



REF
Catalog Number R0018C
IVD
In Vitro Diagnostic

INTENDED USE

The *OnSite* HIV-Ab/Ag 4th Gen Rapid Test is a lateral flow immunoassay for the qualitative detection of antibodies (IgG, IgM, IgA) to anti-HIV-1 (including O) and-2 virus and HIV-1 p24 antigen in human serum, plasma, whole blood. It is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with HIV. Any reactive specimen with the *OnSite* HIV-Ab/Ag 4th Gen Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

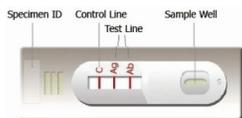
Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped single strain RNA positive viruses. The causative relationship between HIV-1 and HIV-2 viruses and acquired immunodeficiency syndrome (AIDS) has been established over decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy individuals with a high risk for developing AIDS¹. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals². 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 responses³, 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 diagnosis⁴. 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 test⁵.

The *OnSite* HIV-Ab/Ag 4th Gen Rapid test which utilizes recombinant gp-120-41, gp36 and anti-P24 antibodies can qualitatively detect antibodies (IgG, IgM, IgA) to anti-HIV-1 (including O) or -2 viruses and HIV-1 p24 antigen in patient serum, plasma, or whole blood within 15 minutes. The test can be performed without cumbersome laboratory equipment.

TEST PRINCIPLE

The *OnSite* HIV-Ab/Ag 4th Gen Rapid Test is a lateral flow immunochromatographic assay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant HIV-gp120-41 and gp-36 antigen conjugated with colloidal gold (HIV conjugates), monoclonal anti-HIV-p24 antibody conjugated with colloidal gold (P24 conjugates) and rabbit IgG-gold conjugates (for control line), 2) a nitrocellulose membrane strip containing two test bands (band Ab and band Ag) and a control band (C band). The band Ab is pre-coated with HIV-gp120-41 and gp-36 antigens for the detection of antibodies to HIV-1 including O or HIV-2, band Ag is pre-coated with another monoclonal anti-HIV-p24 antibody for the detection of p24 antigen, and the C band is pre-coated with goat anti-rabbit 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 along the cassette. IgG, IgM, or IgA antibodies to HIV-1 or HIV-2, if present in the specimen, migrate through the conjugate pad where they bind to the HIV conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1+2 antigen, forming a burgundy colored band on the Ab 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 pre-coated HIV-p24 antibody, forming a burgundy colored band on the Ag region, indicating a positive test result. Absence of the band Ag 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 rabbit IgG/rabbit 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.

REAGENTS AND MATERIALS PROVIDED

1. Each kit contains 25 or 30 test devices, each sealed in a foil pouch with three (3) items inside:
 - a. One cassette device
 - b. One plastic dropper
 - c. One desiccant
2. Sample diluent (1 bottle, 5 mL).
3. One package insert (instruction for use).

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. A container for holding test specimen
3. Lancet for whole blood collection

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch until ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30 °C) before use.
5. Do not use the components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood for the testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading results after 15 minutes may give erroneous results.
13. 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 2-30 °C. The positive and negative controls should be kept at 2-8 °C. If stored at 2-8 °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 or expose the kit to temperatures above 30 °C.

SPECIMEN COLLECTION AND HANDLING

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

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube. Add whole blood

Test specimens as soon as possible after collecting. If not tested immediately store specimens at 2 to 8 °C for up to 5 days. The specimens should be frozen at -20 °C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

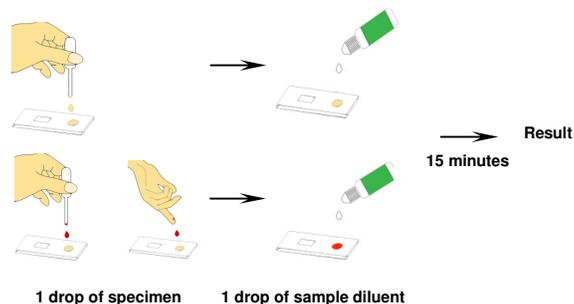
Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

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

- Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
- Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.
- Step 3: Be sure to label the device with specimen's ID number.
- Step 4: Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 30-40 µL) of serum/plasma or 1 drop of whole blood (about 45-55 µL) into the sample well making sure that there are no air bubbles. Immediately add 1 drop (about 35-50 µL) of Sample Diluent to the sample well.



- Step 5: Set up the timer.
- Step 6: Results can be read in 15 minutes. Positive or reactive results can be visible in as short as 1 minute.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Using individual *OnSite* HIV-Ab/Ag 4th Gen Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE OR NON-REACTIVE RESULT: If only the C band is present, the absence of any burgundy color in both test bands (band Ab and band Ag) indicates that neither HIV antibodies nor HIV p24 antigen is detected in the specimen. The result is negative.



2. POSITIVE OR REACTIVE RESULT:

2.1 In addition to the presence of the C band, if the Ab band is developed, the test indicates the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The result is HIV-1+2 Ab positive.



2.2 In addition to the presence of the C band, if the Ag band is developed (including faint line), the test indicates the presence of HIV-p24 in the specimen. The result is HIV-p24 positive.



2.3 In addition to the presence of the C band, if both the Ab band and the Ag band are developed, the result is both HIV-1+2 Ab and p24 antigen positive.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic decision 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

A total of 350 clinical samples were collected and tested by the *OnSite* HIV-Ab/Ag 4th Gen Rapid Test and by an SFDA licensed HIV 1+2 Ab reference kit. Comparisons for all subjects are shown in the following table:

Reference	OnSite HIV Ab/Ag 4 th Gen Rapid Test		Total
	Positive	Negative	
Positive	105	0	105
Negative	0	245	245
Total	105	245	350

Relative Sensitivity: 100.0%, Relative Specificity: 100.0%, Overall Agreement: 100.0%

2. Boston Biomedica Inc (BBI) Seroconversion Panel

The performance of *OnSite* HIV-Ab/Ag 4th Gen Rapid Test was evaluated using BBI seroconversion panel PRB970. The results are shown in the following table:

PRB-970 panel		Abbott HIV 1/2 Ab S/Co	BioMerieux HIV Ag pg/ml	OnSite HIV-Ab/Ag 4 th Gen Rapid Test
Members ID	Days bleed			
PRB970-01	0	0.2	13	Neg
PRB970-02	7	0.3	>400	Pos
PRB970-03	10	4.1	>299.6	Pos
PRB970-04	14	9.9	9.3	Pos

3. BBI HIV-1 Low Titer Performance Panel

The performance of *OnSite* HIV-Ab/Ag 4th Gen Rapid Test was evaluated using BBI HIV-1 low titer performance panel PRB-108(M). The results are shown in the following table:

PRB108(M) Members ID	Abbott HIV1/2 Ab s/co	Abbott HIV Ag EIA s/co	Orasure Advance HIV1/2 Ab	OnSite HIV-Ab/Ag 4 th Gen Rapid Test
PRB108-01	5.5	0.5	Pos	Pos
PRB108-02	0.2	0.3	Pos	Neg
PRB108-04	11.9	0.8	Pos	Pos
PRB108-05	3.4	0.5	Pos	Pos
PRB108-07	5.3	0.7	Pos	Pos
PRB108-08	8	0.5	Pos	Pos
PRB108-09	8.5	2.5	Pos	Pos
PRB108-10	8.6	2.6	Neg	Pos
PRB108-12	1.7	6.6	Neg	Pos
PRB108-15	14.2	13.8	Pos	Pos

Note: s/co < 1: Negative, s/co ≥ 1: Positive

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to HIV and/or p24 antigen in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* HIV-Ab/Ag 4th Gen Rapid Test is limited to the qualitative detection of antibodies to HIV-1, HIV-2 and/or HIV p24 in human serum or plasma. The intensity of the test band does not correlate with antibody titer or antigen level of the specimen.
3. A non-reactive result for an individual subject indicates absence of detectable HIV-1, HIV-2 antibodies and/or HIV p24 antigen. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.
4. A non-reactive 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 /antigen that are detected are not present during the stage of disease in which a sample is collected.
5. If the symptom persists, while the result from *OnSite* HIV-Ab/Ag 4th Gen Rapid Test is a non-reactive result, it is recommended to re-test the patient a few days later or test with alternative test methods.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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5. Busch, M.P., Lee, L.L., Satten, G.A., Henrard, D.R., Farzadegan, H., Nelson, K.E., Read, S., Dodd, R.Y and Peterson, L.R. Time course of detection of viral and serologic markers preceding human immunodeficiency virus type 1 seroconversion: implications for screening of blood and tissue donors. Transfusion (1995) 35:91-7

Index of Symbols

	Consult instructions for use		For <i>in vitro</i> diagnostic use only		Use by
REF	Catalog #		Lot Number		Tests per kit
	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		



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