HIV 1 / 2 quick test
A qualitative screening Test kit for the Detection of Antibodies to HIV 1/2 in Human Serum, Plasma or Whole Blood

FOR PROFESSIONAL USE ONLY

Kit components
Each kit contains the items to perform 40 tests:
- Test devices - 40
- Vial assay diluent - 1
- Capillary pipettes - 40
- Sterile single use lancets (for finger stick blood samples only) - 40
- Sterile alcohol swabs (for finger stick blood samples only) - 40
- Instruction leaflet

Additional Materials required:
- Timer

Storage and stability
The HIV 1/2 test devices should be stored at room temperature between 8° and 30° C. Diluent can be stored between 1 and 30°C. Do not freeze test kits or expose to temperature or humidity extremes!

Precautions
The test is FOR IN VITRO DIAGNOSTIC USE only. FOR PROFESSIONAL USE only.
Handle all specimens as recommended for any potentially infectious human serum or blood specimen.
Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
Do not eat, drink or smoke in the area where the specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.
Do not mix reagents from different lots of test kits.
After the completion of assay, dispose of all specimens, test devices, lancets, pipettes carefully after autoclaving or by treating with solution of bleach (1%). Treat as biohazard waste.
Do not use tests beyond expiration date that appears on the foil pouch.

Sample collection
The Cypress HIV1/2 rapid test is performed on whole blood, serum or plasma.

Whole Blood:
Collect venous whole blood into tubes containing common anticoagulants and preservatives (e.g. EDTA, heparin or sodium citrate).
For fingertip blood, clean the area to be lanced with an alcohol swab and let thoroughly dry. Prick the finger with a sterile lancet and wipe away the first drop. Touch the included capillary pipette to the second blood drop and allow the blood to fill the capillary to the black line (20 µl). Do not squeeze the finger too hard. Follow test procedure instructions.
Whole blood samples should be stored in refrigeration (2-8°C) or on ice prior to testing. Whole blood samples should generally be tested within 24 hours of drawing the sample.

Serum: Serum is used from whole blood collected aseptically by venipuncture into a clean tube without anticoagulant.

Intended Use
The Cypress’ HIV1/2 rapid test is a single use, immunochromatographic screening test which uses a cocktail of recombinant antigens to detect antibodies to HIV1/2 in serum, plasma or whole blood. Positive results are supportive evidence of HIV1/2 exposure and can be used to support a clinical diagnosis of HIV1/2. The HIV 1/2 is intended for use by medical professionals and must be used in accordance with the directions provided.

Summary and explanation
The Human Immunodeficiency Virus (HIV) is a retrovirus, identified in 1983 as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS). AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual the virus causes a depletion of subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, contamination by blood or blood products and mother-to-newborn transmission.

The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of anti-HIV antibodies. The detection of these antibodies can be used as a diagnostic test.

ELISA, Western blots, PCR-based assays and various other test systems are currently available for HIV1/2 detection. The Cypress HIV1/2 test is a rapid immunochromatographic test, which is simple and easy to use. The Cypress HIV1/2 assay system utilizes immobilized recombinant antigens for the detection of antibodies to HIV1/2 in serum, plasma or blood.

Principle of the Test
The Cypress HIV1/2 assay employs a unique combination of a cocktail of recombinant antigens (gp41, p24 and gp36), which is conjugated to colloidal gold dye particles, and a complementary set of recombinant antigens of HIV-1 (gp41, p24) and of HIV-2 (gp 36) which are bound to the membrane solid phase on test band region 1 and on test band region 2 respectively. Since the antigens are recombinant, these are non-infectious. The test will detect all antibodies 
against gp41 (IgG, IgM, IgA) and also subtypes O antibodies. The sample is applied to the SAMPLE (S) well followed by the addition of a assay diluent. The assay diluent facilitates the lateral flow of the released products as well as promoting the binding of antibodies and antigen. If present, the antibodies bind to the gold conjugated antibody binding protein. In a positive sample, the dye-conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the test line 1 (HIV-1) or test line 2 (HIV-2) area producing a purple line. In the absence of HIV1/2 antibodies, there is no line in the TEST area. The sample continues to migrate along the membrane and produces a purple line in the CONTROL (C) area, demonstrating that the test has been performed properly.

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Plasma: Plasma is used from whole blood collected aseptically by venipuncture into a clean tube containing anticoagulant.

Patient serum and plasma samples perform best when tested immediately after collection. If not to be tested immediately, the samples should be refrigerated immediately following collection at 2-8°C and can be used up to 3 days. If testing within 3 days is not possible, the samples should be frozen (-20°C or colder).

NOTE: If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiological agents.

Test Procedure

1. Remove the required number of HIV1/2 test devices from their wrappers by tearing the wrapper and place them on a flat surface (It is not necessary to remove the desiccant).
2. Label the test unit with patient name or identification number.
3. Blood samples: Add 20 µl of the blood sample with micropipette or included capillary pipette to the SAMPLE (S) well of the device. Plasma or serum samples: Add 10 µl of the sample with a micropipette to the SAMPLE (S) well of the device.
4. Invert the assay diluent bottle and hold it vertically (not at an angle) over the sample well. Add the diluent slowly dropwise, 4 drops (120 µl) into the SAMPLE (S) well.
5. Read the test results at 20 minutes after the addition of the assay diluent. Some positive results may appear in less than 20 minutes, but 20 minutes are needed to report a negative result. Read results in a well-lit area. NOTE: Reading results after 20 minutes can give false results.

Interpretation of Results

This cassette contains two test result lines in the test area (T): A test line that detects antibodies to HIV-1 (1) and a test line that detects antibodies to HIV-2 (2). A control line should appear in the control area.

Control line

HIV-2

HIV-1

Sample well

Negative

One purple colored line in the CONTROL (C) area, with no colored lines in the TEST (T) area indicates a negative result. A negative result after 20 minutes indicates that there are no detectable HIV1/2 antibodies in the patient sample, but this result does not exclude HIV infection.

Positive

Two purple colored lines, one in the TEST (T) area and one in the CONTROL (C) area, indicate a positive result. The presence of a test line 1 (1) indicates a positive result for HIV-1. The presence of a test line 2 (2) indicates a positive result for HIV-2.

Three purple colored lines, two test lines (1 and 2) and a control line, indicates a positive result for HIV-1 and/or HIV-2.

If the color intensity of the test line 1 is darker than one of test line 2 in the result window, you can interpret the result as HIV-1 positive. If the color intensity of the test line 2 is darker than one of test line 1 in the result window, you can interpret the result as HIV-2 positive.

Although a positive result for HIV-1 and HIV-2 in one patient is a rare case, it’s possible as there is a homology in the amino acid sequence between HIV-1 and HIV-2. To determine the virus type or diagnose a co-infection accurately, you must perform a confirmatory test as Western Blot.

Inconclusive

A purple colored line should always appear in the CONTROL area, no matter if a TEST LINE appears or not. If there is no distinct purple line visible in the CONTROL area, the test is inconclusive. It is recommended that the test be repeated with a new device.

Quality Control

A purple colored line should always appear in the CONTROL area if the test has been performed correctly and the device is working properly.

Good laboratory practice recommends the use of control materials along with the test samples to ensure proper performance of the test kit. A known positive and negative control should be used for this purpose. All controls should be handled in the same manner as patient samples.

Limitations of the Procedure

- This HIV1/2 procedure and the interpretation of the results must be followed closely. It is a screening test designed for detecting antibodies against HIV1/2 in human serum, plasma or whole blood. Any result from the testing of other body fluids or of pooled serum or plasma should not be used.
- For positive results, testing must be confirmed with Western blot or alternative procedure and the clinical evaluation of the patient’s situation should be performed before a final diagnosis is made.
- 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.
- Rapid testing alone should not be used to diagnose AIDS infection even if antibodies to HIV1/2 are present.
- A negative result at any time does not preclude the possibility of infection with HIV1/2.
- The sample may contain low levels of antibodies to HIV 1/2. The use of hemolytic samples, rheumatoid factors-contained samples and lipidemic, icteric samples can impair the test results.

Performance Characteristics

Sensitivity and Specificity

The relative sensitivity and specificity of the Cypress HIV1/2 Test against a commercially available ELISA system was determined by testing 211 HIV-1 positive, 83 HIV-2 positive and 512 HIV 1/2 negative samples. The results showed a sensitivity of 100% for HIV-1 and HIV-2 and a specificity of 99.6% for the Cypress HIV-1/2 Test.

Bibliography


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