

## Overview

### Useful For

Diagnosing HIV-1 and/or HIV-2 infection in symptomatic patients more than 2 years old

Follow-up testing of individuals with reactive rapid HIV test results

This test is **not offered** as a screening or confirmatory test for blood donor specimens.

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HVDIP	HIV Ab Confirm / Differentiation, P	Yes	No
HIVQN	HIV-1 RNA Detect/Quant, P	Yes	No

## Testing Algorithm

This test begins with HIV-1/-2 antigen and antibody screen by chemiluminescence immunoassay. If the screen result is reactive, then HIV-1/-2 antibody differentiation test by immunochromatographic method is performed at an additional charge.

If HIV-1/-2 antibody differentiation is negative for both HIV-1 antibody and HIV-2 antibody, or indeterminate/negative for HIV-1/HIV-2 antibody, or indeterminate/indeterminate for HIV-1/ HIV-2 antibody, then the HIV-1 RNA detection and quantification is performed at an additional charge.

The following algorithms are available in Special Instructions:

[-HIV Testing Algorithm \(Fourth-Generation Screening Assay\). Including Follow-up of Reactive Rapid Serologic Test Results](#)

[-Meningitis/Encephalitis Panel Algorithm](#)

## Special Instructions

- [HIV Testing Algorithm \(Fourth-Generation Screening Assay\). Including Follow-up of Reactive Rapid Serologic Test Results](#)
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## Method Name

Chemiluminescent Microparticle Immunoassay

## NY State Available

Yes

## Specimen

### Specimen Type

Plasma

**Advisory Information**

If specimen is from either autopsy or cadaver blood sources, the proper FDA-licensed assay is HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum.

Screening, supplemental or confirmatory serologic tests for HIV-1 or HIV-2 antibodies cannot distinguish between active neonatal HIV infection and passive transfer of maternal HIV antibodies in infants during the postnatal period (up to 2 years old). Diagnosis of HIV infection in newborns and infants up to 2 years old should be made by virologic tests, such as detection of HIV-1 DNA and RNA (HIVP / HIV-1 DNA and RNA Qualitative Detection by PCR, Plasma) or HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

**New York State clients:** This test should not be requested for maternal/newborn HIV screening on specimens originating in New York State, due to state regulatory requirements for expedited result reporting.

**Specimen Required**

**Collection Container/Tube:** Lavender top (EDTA)

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 4 mL

**Collection Instructions:**

1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot plasma into a plastic vial.

**Specimen Minimum Volume**

1.2 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Plasma	Refrigerated (preferred)	6 days	
	Frozen	30 days	

**Clinical and Interpretive**
**Clinical Information**

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AIDS is caused by 2 known types of HIV. HIV type 1 (HIV-1) is found in patients with AIDS, AIDS-related complex, and asymptomatic infected individuals at high risk for AIDS. The virus is transmitted by sexual contact, by exposure to infected blood or blood products, or from an infected mother to her fetus or infant. HIV type 2 (HIV-2) infection is endemic only in West Africa, and it has been identified in individuals who had sexual relations with individuals from that geographic region. HIV-2 is similar to HIV-1 in viral morphology, overall genomic structure, and its ability to cause AIDS.

Antibodies against HIV-1 and HIV-2 are usually not detectable until 6 to 12 weeks following exposure and are almost always detectable by 12 months. They may fall to undetectable levels (ie, seroreversion) in the terminal stage of AIDS when the patient's immune system is severely depressed.

Routine serologic screening of patients at risk for HIV-1 or HIV-2 infection usually begins with a HIV-1/-2 antigen and/or antibody screening test, which may be performed by various FDA-approved assay methods, including rapid HIV antibody tests, enzyme immunoassays, and chemiluminescent immunoassays. In testing algorithms that begin with these methods, supplemental or confirmatory testing should be requested only for specimens that are repeatedly reactive by these methods.

## Reference Values

Negative

## Interpretation

Negative HIV-1/-2 antigen and antibody screening test results usually indicate the absence of HIV-1 and HIV-2 infection. However, such negative results do not rule-out acute HIV infection. If acute HIV-1 infection is suspected, it is recommended that a specimen be submitted for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) or HIV-1 DNA and RNA (HIVP / HIV-1 DNA and RNA Qualitative Detection by PCR, Plasma).

Reactive HIV-1/-2 antigen and antibody screening test results suggest the presence of HIV-1 and/or HIV-2 infection, but it is not diagnostic for HIV infection and should be considered preliminary. Reactive result of this assay does not differentiate among reactivity with HIV-1 p24 antigen, HIV-1 antibody, and HIV-2 antibody. Diagnosis of HIV infection must be based on results of supplemental tests, such as HIV antibody confirmation/differentiation test (automatically reflexed on all samples with reactive screen test results at an additional charge).

All initially positive supplemental or confirmatory HIV test results (by serologic or molecular test methods) should be verified by submitting a second serum specimen for repeat testing. Such positive HIV test results are required under laws in many states in the United States to be reported to the departments of health of the respective states where the patients reside.

See [HIV Testing Algorithm \(Fourth-Generation Screening Assay\), Including Follow-up of Reactive Rapid Serologic Test Results](#) in Special Instructions.

## Cautions

Reactive result of this assay does not differentiate among reactivity with HIV-1 p24 antigen, HIV-1 antibody, and HIV-2 antibody.

A reactive screening test result is not diagnostic for HIV infection and should be considered preliminary.

The positive predictive value of a reactive screening test result is highly dependent on the prevalence of HIV infection in the population tested. The lower the prevalence of HIV infection, the lower the positive predictive value and higher the false-positive rate of the test. Diagnosis of HIV infection must be based on positive results of the supplemental or confirmatory serologic or molecular tests.

Recipients of experimental HIV-1 vaccines may have false-reactive HIV antibody test results due to the presence of vaccine-induced, HIV-1-specific antibodies without actual HIV infection.

Negative serologic or molecular HIV screening test results should be evaluated with caution in patients with clinical symptoms and/or a history of high-risk behavior for HIV infection. Repeat testing in 1 to 2 months is recommended in these at-risk individuals.

Assay performance characteristics have not been established for the following specimen characteristics:

- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Grossly lipemic (triglyceride level of >1250 mg/dL)
- Grossly icteric (total bilirubin level of >20 mg/dL)
- Heat-inactivated specimens
- Cadaveric specimens
- Presence of particulate matter

### Clinical Reference

1. Chavez P, Wesolowski L, Patel P, et al: Evaluation of the performance of the Abbott ARCHITECT HIV Ag/Ab Combo assay. *J Clin Virol.* 2011;52(Suppl 1):S51-S55
2. Branson BM, Owen SM, Wesolowski LG, et al: Laboratory testing for the diagnosis of HIV infection: Updated recommendations. Centers for Disease Control and Prevention; June 27, 2014. Available at <http://stacks.cdc.gov/view/cdc/23447>
3. Centers for Disease Control and Prevention: 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Available at <https://stacks.cdc.gov/view/cdc/50872>
4. Centers for Disease Control and Prevention. Technical update: Use of the Determine HIV 1/2 Ag/Ab combo test with serum or plasma in the laboratory algorithm for HIV diagnosis. CDC; October 4, 2017. Available at <https://stacks.cdc.gov/view/cdc/48472>

### Performance

#### Method Description

The Abbott Architect HIV Ag/Ab Combo assay for use on the Architect *i* System is a 2-step immunoassay to determine the presence of HIV-1 p24 antigen, antibodies to HIV-1 (groups M and O), and antibodies to HIV-2 in human serum or plasma using chemiluminescent microparticle immunoassay technology. First, patient's specimen, Architect *i* wash buffer, assay diluent, and paramagnetic microparticles are combined in a single reaction well. HIV-1 p24 antigen and HIV-1/HIV-2 antibodies present in the patient's specimen bind to the HIV-1 antigen-, HIV-2 antigen-, and HIV-1 p24 monoclonal (mouse) antibody-coated microparticles. After washing, the bound HIV-1 p24 antigen and HIV-1/HIV-2 antibodies bind to the acridinium-labeled conjugates. Following another wash cycle, pretrigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLU). The amount of HIV antigen and antibodies present in the patient's specimen is directly proportionate to the RLU detected by the Architect *i* System optics. The presence or absence of HIV-1 p24 antigen or HIV-1/HIV-2 antibodies in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined periodically by assay calibration. Patients' specimens with signal-to-cutoff (S/CO) values

greater than or equal to 1.00 are considered reactive for HIV-1 p24 antigen or HIV-1/HIV-2 antibodies. Specimens with S/CO values under 1.00 are considered nonreactive or negative. (Package insert: HIV Ag/Ab Combo. Abbott Laboratories; 08/2017)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday through Saturday; Varies

**Analytic Time**

1 day

**Maximum Laboratory Time**

2 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees and Codes**
**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

87389

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
HIVDX	HIV-1/-2 Ag and Ab Diagnostic, P	56888-1

Result ID	Test Result Name	Result LOINC Value
HIVC4	HIV-1/-2 Ag and Ab Diagnostic, P	56888-1