HIV 1+2 Ab Rapid Test

Cat. No.: S025-01

In vitro Diagnostic

INTENDED USE

Sensit One Step Human Immunodeficiency Virus 1+2 (HIV 1+2) Antibody Test is an 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. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY &TEST DESCRIPTION

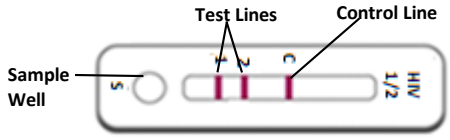
The human immunodeficiency virus (HIV) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS). HIV attacks the immune system, resulting in a chronic, progressive illness that leads to life-threatening opportunistic infections. There are two types of HIV, HIV-1 and HIV-2. HIV-1 has been 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-retroviral 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.

Sensit HIV 1+2 Ab Rapid Test contains a test device for HIV 1 and 2 Ab, which utilizes Recombinant antigens of HIV-1 (gp 41) and HIV-2 (gp 36) as the capture molecules. Recombinant antigen of HIV 1&2 conjugated to colloidal gold is used as detection molecule.

TEST PRINCIPLE

Sensit HIV 1+2 Ab Rapid Test works on chromatographic immunoassay. Basic components of test strip include: a) Conjugate pad which contains HIV 1&2 Recombinant Antigen, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines; 2: HIV-2 Ag (gp 36), 1: HIV-1 Ag (gp 41) and C: Goat Anti Mouse which are housed in a test device as shown below.



Test sample that is added to the sample well (S), with adequate amount of assay diluent migrates from the sample pad along the conjugate pad. HIV 1&2 specific antibodies if present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized HIV-1 & 2 Ag's (on test lines **1** and **2**) producing a visible line on the membrane. If the respective analyte is not present in the sample, no reaction occurs in the respective capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane as control line C irrespective of the presence of antibodies against HIV 1 and HIV 2 in the sample. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each kit contains 25 test devices, each sealed in a foil pouch containing following items:
   a. One Test card
   b. Dropper
   c. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Do not reuse the test device; each test can be used ONLY SINGLE TIME.
6. Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Plasma:

- Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, it should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20°C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1) Take out the test card from the foil pouch and place it on a horizontal surface.
2) Add 1 drop of specimen without air bubble to the Sample well "S".
3) When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4) Wait for 10-15 minutes and interpret results. Do not read the result after 15 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS C, 1 and 2 ON THE DEVICE AS SHOWN BELOW.)

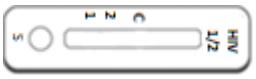
Positive for HIV 1 and HIV 2 antibodies in sample: Pink Color bands at position **C, 1 & 2**

Negative for HIV 1 and HIV 2 antibodies in sample: No pink color at position **1 & 2**

HIV 2 Positive and HIV 1 Negative: Color bands at position 2 and C

HIV 1 Positive and HIV 2 Negative: Color bands at position 1 and C

Invalid: Color band at C does not appear



READ THE SYMBOLS ON PACKAGE AS FOLLOWS:

References:

1.Constantine NT, van der Groen G, Belsey EM, Tamashiro H. Sensitivity of HIV-antibody assays determined by seroconversion panels. Aids 1994; 8:1715-20.

2.Feinberg MB. Changing the natural history of HIV disease.Lancet 1996; 348:239-46.

Product Disclaimer:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the use of this product occurs outside of the control of the manufacturer and distributor and the result may accordingly be affected by environmental factors and / or user error. The result should be further confirmed by consulting a doctor.

Warning: The manufacturer and distributors of this product shall not be liable for any losses, for any liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis whether positive or negative, in the use of this product.

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