

PAREEKSHAK[®]

HIV 1/2 Triline Card Test



CE 1023

IVD

For Professional Use

Screening test for the detection of antibodies to HIV - 1 and / or HIV - 2 in human serum or plasma



READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

CATALOGUE No.: PTC

Intended Use : Pareekshak[®] HIV ½ Triline Card Test is an immuno chromatographic based assay for the detection of antibodies to HIV 1 & HIV 2 in Human Serum or Plasma.

Introduction : Human Immunodeficiency Virus type-1 (HIV-1) and type-2 (HIV-2) are the etiological agents of Acquired Immunodeficiency Syndrome (AIDS). Current data indicate that the HIV is transmitted through sexual contact, exposure to blood (including sharing contaminated needle and syringe) or certain blood products or from an infected mother to her child during the prenatal period. People with increased risk of HIV infection include intravenous drug users, homosexuals and haemophiliacs. The presence of antibodies to HIV- 1/HIV-2 indicates previous exposures to HIV-1/HIV-2 virus.

This is a rapid test device used for the detection of HIV - 1 & 2 antibodies in human serum or plasma. THIS IS ONLY A SCREENING TEST FOR HIV-1 & 2 antibodies. If the sample gives a positive result confirmatory tests such as Western Blot, should be performed. HIV-1 and HIV -2. Since HIV antigens are used for both binding and capturing, this test can detect all classes of HIV antibodies, hence detects early seroconversion.

TEST PRINCIPLE : The test employs lateral flow immuno - chromatographic type assay, The test device consists of sample window containing a reagent releasing pad. The reagent releasing pad is held in contact with the porous membrane material. The membrane has four zones. The first zone is mobile and it is at the sample window and it consists of coloured colloidal gold particles sensitized to HIV-antigen. The second and third zone consists of recombinant HIV antigens (recombinant HIV-1gp 41 antigen and C terminal of gp -120 for HIV-1 & recombinant HIV-2gp36 antigen for HIV-2) immobilized on the membrane (Test line). The fourth zone (Control line) consists of control antibody, which is also immobilized on the membrane. If HIV antibody is present in the test sample, it will form a complex with the HIV antigen colloidal gold conjugate and then move on, to be trapped by the test line, causing the formation of red line. The unbound colloidal gold particles continue to move along the strip by capillary action until they come in contact with the control line and are trapped, giving a red line demonstrating the validity of the test.

STORAGE AND STABILITY : Kit should be stored between 2°C- 30°C in the sealed pouch. The test kit is stable until the expiration date mentioned on the pouch when stored under these conditions. Do not use the test device, if the pouch is damaged or the seal is broken. Keep the test device in the sealed pouch until ready for use.

Pack Size : Available in packs of 10's, 20's, 50's and 100's.

CONTENTS OF THE KIT

| Pack Size | 5 Test | 10 Test | 20 Test | 50 Test |
|----------------|---------|---------|---------|---------|
| Testing Device | 5 Nos. | 10 Nos. | 20 Nos. | 50 Nos. |
| Diluent | 0.75 ml | 1.5 ml | 3.0 ml | 7.5 ml |
| 10µl Dropper | 5 Nos. | 10 Nos. | 20 Nos. | 50 Nos. |
| Silicagel | 5 Nos. | 10 Nos. | 20 Nos. | 50 Nos. |

MATERIAL REQUIRED BUT NOT PROVIDED :

- Sterilized Vial.
- Disposable gloves.
- Precession Pipette.
- Sodium hypochlorite solution (free available chlorine 50-500 mg/L).
- Autoclaved Tips.

In order to obtain reproducible results, the following rules must be made.

- Read this pack Insert carefully.
- DO NOT FREEZE THE KITS. If refrigerated the kit should be brought to room temperature before testing Assay should be conducted between 15-30°C.
- If the sample is turbid or visocus centrifuge the sample at 5,000rpm for 15 minutes.
- Do not use the kit beyond their expiry date.
- Use only serum or plasma.
- Carefully observe the prescribed number of drops to be added, 10µl or 1 drop of Serum or plasma and 2 drops of diluent only.
- Use the test device soon after it is removed from the pouch.
- do not use the test device after it is removed from the pouch.
- Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.
- Read the positive result in 10 minutes and Negative results in 20 minutes. Do not interpret the result. After 20 minutes.
- Do not smoke, eat drink or apply cosmetic during the assay.
- For Invitro Diagnostic Use only.
- For Single use only.
- Avoid using hemolytic, lipaemic, ecteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institute of Health manual "Biosafety in Microbiological and Biomedical Laboratories", 1984.

Never pipette by mouth.

Do not smoke, eat or drink in areas in which specimens or kit reagents.

Afterwards wash hands carefully.

Avoid splashing of forming aerosols.

Discard all materials and specimens as if capable of transmitting infection.

The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid waste not containing acid may be mixed with sodium hypochlorite so that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination.

Note : Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.

Spills should be wiped up thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.

Reagents are stored between 2-30°C. Avoid unnecessary exposure to light. Do not use reagents after expiration date.

Do not mix or interchange reagents from different kits or kit batches. Cross contamination of reagents or samples can cause erroneous results.

Use a new pipette tip for each sample.

Optimal results are obtained by strictly adhering to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, is essential.

Once the assay has been started, all steps should be performed without interruption.

SPECIMEN : Fresh Serum or Plasma

SPECIMEN COLLECTION & PREPARATION :

- Collect blood in a clean, dry, sterilized, vial and allow it to clot. Separate the serum by centrifugation at 5000 r.p.m. for 15 minutes at room temperature.

b) If serum is not to be assayed immediately it should be stored at 2-8°C or if storing more than 3 days, then freeze the specimen at -20°C or below

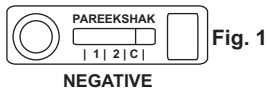
ASSAY PROCEDURE :

- a) Bring the kit and samples to Room Temperature.
- b) Removed the test device from the pouch just prior to testing.
- c) Place the device on a flat surface.
- d) Add 10µl or 1 drop of serum or plasma into the sample window and allow to soak in
- e) Add 2 drops of diluent provided in the dropper bottle into the same sample window
- f) Read the Positive result in 10 minutes & Negative result in 20 minutes.

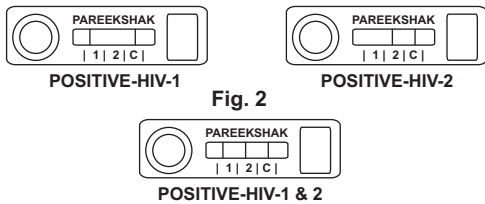
DO NOT READ ANY RESULT BEYOND TWENTY MINUTES.

INTERPRETATION OF RESULTS :

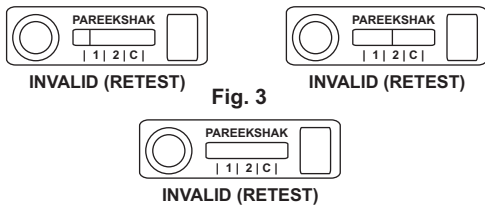
Negative result : The presence of only on band at 'C' indicates a negative result (Figure 1).



Positive result : The presence a band at 'C' and bands at '1' and / or '2' with in the Result Window, no matter which band appear first, indicates a positive result for HIV-1 or I and HIV-2 respectively (Figure 2).



Invalid result : If the read color band is not visible or only test band appears within the Result Window after performing the test, the result is considered invalid (Figure 3) . the directions may be not have been followed correctly or test may have deteriorated. It is recommended that the specimen be re-tested.



PERFORMANCE CHARACTERISTICS :

ACCURACY : PAREEKSHAK® HIV ½ Triline card Test Meets the requirements when tested against other approved kit.

PERFORMANCE CHARACTERISTICS

Accuracy : Pareekshak® HIV-1/2 Triline Card Test meets the requirements when tested against DCI approved Kit.

SENSITIVITY

| a) | No. of Positive Samples Tested | No. of Positives by Pareekshak® HIV-1/2 TrilineCard Test | Sensitivity (%) |
|----|--------------------------------|--|-----------------|
| | 56 | 56 | 100 |

SPECIFICITY :

| b) | No. of Negative Samples Tested | No. of Negative by Pareekshak® HIV-1/2 TrilineCard Test | Specificity (%) |
|----|--------------------------------|---|-----------------|
| | 105 | 104 | 99 |

LIMITATIONS OF THE TEST : 1. Assay procedure and the interpretation must be followed exactly to avoid erratic results. 2.

Because a variety of factors may cause non-specific reactions, samples found to be reactive must be retested by using a confirmatory test for HIV, such as western Blot.

KIT PERFORMANCE : Please refer to the scheduled below for quality performance as tested with Boston Biomedica. Inc. HIV-I seroconversion panel PRB 932..

| Panel Member | Result | Abbott ELISA Test |
|--------------|--------|-------------------|
| 04 | - | - |
| 05 | + | + |
| 06 | ++ | + |
| 07 | ++ | + |
| 08 | ++ | + |
| 09 | ++ | + |

REFERENCES :

- Samgadhara MG, Markham PD : The role human T- lymphotropic retroviruses in leukemia and AIDS, InWormser GP (ed):ADIS and Other Manifestations of HIV Infection. NewJersey,Noyes Publications, 1987,pp 218-220
- Baree-Sinoussi F, Chermann JC, Rey F: Isolation of T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science 220:868-871,1983.
- Gallo RC, Salahuddin SZ, Popovic M : Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. Science224:500-503,1984.
- Coffin J. Hasse, Levy JA: what to call the AIDS virus? Nature 321:10, 1986.
- Clavel F, Guetard D, Brun-Vezinet F: Isolation of a new human retrovirus from West African patients with AIDS. Science233:343-346,1986.

EN 980:2008 (E) MEDICAL DEVICES SYMBOL

| | | | |
|--|--------------------------------------|--|---|
| | Temperature Limitation 2°C - 30°C | | Date of Manufacture 2001-06 |
| | Batch Code | | Company name & address |
| | Use by | | Company name |
| | In vitro Diagnostic Device | | Authorised Representative in European Community |
| | Refer Operating Instructions | | Do Not Reuse |
| | Sufficient for | | KEEP AWAY FROM SUNLIGHT |
| | KEEP DRY | | NON-STERILE |
| | NEGATIVE CONTROL | | POSITIVE CONTROL |

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