



In vitro Diagnostic
Catalog Number: R0011C

INTENDED USE

The HIV-1/2 Ab Rapid Test is an indirect lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG anti-HIV-1 and anti-HIV-2 antibodies in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HIV. Any reactive specimen with the HIV-1/2 Ab Combo Rapid Test must be confirmed with alternative testing method(s)

SUMMARY AND EXPLANATION OF THE TEST

Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped single strain RNA positive virus. The causative relationship between HIV-1 and HIV-2 virus 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 AIDS¹. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals².

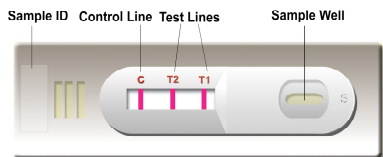
The two types of HIV have significant variation in sequences. HIV-1 has been divided into three groups: group M (for major), including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O). Similarly, the HIV-2 has been classified into at least five subtypes (A through E). Some HIV-1 variants share up to 50% homology in their envelope genes with the sequences of more common prototype strains.

Both HIV-1 and HIV-2 virus can elicit strong immune responses³, including the production of anti virus antibodies. Presence of specific anti HIV-1 and/or HIV-2 virus antibody in blood, serum and plasma indicates the exposure of an individual to the HIV-1 and/or HIV-2 virus, being of great value for clinical diagnosis⁴.

The HIV-1/2 Ab Rapid Test utilizes the conserved envelope antigen domains, which allows IgG antibodies to the HIV-1 including O subtype or HIV-2 to be detected.

TEST PRINCIPLE

The HIV-1/2 Ab Rapid Test is an indirect lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse monoclonal anti-human IgG antibody conjugated with colloidal gold (Human IgG Conjugates), 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with recombinant HIV-1 antigen gp 120 / gp41 for the detection of antibodies to HIV-1, T2 band is pre-coated with HIV-2 antigen gp36 for the detection of antibodies to HIV-2, and the C band is pre-coated with goat anti-mouse IgG antibody.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-HIV-1 antibodies if present in the sample migrate through the conjugate pad where they bind to the Human IgG conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1 antigen, forming a burgundy colored band on the T1 region, indicating a positive test result. Absence of this band in the test region suggests a HIV -1 antibody negative result.

IgG anti-HIV-2 antibodies if present in the sample migrate through the conjugate pad where they bind to the Human IgG Conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-2 antigen, forming a burgundy colored band on the T2 region, indicating a positive test result. Absence of this band in the test region suggests a HIV -2 antibody negative result.

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

REAGENTS AND MATERIALS PROVIDED

- Each kit contains 30 test devices, each sealed in a foil pouch with four items inside:
 - One cassette device.
 - One plastic dropper
 - One sealed plastic dropper containing sample diluent
 - One desiccant
- One package insert (instruction for use).

MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE

- Positive Control (1 vial, red cap, 1 mL)
- Negative Control (1 vial, green cap, 1 mL)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock/watch or Timer
- Lancing device or finger tip puncture device for taking blood specimen
- Clean scissors for cutting tip of the dropper containing sample diluent

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood for the testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Handle the Negative and Positive Control in the same manner as patient specimens.
- The testing results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

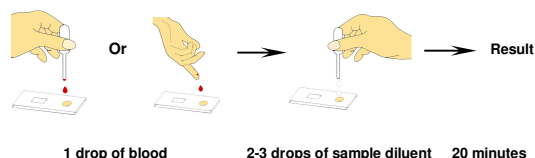
Drops of whole blood can be obtained in a clean container containing anti-coagulant (EDTA, citrate or heparin) by either finger tip puncture or veinpuncture.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

- Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
- When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
- Be sure to label the device with specimen's ID number.
- Dispense 1 drop of the whole blood specimen into the sample well. Then immediately cut the tip of the dropper containing sample diluent with scissors and add 2-3 drops of sample diluent into the sample well.

Note: be sure to check for air bubbles close to the dispensing tip of the dropper. Remove any air bubbles at the tip by squeezing a few drops of liquid out. Then immediately squeeze 2-3 drops of sample diluent into the sample well.



- Set up clock/watch or timer.
- Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

- NEGATIVE RESULT:** If only the C band is present, the absence of any burgundy color in the both T bands (T1 and T2) indicates that no HIV antibodies are detected in the specimen. The result is negative.



- POSITIVE RESULT:**
 - In addition to the presence of C band, if T1 band is developed, the test indicates the presence of antibodies to HIV-1 in the specimen. The result is HIV-1 positive.



- 2.2 In addition to the presence of C band, the test indicates for the presence of antibodies to HIV-2 in the specimen. The result is HIV-2 positive.



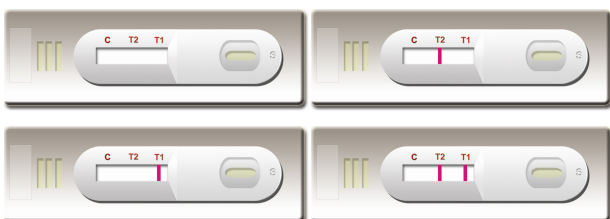
- 2.3 In addition to the presence of C band, if both T1 and T2 bands are developed, the test indicates for the present antibodies to HIV 1 and or HIV 2. The rest result is HIV positive.



To differentiate the type of virus infection, dilute the specimen at 1:100 dilution with the sample diluent provided, re-run the test. Interpret the result as illustrated above (also See **Limitations of Test 5.**).

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the T bands as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For HIV-1 Ab Test

A total of 2,000 samples from susceptible subjects were tested by the HIV-1/2 Ab Rapid Test and by a Chinese State Drug Administration (SDA) licensed EIA. Comparison for all subjects is showed in the following table:

EIA	HIV-1/2 Ab Combo Rapid Test		Total
	Positive	Negative	
Positive	31	0	31
Negative	11	1958	1969
Total	42	1958	2000

Relative Sensitivity: 100% , Relative Specificity: 99.4%, Overall Agreement: 99.5%

2. Clinical Performance For HIV-2 Ab Test

A total of 300 samples from susceptible subjects were tested by the HIV-1/2 Ab Rapid Test and by a Chinese State Drug Administration (SDA) licensed EIA. Comparison for all subjects is showed in the following table:

EIA	HIV-1/2 Ab Combo Rapid Test		Total
	Positive	Negative	
Positive	25	0	25
Negative	1	274	275
Total	26	274	300

Relative Sensitivity: 100% , Relative Specificity: 99.6%, Overall Agreement: 99.8%

LIMITATIONS OF TEST

- The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to HIV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The HIV-1/2 Ab Rapid Test is limited to the qualitative detection of antibodies to HIV-1 or HIV-2 in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable HIV-1 or HIV-2 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
- A negative result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- As illustrated in **INTERPRETATION OF ASSAY RESULT-2.3**, all the three positive bands (T1, T2 and C) may develop when tested with samples containing high titer of HIV-1 antibodies. **To differentiate the cross reactivity:** dilute the test specimen with Sample Diluent at 1:100 dilution, then re-test the diluted specimen with a new test device. Only T1 band and C will appear if it is a HIV-1 Ab response. If T1, T2 and C band all appear, the test indicates for the exposure of both HIV-1 and HIV-2.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- If the symptom persists, while the result from HIV-1/2 Ab Rapid Test is negative, it is recommended to re-test the specimen with an alternative test device.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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