Atlas Link (Beijing) Technology Co., Ltd

One Step Human Immunodeficiency Virus 1/2 (HIV 1/2) antibody Rapid Test

Instructions For Use

Format: Cassette
Catalog Number: HIV312
Specimen: Serum/Plasma

CE 2265

* Please carefully read the instructions before use

INTENDED USE

One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Rapid Test is a rapid and convenient immunochromatographic assay for the qualitative detection of antibodies against HIV type 1 and type 2 in human serum, plasma or blood sample. It is intended for professional use as an aid in diagnosis of HIV infections. This assay provides only a preliminary result and all positive specimens should be confirmed with other qualified assays.

SUMMARY AND PRINCIPLE OF THE ASSAY

The human immunodeficiency virus (HIV) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS). HIV attacks the immune system, resulting in a chronic, progressive illness which leads to life-threatening opportunistic infections. There are two types of HIV: HIV-1 and HIV-2. HIV-1 has been isolated from patients with AIDS and AIDS related complex, and from healthy persons with high potential risk of developing AIDS. Patients with HIV-2 are found primarily in parts of West Africa. Both types are transmitted by sexual contact, through blood, and from mother to child; they appear to cause clinically indistinguishable AIDS. HIV infection is staged by CD4 cell counts and clinical symptoms. Not everyone progress through all "stages" and the time frames may also vary greatly from person to person. Treatment with anti-retrovirals increases the life expectancy of people infected with HIV.

HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and generic structure. Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less so in the envelope antigens. This clinical diagnostic issues related to HIV are the detection of antibodies to HIV1/2 in human plasma or serum by immunoassay.

One Step HIV 1/2 antibody test is an antibody-capture immunochromatographic assay, which detects the presence of HIV1/2 antibodies in blood samples. Specific HIV1/2 antigens, GP41 and GP 36, are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test zone (T) of the nitrocellulose membrane, respectively. When sample is added, it rehydrates the gold-antigen conjugate. If the HIV1/2 antibodies are present in the sample, they will interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test zone (T) where they will be captured by immobilized antigen, forming a visible red line (Test band) indicating a positive result. If HIV1/2 antibodies are absent in the sample, no red line will appear in the Test Zone (T).

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant
- Test instruction

OTHER REQUIRED MATERIALS (NOT PROVIDED)

- Glove
- Clock or timer

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1

Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

2

Holding the sample dropper vertically, add three full drops (120 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

4

Read the result in 10 minutes. Read results as shown under interpretation of Results.

NOTE: Specimens with high concentrations of HCV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 10 - 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS

Negative
A red colored band appears only at the control region (C), indicating a negative result for HIV infections

Positive
A clear red control line (C) and a detectable test line (T) appear, indicating a positive result for HIV infections (type 1 and/or type 2).

Invalid
No visible band appears at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper

testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- 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.
- A negative result does not eliminate the possibility of HIV-1 / HIV-2 infection. The specimen may contain low levels of antibodies to HIV-1 / HIV-2.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrate superior accuracy in detecting HIV 1/2 infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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

	• PERFORMANCE CHARACTERISTICS
• Diagnostic Sensitivity	• The diagnostic sensitivity of HIV1/2 Antibody Rapid Test was 99.69% (637/639) and could identify HIV1 subtypes and HIV2.
• Diagnostic Specificity	• The diagnostic specificity of HIV1/2 Antibody Rapid Test was 99.66% (1745/1751)
• Analytical Sensitivity •	• Reactivity with Worldwide HIV Performance Panel • The sensitivity of HIV-1/2 Antibody Test for the detection of antibodies to HIV-1 Group M subtypes (A,B,C,D,E,F,G) from various geographic regions was assessed by testing a worldwide HIV performance panel. • Seroconversion panels 10 seroconversion series from ZMC and 20 seroconversion series from BBI were tested on HIV1/2 Antibody Rapid Test. The assay results were compared with the data from the testing results of Abbot HIV1/2 Antibody EIA reported on the BBI and ZMC panel data sheets. Overall, HIV1/2 Antibody g Rapid Test demonstrated an ability to detect earlier in the conversion of a

	patient from seronegative to seropositive in comparison with Abbot HIV1/2 Antibody EIA products.
• Analytic Specificity	• No cross reaction with seromarkers associated with unrelated medical conditions: C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF), infectious mononucleosis, Helicobacter pylori IgG/IgM antibodies, hepatitis B virus seromarkers (HBsAg, anti-HBc IgG/IgM, and anti-HBs), hepatitis C virus (anti-HCV antibody), hepatitis A virus IgM (anti-HAV), parvovirus IgG/IgM, herpes simplex virus IgG (HSV), cytomegalovirus IgG/IgM, mycoplasma IgM, EBV, human T-Lymphotrophic virus, rubella IgM, syphilis reagin (RPR/TPPA), Dengue Virus IgG/IgM
• Interference	• Analytes commonly found in OTC, prescription and/ or abuse drugs, chemical analytes, and pH did not interfere HIV Antibody Test.
• Repeatability and Reproducibility	• Tests showed positive results with all positive samples and showed negative results with negative samples. no appreciable intra and inter lot variation were observed among different tests for each lot, different lots, different operators at different test sites in different time for the same sample. • Demonstrate: the repeatability and reproducibility of HIV Antibody Test are satisfactory.
• Storage and Expiration Date	• Store at 2-30°C, avoid direct sunlight and freezing • 36 months

REFERENCES

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INDEX OF SYMBOLS

	Do not reuse		Batch code
	In vitro diagnostic medical device		Use by
	Temperature limitation		Contains sufficient for < n > tests
	Caution		Catalog number
	Manufacturer		Consult instructions for use
	Authorized representative in the European community		CE Mark

MANUFACTURER CONTACT INFORMATION

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