HIV-1/2 Triline Card Test

PAREEKSHAK® For Professional Use

A Rapid Card Test to Detect Antibodies to HIV1 & 2 in Human Serum/ Plasma / WHOLE BLOOD IVD

Read the pack Insert before use provided along with the kit

REF PTC WB - 50

INTENDED USE : HIV 1/2Triline Card Test PAREEKSHAK® is an immuno chromatographic based assay for the detection of antibodies to HIV 1 & HIV 2 in Human Serum/ Plasma / Whole Blood.

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 hemophiliacs. 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 /Plasma/Whole blood. 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. Since HIV antigens are used for both binding and capturing, this test can detect all classes of HIV antibodies, hence detects early sero conversion.

TEST PRINCIPLES : 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 colored 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 immobillized 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 to 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.

The opened diluent bottle is stable for 2 years.

PACK SIZE : Available in pack of 50 test.

CONTENTS OF THE KIT

Pack Size	50 Test
1. Test Device	50 Nos.
2. Test Diluent	7.5 ml
3. 10µl Dropper	50 Nos.
4. Silicagel	50 Nos.
5. Pack Insert	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED :

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

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

a) Read this pack Insert carefully.
b) DO NOT FREEZE THE KITS. If refrigerated the kit should be brought to room temperature before testing Assay should be conducted between 15 to 30°C.
c) If the sample is turbid or viscous centrifuge the sample at 5,000rpm for 15 minutes.
d) Do not use the kit beyond their expiry date.
e) Use only Serum /Plasma/Whole blood.
f) Carefully observe the prescribed number of drops to be added, 10µl (1 drop) of Serum or plasma and 2 drops of diluent only or 20µl (2 drops) of Whole blood and 2 drops of diluent only.
g) Use the test device soon after it is removed from the pouch.
h) Do not use the test device, if the pouch seal is broken.
i) Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.
j) Read the positive result in 10 minutes and Negative results in 20 minutes. Do not interpret the result after 20 minutes.
k) Do not smoke, eat ,drink or apply cosmetic during the assay.
l) For In vitro Diagnostic Use only.
m) For Single use only.
n) Avoid using hemolytic, lipemic, icteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

All human serum, plasma and Whole blood 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 are handled.

Afterwards wash hands carefully.

Avoid splashing or forming aerosols.

Discard all materials and specimens as it is 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 throughly 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 / Plasma/Whole Blood

SPECIMEN COLLECTION & PREPARATION :

A. Serum Specimen Collection :

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

B. Whole Blood Specimen collection by Veni Puncture :

a). Collect whole blood into a sterilized vial (Containing EDTA, Citrate or Heparin) by veni puncture.

b). If specimens are not immediately tested, they should be refrigerated at 2-8°C.

c). When stored at 2-8°C the whole blood sample should be used with in 3days.

C.Whole Blood Specimen collection using a lancet :

a). Clean the area to be lanced with an alcohol swab.

b). Squeeze the end of the finger and pierce with a sterile lancet.

c). Wipe away the first drop of blood with sterile gauze or cotton.

d). Using the dropper provided, while gently squeezing the bulb immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

ASSAY PROCEDURE :

a) Bring the kit and samples to room temperature

b) Open the pouch just prior to testing and remove the card.

c) Add 10 µl (1 drop) of serum / plasma or 20µl(2 drops) of whole blood into sample window and allow to soak in.

d) Add 2 drops of diluent provided in the dropper bottle into the same sample window

e) Interpret test results in 20 minutes.
DO NOT INTERPRET AFTER 20 MINUTES.

INTERPRETATION OF RESULTS :

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

Fig 1:

Positive result : The presence of 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 and HIV-2 respectively (Figure 2).

Fig . 2:

Invalid result : If the red 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.

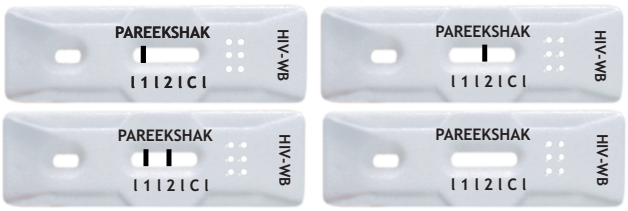

Fig 3.

PERFORMANCE CHARACTERISTICS :

ACCURACY : HIV 1/2 Triline card Test PAREEKSHAK® meets the requirements when tested against other approved kit.

SENSITIVITY

a)

No. of Positive Samples Tested	No. of Positives by HIV-1/2 Triline Card Test PAREEKSHAK®	Sensitivity (%)
87	87	100

SPECIFICITY :

b)

No. of Negative Samples Tested	No. of Negative by HIV-1/2 Triline Card Test PAREEKSHAK®	Specificity (%)
390	389	99.74

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 :

1. Samgadharan MG, Markham PD : The role human T-lymphotropic retroviruses in leukemia and AIDS, In Wormser GP (ed):ADIS and Other Manifestations of HIV Infection. NewJersey, Noyes Publications, 1987,pp 218-220

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4. Coffin J. Hasse, Levy JA: what to call the AIDS virus? Nature 321:10, 1986.

5. Clavel F, Guetard D, Brun-Vezinet F: Isolation of a new human retrovirus from West African patients with AIDS. Science233:343-346,1986.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2°C 30°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL -	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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