CHEMBIO DIAGNOSTIC SYSTEMS

NEW FORMAT
PLEASE READ
INSTRUCTIONS CAREFULLY

INSTRUCTIONS FOR USE

HIV101 - 20 TEST KIT
HIV133 - Bulk

HIV1/2 STAT-PAK

A Qualitative Screening Test Kit for the Detection of Antibodies to HIV1/2 in Human Serum, Plasma or Whole Blood

FOR EXPORT ONLY
FOR *IN VITRO* DIAGNOSTIC USE
FOR PROFESSIONAL USE ONLY
READ INSTRUCTIONS FOR USE CAREFULLY BEFORE PERFORMING TEST

INTENDED USE

The Chembio HIV1/2 STAT-PAK is a single use, immunochromatographic screening test which uses a cocktail of antigens to detect antibodies to HIV1/2 in serum, plasma or whole blood. Positive results are supportive evidence of exposure to HIV1/2 and can be used to support a clinical diagnosis of HIV1/2. Negative results, however, should not be used to exclude HIV1/2. The HIV 1/2 STAT-PAK 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) [1]. 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 [2-4].

Medical experts working for the United Nations (UN) have reported that almost 16,000 new infections are occurring a day. The UN has reported that worldwide, about 11.7 million people of all ages have died from AIDS in the 70's and 80's [3,4]. In July 1996, an estimated 22 million people worldwide were living with HIV infection and HIV epidemics are rapidly increasing [5].

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 tool.

ELISA, Western blots, PCR-based assays and various other test systems are currently available for HIV1/2 detection [6-10]. The Chembio HIV1/2 STAT-PAK is a rapid immunochromatographic test, which is simple and easy to use. The Chembio HIV1/2 STAT-PAK assay system utilizes immobilized antigens for the detection of antibodies to HIV1/2 in serum, plasma or blood.

PRINCIPLE OF TEST

The Chembio HIV1/2 STAT-PAK assay employs a unique combination of a specific antibody binding protein, which is conjugated on colloidal gold dye particles, and antigens to HIV1/2, which are bound to the membrane solid phase. The sample is applied to the SAMPLE (S) well followed by the addition of a running buffer. The running buffer 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 (T) area producing a pink/purple line. In the absence of HIV1/2 antibodies, there is no pink/purple line in the TEST area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area, demonstrating that the reagents are functioning properly.

STAT-PAK KIT COMPONENTS

Each kit contains the items to perform 20 tests :

1. Chembio HIV1/2 STAT-PAK test devices - 20, each containing a cocktail of antigens of HIV1/2 and gold conjugate
2. Chembio HIV1/2 running buffer – 1 vial
3. Disposable 5 µl sample loops - 20
4. Instruction leaflet – 1

Additional Materials Required :

Timer
Sterile single use lancets (for finger stick blood samples only).
Sterile alcohol swabs (for finger stick blood samples only).

STORAGE AND STABILITY

The HIV1/2 STAT-PAK test devices should be stored at any temperature between 8-30°C in the original sealed pouch. The running buffer should be stored at 8-30°C in the original vial.

NOTE : Do not use test kits beyond the expiration date imprinted on the box label and/or pouch.

CAUTION : DO NOT FREEZE TEST KITS.

PRECAUTIONS

1. The test is FOR *IN VITRO* DIAGNOSTIC USE only. FOR PROFESSIONAL USE only. Use the test only in accordance with instructions supplied with the kit.
2. Handle all specimens as recommended for any potentially infectious human serum or blood specimen in the CDC-NIH manual, Biosafety in Microbiological and Biomedical Laboratories, 1993.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
4. 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.
5. Do not mix reagents from different lots of test kits.
6. After the completion of assay, dispose of all specimens, test devices, sample loops carefully after autoclaving at 125ºC for 1 hour or by treating with 10% solution of bleach for 30 minutes. Treat as biohazard waste.
7. Do not use tests beyond expiration date which appears on the foil pouch.

SPECIMEN COLLECTION

The Chembio HIV1/2 STAT-PAK test is performed on whole blood, serum or plasma.

Whole Blood: Collect whole blood into tubes containing EDTA, heparin or sodium citrate. For fingertip blood, prick the finger and wipe away the first drop. Collect the sample from the second drop with the included disposable sample loop. Do not squeeze the finger too hard. Follow test procedure instructions.
Serum: Serum is used from whole blood collected aseptically by venipuncture into a clean tube without anticoagulant. Allow the blood to clot at room temperature. Centrifuge the blood at 2000 rpm for 10 minutes at room temperature. Remove the serum from the clot as soon as possible to avoid hemolysis.
Plasma: Collect whole blood with anticoagulants, centrifuge at 2000 rpm for 10 minutes and isolate the plasma supernatant.

Patient samples perform best when tested immediately after collection. If not to be tested immediately, specimens 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 specimens should be frozen (-20ºC or colder).

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

CONFIRMATION OF TEST PERFORMANCE

When the test is complete, you will see the familiar pink/purple colored line in the CONTROL area of the test device on negative as well as positive samples. This control line serves as an internal control and gives confirmation of proper test performance. Pink/purple colored lines in both the TEST and CONTROL areas indicate a positive response.

TEST PROCEDURE

If the HIV1/2 STAT-PAK sample to be tested is refrigerated, remove it from the refrigerator and allow it to come to room temperature prior to testing.

1. Remove the required number of HIV1/2 STAT-PAK 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. Touch the 5 µl sample loop provided to the material to be tested allowing the opening of the loop to fill with the liquid.
4. Holding the sample loop vertically, touch it to the sample pad in the center of the SAMPLE (S) well of the device to dispense ~5 µl of sample (serum, plasma or whole blood) onto the sample pad
5. Invert the running buffer bottle and hold it vertically (not at an angle) over the sample well. Add the buffer slowly dropwise, 3 drops (~ 120 µl) into the SAMPLE (S) well.
6. If there is no migration after ~3 minutes, add one more drop of running buffer.
7. Read the test results at 10 minutes after the first addition of the running buffer. Some positive results may appear in less than 10 minutes, but 10 minutes are needed to report a negative result. Read results in a well-lit area.

NOTE : Discard the used sample loop, test device and gloves into a biohazard waste container.

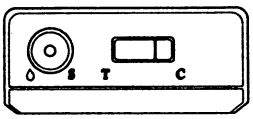
QUALITY CONTROL

A pink/purple colored line should always appear in the CONTROL area if the test has been performed correctly and the device is working properly. It serves as an internal procedural control. A clear background in the TEST area is an internal negative procedural control.

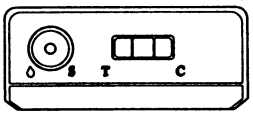
Good laboratory practice recommends the use of control materials along with the test samples to ensure proper performance of the test kit. Positive and negative serum or plasma based commercial controls should be used for this purpose. Use controls, as per the TEST PROCEDURE instructions of this insert. Please note that certain commercial controls designed for ELISA may not perform properly with the Chembio HIV1/2 STAT-PAK. Serum or plasma based controls for example from BBI (Boston Biomedica Inc, USA) or NABI (Nabi Diagnostics, USA) can be used.

INTERPRETATION OF RESULTS

Negative
One pink/purple colored line in the CONTROL (C) area, with no colored line in the TEST (T) area indicates a negative result. A negative result after 10 minutes indicates that there are no detectable HIV1/2 antibodies in the patient sample, but this result does not exclude HIV infection.



Positive
Two pink/purple colored lines, one in the TEST (T) area and one in the CONTROL (C) area indicate a positive result. The line in TEST (T) area may look different from the line in the CONTROL (C) area. The intensity of the line in the TEST (T) area will vary with the concentration of specific antibodies, from barely visible to very dark.



NOTE : Even a very faint line in the TEST area should be considered positive. A positive must be confirmed by Western blot or IFA in accordance with the CDC (Center for Disease Control) recommendations.

Inconclusive

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

LIMITATIONS OF THE PROCEDURE

The HIV1/2 STAT-PAK 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 IFA according to CDC recommendations, and the clinical evaluation of the patient's situation should be performed before a final diagnosis is made. 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.

EXPECTED RESULTS

This is a qualitative test for the detection of antibodies to HIV1/2 in whole blood, serum or plasma. As described in the PERFORMANCE CHARACTERISTICS section below, he sensitivity of the Chembio HIV1/2 STAT-PAK was found to be substantially equivalent to the EIA and Western blot tests when tested on selected performance panels.

PERFORMANCE CHARACTERISTICS

In-house studies demonstrate that the sensitivity of the Chembio HIV1/2 STAT-PAK is substantially equivalent to the EIA and Western blot tests when tested on BBI performance panels PRZ204 Anti-HIV 1/2 Combo Performance Panel, PRF202 Anti-HIV 2 Performance Panel and PRB203 Anti-HIV 1 Mixed Titer Performance Panel as well BBI Seroconversion panels PRB904 and PRB909.

In an external evaluation of the performance of the HIV 1/2 STAT-PAK using 336 confirmed negative and positive serum, plasma and whole blood samples, sensitivity was 100% (129/129) and specificity, 100% (207/207). This included 34 finger-stick blood samples – 29 positive and 5 negative. In this same study, excellent analytical sensitivity relative to EIA was demonstrated using BBI seroconvertor panels PRB940 and PRB931.

PRECISION

Intraassay
Within run precision was determined by using 10 replicates of two specimens containing different levels of HIV1/2 antibodies. The negative and positive results were correctly identified 100% of the time.

Interassay
Between run precision was determined by using the same two specimens in 10 different replicates from three different lots of test devices. Again negative and positive results were observed 100% of the time.

Cross Reactivity and Interference
No cross reactivity was observed from Hepatitis B, rheumatoid factor (~80 IU/ml) and hCG (500 mIU/ml) with Chembio HIV1/2 STAT-PAK assay. In addition, no interference from bilirubin, hemoglobin and triglycerides was observed.

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ORDERING INFORMATION

HIV101 HIV 1/2 STAT-PAK, 20 Tests

HIV133 HIV 1/2 STAT-PAK, Bulk Tests

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