Atlas Medical

HIV 1/2
Human Immunodeficiency Virus
A rapid test device for the qualitative detection of antibodies to human Immunodeficiency Virus-1 and/or 2 in Whole blood,serum or plasma.

IVD *For In-vitro diagnostic and professional use only*

Store at 2-30°C

INTENDED USE

Atlas HIV 1/2 Rapid Test cassette (Whole blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in whole blood,serum or plasma.

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoprotiens are on the omic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high potential risk for developing AIDS. HIV-2 has been isolated from West Africa AIDS patients and from seropositive asymptomatic individual. Both HIV-1 AND –2 elicit an immune response. Detection of HIV antibodies in whole blood, serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV. Despite the difference in their biological characteristics, serological activities and genome sequences of HIV-1 and –2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

Atlas HIV 1/2 Rapid Test device is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or –2 in Whole blood serum or plasma specimen. The test utilizes a combination of protein A coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in Whole blood , serum or plasma.

PRINCIPLE

Atlas HIV 1&2 Test employs chromatographic lateral flow device in a test cassette . Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HIV-1 gp120, gp41 and HIV-2 gp-36 are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1+2 antigens are bond at the Test Zone (T) and rabbit anti-HIV 1+2 antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If there are HIV1 or HIV 2 antibodies in sample, they will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the sheet until the Test Zone (T) zone where they are captured by the HIV 1+2 antigens generating a visible red line. If there are no HIV 1 or HIV 2 antibodies in sample, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-HIV 1+2 antibodies aggregating in a red line, which indicates the validity of the test.

MATERIALS

Materials Provided

- Test device
- Dropper.
- Package insert

Materials Required But Not Provided

- Disposable Gloves.
- Sample buffer.
- Disinfectant.
- Safety Lancet.
- Alcohol Prep-Pad.
- Timer.
- Specimen Collection Container.
- Centrifuge.
- Biohazard Waste Container.

Packaging Content

REF **8.04.27.0.0001 (1 Individually Pouched Test Cassette)**
REF **8.04.27.0.0020 (20 Individually Pouched Test Cassette)**
REF **8.04.27.0.0025 (25 Individually Pouched Test Cassette)**
REF **8.04.27.0.0030 (30 Individually Pouched Test Cassette)**
REF **8.04.27.0.0040 (40 Individually Pouched Test Cassette)**

PRECAUTIONS

- For in-vitro diagnostic use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposable capillary tubes.
- Wear productive clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.
- ALL positive results must be confirmed by an alternate method.
- Cassette used for testing should be autoclaved before disposal.
- Do not interchange reagents from one kit lot to another.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30ºC).
- 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.

SPECIMEN COLLECTION AND PREPARATION

1. The human serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause Hemolysis and protein denaturation, should be avoided.
3. Patient samples are performed best when tested immediately after collection. Specimen may be stored, if the sample cannot be tested within 24 hours. The red blood cells should be removed to avoid hemolysis. Serum or plasma should be frozen until the test can be performed. Whole blood samples should be refrigerated at 2–8oC in stead of being frozen.
4. Allow sample to reach room temperature before proceeding.
5. Sodium azide can be added as a preservative up to 0.1% without affecting the test result.

QUALITY CONTROL

The control zone is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PROCEDURE

A) Whole Blood sample Procedure:

1. Bring all materials and specimens to room temperature.
2. Remove the test cassette from the sealed foil pouch.
3. Label the test cassette with specimen identity.
4. Place the test device on a flat horizontal surface.
5. Dispense **2 drop (80-100µL)** of whole blood sample into the specimen well “S” using the sample dropper provided.
6. Read the result within 20 minutes. Reactive samples can be read as soon as distinct colored bands appear on both test zone and control zone. To confirm a negative result, please read the result at 20 minute after adding sample.

B) Serum/Plasma sample Procedure:

1. Bring all materials and specimens to room temperature.
2. Remove the test cassette from the sealed foil pouch.
3. Label the test cassette with specimen identity.
4. Place the test device on a flat horizontal surface.
5. Dispense **2 drops (80-100µL)** of sample into the specimen well “S” using the sample dropper provided.

6. Read the result within 20 minutes. Reactive samples can be read as soon as distinct colored bands appear on both test zone and control zone. To confirm a negative result, please read the result at 20 minute after adding sample.

Note: 1- Results read after 30 minutes may not be accurate.

2- Occasionally some whole blood samples are too sticky to move on the device .If it happens, re-test the sample by adding one drop of the blood sample and followed by adding one drop of the normal saline.

INTERPRETATION OF RESULTS

Positive:

Two colored bands appear within 20 minutes. One colored band appears in the Control Zone (C) and another colored band appears in the Test Zone (T). The test result is positive and valid.

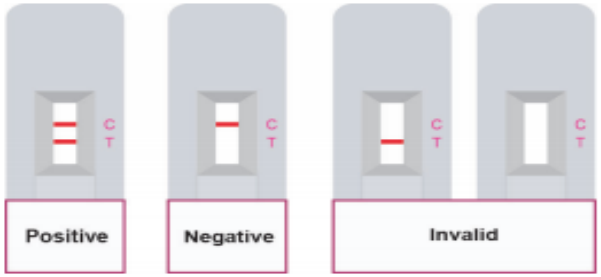
No matter how faint the colored band appears in the Test Zone (T), the test result should be considered as positive result.

Negative:

One colored bands appears in the Control Zone (C) within 20 minutes. No colored band appears in the Test Zone(T). The test result is negative and valid.

Invalid:

No colored band appears in the Control Zone (C) within 20 minutes. The test result is invalid. Repeat the test with a new test device. **(SEE ILLUSTRATION BELOW:)**



LIMITATION:

1. Negative results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV may not be detectable. For positive or reactive results, line intensity cannot be used to evaluate the anti-HIV antibody levels. A test giving an invalid result should be repeated. Rapid HIV I&II Test is not intended use for differentiation between recognition of HIV-1 antibodies and HIV-2 antibodies.
2. If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many highly sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity.
3. This kit is intended ONLY for testing of individual sample. Do not use it for testing of cadaver sample, saliva, urine or other body fluid, or pooled (mixed) blood.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

PERFORMANCE CHARACTERISTICS

In a clinical evaluation of the performance of Rapid HIV I&II Test using 2567 confirmed negative and 510 positive samples sensitivity was 99.6% and specificity was 99.7% . The overall agreement with the reference ELISA tests is 99.7%.

Sites	**HIV positive sera**		**HIV negative sera**	
	TOTAL	POSITIVE	TOTAL	POSITIVE
one	101	99	149	142
two	7	7	1784	1784
three	300	300	436	436
four	102	102	198	198
Total	**510**	**508**	**2567**	**2560**
Agreement	**99.6%**		**99.7%**	

The precision of three lots tested showed 100% agreement. In order to check possible interferences with potentially cross-reactive sera, an independent evaluation was performed with one hundred samples. The variety of sera samples containing possibly interfering substances were tested and found no interfering with Rapid HIV I&II Test.

Serum type	**No. Of samples tested**	**Rapid HIV I&II Test**	
		Negative	**Positive**
RF positive	15	15	0
Acute Hepatitis A	10	10	0
Syphilis Positive	5	5	0
Hepatitis A Recovery Phase	10	10	0
Hepatitis C	16	16	0
Infectious disease with non hepatitis B	20	20	0
HBsAg, HBeAg and HBcAb Positive	20	20	0
Fetal Serum	4	4	0

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3. Gallo, R.C., Saluahuddin, S.Z., Popovic, M., et al. (1984) Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science 224: 500-503.
4. Kenealy, W., Reed, D., Cybulsky, R., et.al. (1987) Analysis of human serum antibodies to human immunodeficiency virus (HIV) using recombinant ENV and GAG antigens. AIDS Res Human Retrovir 3: 95-105.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry