Undifferentiated (PLR475) 3. Non-Reactive (131194007)

Current Procedural Terminology (CPT) Codes

When testing for HIV-1 p24 antigen and HIV-1 and HIV-2 antibodies with an **overall composite single result** (Ag-Ab) the following CPT code should be reported:

- 87389 Antibody; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result

When the BioPlex 2200 HIV Ag-Ab Assay is used to determine **separate results** for HIV-1 antibody, HIV-2 antibody or HIV-1 p24 antigen, the following CPT codes should be utilized:

- HIV-1 Antibody: 86701 Antibody; HIV-1
- HIV-2 Antibody: 86702 Antibody; HIV-2
- HIV-1 p24 Antigen: 87390 Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, multi-step method; HIV-1

Medicare Coding for HIV Screening Tests

The following HCPCS code is reported when billing HIV screening for covered individuals using whole blood (finger stick or venous), serum, or plasma specimens, and is applicable with the BioPelx 2200 HIV Ag-Ab for serum and plasma specimens:

- G0432 Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening

Summary of HIV Diagnostic and Screening Coding

Description		Screening	Diagnostic
HIV-1 p24 Ag and HIV-1 and HIV-2 Ab, single overall Assay (Ag-Ab):	Medicare	G0432	87389
	Non-Medicare	87389	87389
HIV-1 Antibody:	Medicare	G0432	86701
	Non-Medicare	86701	86701
HIV-2 Antibody:	Medicare	G0432	86702
	Non-Medicare	86702	86702
HIV-1 p24 Antigen:	Medicare	Not Covered	87390
	Non-Medicare	87390	87390

Reference website: ***www.codemap.com/biorad***

National Correct Coding Initiative Edits

A National Correct Coding Initiative (NCCI) edit prohibits billing 87390 on the same date of service as 87389. **However**, these edits may be bypassed by using a **-59 modifier** with the prohibited codes. According to the NCCI: "If the result of testing described by CPT code 87389 is positive [reactive], a provider may use an NCCI-associated modifier to additionally report CPT code 87390 if such testing is medically reasonable and necessary."

NCCI edits also prohibits billing 86701 or 86702 on the same date of service as 87389. **However**, these edits may be bypassed by using a **-59 modifier** with the prohibited codes.

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