Artron

Human Immunodeficiency Virus 1/2 (HIV 1/2) antibody Test

Instructions For Use

Format: Cassette

For:

Catalog Number: A02-07-322

Specimen: Whole blood/Serum/Plasma

and

Catalog Number: A02-07-222

Specimen: Serum/Plasma

* Please read the instructions carefully before use

INTENDED USE

Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test is a rapid and convenient immunochromatographic assay used 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 that 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 complexes, and from healthy persons with high potential risks of developing AIDS. Patients with HIV-2 are found primarily in parts of West Africa. Both types are transmitted by sexual contact, through blood, or from mother to child and appear to cause clinically indistinguishable AIDS. HIV infections are staged by CD4 cell counts and clinical symptoms. Not all people 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. The clinical diagnostic issues related to HIV are the detection of antibodies to HIV1/2 in human plasma or serum by immunoassay.

Artron One Step HIV 1/2 antibody test is an antibody-capture immunochromatographic assay, detecting 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) on the nitrocellulose membrane, respectively. When the serum/plasma sample is added the gold-antigen conjugate is rehydrated and the HIV1/2 antibodies, if any in the sample, 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 antigens, forming a visible pink line (Test band) indicating positive results. If HIV1/2 antibodies are absent in the sample, no pink 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 pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant.
- Sample buffer (3 ml) per bottle for 25 tests (for whole blood sample, catalog: A02-07-322 only).
- Test instructions.

MATERIALS REQUIRED (BUT 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 and 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 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 of 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.

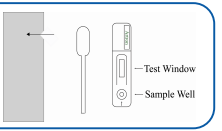
SPECIMEN PREPARATION

- 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.
- For whole blood samples, collect blood in a tube containing anticoagulant.
- Whole blood samples should be tested immediately after sample collection.
- 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

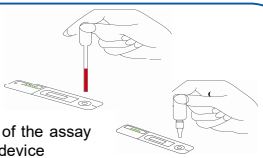
Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



2

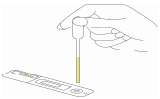
For Whole Blood Sample:

- Hold the sample dropper vertically. Add one drop (35 µl) of the specimen without air bubbles into the Sample Well that is marked with an arrow on the testing device;
- Wait for 20-30 sec, then add 2 drops (90 µl) of the assay buffer to the same Sample Well of the testing device



For Serum/plasma Sample:

- Hold the sample dropper vertically. Add two full drops (80 µl) of the specimen without air bubbles into the Sample Well that is marked with an arrow on the testing device



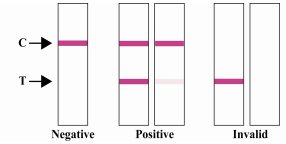
3

Read the results in 10-30 minutes. Read results as shown under interpretation of Results

NOTE: Specimens with high concentrations of HIV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 10-20 minutes (for whole blood samples, confirm negatives in 20-30 minutes).

DO NOT INTERPRET RESULTS AFTER 40 MINUTES.

RESULT INTERPRETATIONS



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

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

Invalid
No visible band at the control region. Repeat with a new test device. If the 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.

MANUFACTURER CONTACT INFORMATION

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