

“See Now” Anti HIV 1.2 Cassette Test

Whole blood/Serum/Plasma

For in vitro Diagnosis Use

Product Code: SN 2.3

INTENDED USE

The “See Now” HIV1,2 Test is for the qualitative detection of antibodies specific to human immunodeficiency of virus (HIV) in whole blood, human serum or plasma. This test kit is intended as an aid in the diagnosis of HIV1 and HIV2 infection.

PRINCIPLE

The “See Now” HIV1,2 Test has been designed to detect the HIV infection through visual interpretation of color development in the test device, which is a sandwich solid phase gold conjugate immunoassay. The test device contains membrane strip that is pre-coated with HIV antigens on the test band region and goat-anti-mouse polyclonal antibody on the control band region. The HIV antigens-colloid gold conjugate pad is placed at the end of the membrane. When the HIV specific antibodies are present in samples, the mixture of colloid gold conjugate, sample and developer buffer moves along the membrane chromatographically by a capillary action. This mixture then migrates to the test band region and forms a visible line as the antigen-antibody-antigen complex forms. Therefore, the formation of a visible precipitation in the test band region occurs when the sample is possible for the HIV specific antibodies. When the HIV specific antibodies are absent in the sample, no visible color band will form on the test line region. Therefore, the absence of the color band on the test line region indicates a negative result. A colored band will always appear at the control region. This control band serves as a procedural indicator for the proper performance of the test and the device.

REAGENTS AND MATERIALS SUPPLIE

- Test instruction, buffer (diluent) solution
- Pouch Contents: Cassette, Sample Dropper, Desiccant.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container
- Timer

STORAGE AND STABILITY

The kit should be stored at refrigeration (2-8°C) or at room temperature (10-30°C) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.
- Do not interchange reagents from different lots or use test kit beyond expiration date.
- There should be no smoking or eating where antigen containing materials are being handled.
- Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards. Use appropriate precautions in the collection, handling, storage and disposal of specimens, used pipette, and gloves. Discard used materials in a proper biohazard container.
- Do not open the foil pouch until you are ready to perform the test.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

SPECIMEN COLLECTION AND STORAGE

- 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 (EDTA, citrate or heparin, respectively).
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature.
- Fingertick sampling is recommended for this assay. Middle or ring finger is the preferred puncture site.
- Clean patient's finger with an alcohol swab. Wait until it is dry.
- Puncture the fingertip with the lancet. Wipe away first sign of blood.
- Gently rub the hand from palm to finger to help form a drop of blood over the punctured site.
- Use the provided pipette to pick up the blood, and apply one drop of the blood to the sample well of the device

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- **For serum or plasma**, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.
- **For whole blood** specimen add one full drop (40ul) of sample; after the blood was absorbed add two drops (80ul) of diluents.
- Read the results at 15-20 minutes. Ensure that the background of the test area is white before interpreting the result

INTERPRETATION OF RESULTS

Negative

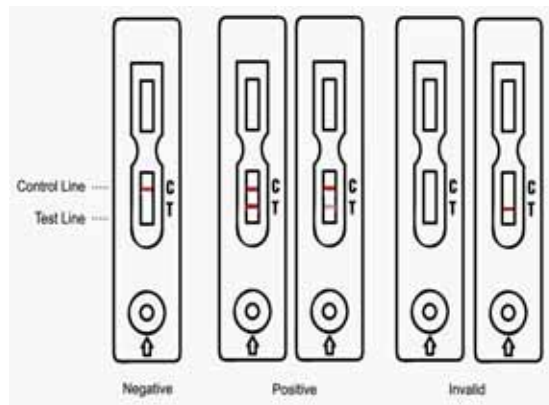
Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

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



number.

LIMITATION OF PROCEDURE

- The assay is designed for human blood, serum or plasma use.
- This test kit is to be used for the qualitative detection of antibodies to HIV.
- Negative result does not rule out infection by HIV because the antibodies to HIV may be absent or may not be present in sufficient quality to be detected at early stage of infection.

QUALITY CONTROL

The procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance of the test and the device.