

HIV Ag/Ab Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

INTENDED USE

The HIV Ag/Ab Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid, qualitative test for the detection of HIV p24 antigen and antibodies (IgG, IgM and IgA) to anti-HIV-1(including O) and HIV-2 virussimultaneously in human serum, plasma or whole blood.

The HIV Ag/Ab Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro use and intended for professional use. This kit is intended only for an initial screening test and reactive samples must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped single strain RNA positive viruses. The causative relationship between HIV-1 and HIV-2 viruses and acquired immunodeficiency syndrome (AIDS) has been established over decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy individuals with a high risk for developing AIDS.¹ HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals.² HIV-1 is much more prevalent than HIV-2 worldwide. Recent studies have shown that over 30 million people have been infected with HIV-1.

Both HIV-1 and HIV-2 viruses can elicit strong immune responses,³ including the production of anti viral antibodies. Presence of specific anti HIV-1 or HIV-2 virus antibody in blood, serum and plasma indicates the exposure of an individual to the HIV-1 or HIV-2 virus, which is of great value for clinical diagnosis.⁴ Tests that detect HIV p24 antigen may be useful for the early diagnosis of HIV, as p24 antigen is one of the earliest markers of HIV infection. It has been suggested that HIV infection is detectable with a p24 antigen test 6 days earlier than an antibody test.⁵

TEST PRINCIPLE

The HIV Ag/Ab Combo Rapid Test Cassette is a lateral flow immunochromatographic assay. It contains a membrane strip, which is pre-coated with recombinant HIV-1/HIV-2 antigen on Ab test line region for the detection of antibodies to HIV-1 including O or HIV-2, and monoclonal anti-HIV-p24 antibody on Ag test line region for the detection of p24 antigen respectively. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. IgG, IgM, or IgA antibodies to HIV-1 or HIV-2, if present in the specimen, migrate through the conjugate pad (containing recombinant HIV-1/HIV-2 antigen and monoclonal anti-HIV-p24 antibody conjugated with colloidal gold) where they bind to the HIV conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1/HIV-2 antigen, forming a burgundy colored band on the Ab test line region, indicating a positive test result. Absence of the Ab band in the test region suggests an HIV -1 and HIV-2 antibody negative result.

HIV-1 p24 antigen, if present in the specimen, migrates through the conjugate pad where they bind to the P24 conjugate. The immunocomplex is then captured on the membrane by the precoated HIV-p24 antibody, forming a burgundy colored band on the Ag region, indicating a positive test result. Absence of the Ag band in the test region suggests an HIV-p24 antigen negative result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of goat anti mouse IgG/mouse IgG immunocomplex conjugates regardless of the presence of any colored test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

1. Test Cassette 2. Pipette Dropper 3.Desiccant 4.Buffer 5.Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

2. 1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUT

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results .
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

1. The HIV Ag/Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
2. **To collect Fingerstick Whole Blood specimens:**
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
 - ◆ Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
 - ◆ Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
 - Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
 - ◆ Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
 - ◆ Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

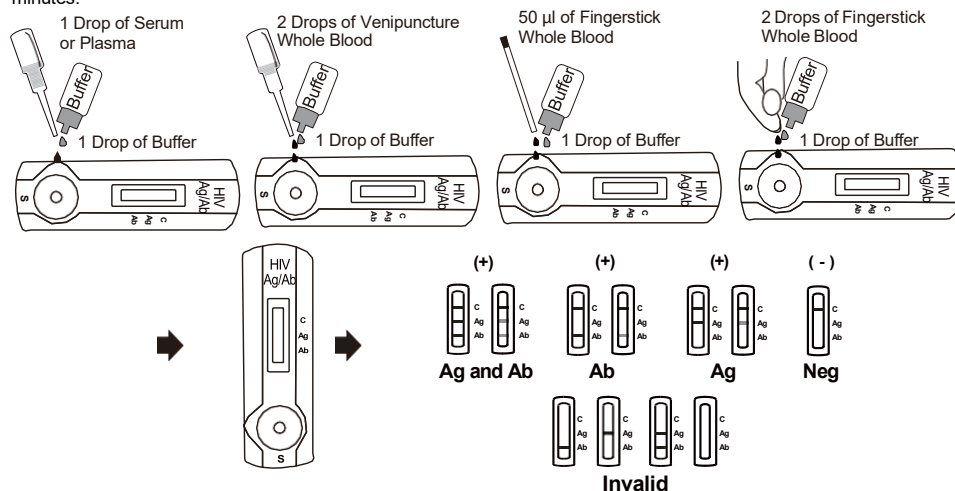
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer

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(approximately 40 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



LIMITATIONS

1. The HIV Ag/Ab Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HIV-1, HIV-2 and/or HIV p24 in whole blood, serum or plasma.
2. The HIV Ag/Ab Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is limited to the qualitative detection of antibodies to HIV-1, HIV-2 and/or HIV p24 in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody/antigen titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable HIV-1, HIV-2 antibodies and/or HIV p24 antigen. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
4. A negative result can occur if the quantity of the HIV-1/HIV-2 antibodies and/or HIV p24 antigen present in the specimen is below the detection limits of the assay, or the antibodies/antigens that are detected are not present during the stage of disease in which a sample is collected.
5. Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly tested as positive, more specific supplemental tests must be performed.
6. Immunochromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 and/or HIV-2 are present in a patient specimen.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

A total of 1263 clinical samples were collected and tested by the HIV Ag/Ab Combo Rapid Test (Whole Blood/Serum/Plasma) and a leading commercial HIV EIA test. Comparisons for all subjects are shown in the following table:

Method		EIA		Total Results
HIV Ag/Ab Combo Rapid Test	Results	Positive	Negative	
	Positive	210	2	212
	Negative	1	1050	1051
Total Results		211	1052	1263

Relative sensitivity: 99.5%

Relative specificity: 99.8%

Accuracy: 99.8%

REFERENCES

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