# HIV-1/2 RAPID TEST KIT

# PAREEKSHAK®

**For Professional Use**

A Rapid test for the qualitative detection of antibodies to HIV-1 & HIV-2 in Human Serum or Plasma IVD

**Read pack Insert before use provided along with the kit**

REF PRT

**Intended Use** : HIV ½ Rapid Test Kit Pareekshak® Rapid is an immuno concentration 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 perinatal 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/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.

**Principle** : HIV Recombinant Protein antigens-gp-41, C terminal of gp-120 and gp-36 representing the immunodominant regions of HIV - 1 & 2 envelope genes structure respectively are immobilized on a Nitrocellulose membrane. As the sample passes through the membrane HIV antibodies, if present bind to the above mentioned immobilized antigens. These bound antibodies are visualized by reacting with Protein A Gold conjugate, which binds to the HIV antibodies, giving a distinct red spot against a white background. Proper test performance is verified by the appearance of a red spot next to 'C' produced by binding of Protein A gold to the control antibody immobilized next to 'C'.

**STORAGE AND STABILITY :** Store the test devices at 2 to 30°C temperature. Store the Buffer Solution and Gold Conjugate bottles at 2 to 8°C temperature. Do not use the kit beyond the expiry date mentioned on it.

Before running the test bring all the kit components to room temperature (25±5°C) for best results. Return the Buffer Solution & Gold Conjugate bottles to 2 to 8°C. when not in use. DO NOT FREEZE KIT COMPONENTS.

1. The un-opened kits are stable for 1½ year from the date of manufacturing as indicated on the package.
2. Opened kits must be used with in 18 months of opening. Test device once opened from the pouch must be used immediately.
3. Repeated 'freeze-thaw cycles' i.e., bringing the kits to room temperature and back to the refrigerator several times will reduce the stability of the kit.
4. The opened gold conjugate & buffer solution bottles are stable for 18 months.
5. Store the opened buffer solution and gold conjugate bottles at 2-8ºC

**Pack Size :** Available in packs of 10test, 25test and 50test.

**CONTENTS OF THE KIT**

| Pack Size | 10 Test | 25 Test | 50 Test |
|---|---|---|---|
| 1. Test Device | 10 Nos. | 25 Nos. | 50 Nos. |
| 2. Buffer Solution (Ready to Use) | 1 x 6.0 ml | 1 x 15.0 ml | 2 x15.0 ml |
| 3. Gold Conjugate (Ready to use) | 1 x 1.5 ml | 1 x 3.0 ml | 2 x 3.0 ml |
| 4. Dropper | 10 Nos. | 25 Nos. | 50 Nos. |
| 5. Pack Insert | 1 No. | 1 No. | 1 No. |

**MATERIAL REQUIRED BUT NOT PROVIDED :**

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

**WARNINGS :**

1. For *in vitro* diagnostic use only.
2. Wear disposable latex gloves while handling specimens and kit reagents.
3. After the test, wash hands carefully.
4. Reagents to be stored between +2°C and +8°C.
5. **Prewarm all reagents to 25±5°C before use.**
6. The expiration date is printed on each component and on the package.
7. Do not expose the conjugate to excessive light and high temperature.
8. Once opened, the components must be closed tightly.
9. Do not use competitors gold conjugate or buffer solution. If used chances of wrong results are more.
10. Do not use different batches of gold conjugate or buffer solution. If used chances of wrong results are more.

**SPECIMEN :** Fresh Serum or Plasma.

**SPECIMEN COLLECTION AND HANDLING :**

1. Collect blood in a clean sterilized vial and allow it to clot. Separate the serum by centrifugation at 5000 r.p.m. for 15 min at room temperature. it is recommended that FRESH Samples should be used. If serum is not to be assayed immediately it should be stored at 2 to 8°C or frozen at -20°C. Serum may be stored at 2 to 8°C for up to 3 days and stored frozen at-20° C for 3 months. Bring specimen to room temperature (25±5 °C) and mix each specimen thoroughly prior to use.

DO NOT HEAT OR REPEATEDLY FREEZE/THAW SPECIMEN.

**SPECIMEN PROCESSING** : Use only serum or plasma for testing. The specimen should be clean and transparent. Viscous or turbid specimens should be centrifuged at 5,000 r.p.m. for 15 minutes before use. Specimen should be frozen, if not used within 3 days after being collected. Do not use repeatedly frozen and thawed samples.

**PRECAUTIONS**

1. 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.
2. Never pipette by mouth.
3. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled. Wear disposable latex gloves while handling specimens and kit reagents, Afterwards wash hands carefully.
4. Avoid splashing or forming aerosols.
5. Discard all materials and specimens as if capable of transmitting infection.
6. The preferred method of disposal is if is autoclaving for a minimum of one hour at 121° C. Liquid wastes not containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination to be completed.

**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.

7. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.
8. Store reagents between +2° C and +8° C. Avoid unnecessary exposure to light. The light sensitive reagents is the conjugate. Storage of samples in self-defrosting freezers is not recommended.
9. Do not use reagents after the expiration date printed on the label.
10.Do not mix or interchange reagents from different kits or kit lots. Cross contaminaton of reagents or samples can cause erroneous results.
11.Do not interchange vial caps. Use a new dropper for each sample.
12.Optimal results will be obtained by strict adherence to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, are essential.
13. Once the assay has been started, all steps should be performed without interruption. Reusable glassware must be disinfected, washed out and rinsed free of detergents.

**ASSAY PROCEDURE :** Gold Conjugate is stable for 18 months, when stored at 2-8° C and should be avoided repeated exposure to room temperature for long time. Use fresh gold conjugate vial only after finishing the one used earlier.

1. Bring all the reagents and specimens to room temperature (25±5° C).
2. Add 2 drops of buffer solution to the test device.
3. Add 2 drops of serum/plasma.
4. Add 4 drops of buffer solution.
5. Add 2 drops of gold conjugate.
6. Add 4 drops of buffer solution and read the result.
7. Read the result immediately. Do not read after 5 minutes.

**Hold the dropper vertically and ensure free falling of drops. At each step allow the solution to drain through the membrane before adding the next solution.**

## INTERPRETATION OF RESULTS :

**1. Negative Result :** If only one red spot (control spot) appears as shown in Fig 1, the specimen does not contain antibodies either to HIV-1 & 2.

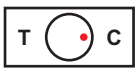

Fig. 1

**2. Positive Result :**If two red spots (control spot and test spot) appear as shown in Fig 2, the specimen is reactive for antibodies to HIV-1 & 2.

Fig. 2

**3. Invalid Test :** If neither of the spot appears or only test spot appears after the test is complete, as shown in Fig. 3 & Fig. 4 the test has been performed incorrectly. Repeat the test with new device.

Fig. 3

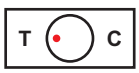

Fig. 4

## TROUBLESHOOTING

### FALSE POSITIVE

| Cause / Error | Remedy |
|---|---|
| Addition of more than 2 drop of sample or gold conjugate. | Use only 2 drops of sample and 2 drops of gold conjugate. |

### WEAK INTENSITY OF CONTROL SPOT

| Cause / Error | Remedy |
|---|---|
| Very cold reagent | Bring the sample, test device, buffer and gold conjugate to room temperature before testing (25±5° C) |

### POOR SENSITIVITY

| Cause / Error | Remedy |
|---|---|
| Frozen sample not mixed properly after thawing. | Mix well sample before pipetting. |

## PERFORMANCE CHARACTERISTICS

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

| No. of Negatives Tested | No. of Negatives by HIV-1/2 Rapid Test Kit Pareekshak® | Specificity (%) |
|---|---|---|
| 68 | 68 | 100 |

### SENSITIVITY

a)

| No. of HIV-1 Positive Samples Tested | No. of Positives by HIV-1/2 Rapid Test Kit Pareekshak® | Sensitivity (%) |
|---|---|---|
| 42 | 42 | 100 |

b)

| No. of HIV-2 Positive Samples Tested | No. of Positives by HIV-1/2 Rapid Test Kit Pareekshak® | Sensitivity (%) |
|---|---|---|
| 14 | 14 | 100 |

## LIMITATIONS OF THE TEST

1. The HIV-1/2 Rapid Test kit Pareekshak® Test detects anti-HIV antibodies in human serum or plasma and is only a screening test. All reactive samples should be confirmed by supplemental assays like ELISA, RIA or Western Blot. Therefore, for a definitive diagnosis, the patient's clinical history, symptomatology as well as serological data should be considered. The results should be reported only after complying with above procedure.
2. The assay is only validated for serum and plasma from individual bleeds and not for pools of serum or plasma or other body fluids.
3. A non-reactive result does not exclude the possibility of exposure to or infection with HIV.
4. It should be noted that repeated false reactive results may occur due to non specific binding of the sample to the membrane or due to cross-reaction of non-specific antibodies to the HIV antigen.
5. The presence of anti-HIV does not imply a HIV infection but may be indicative of recent and / or past infection by HIV.
6. Patients with auto-mmune liver diseases may show falsely reactive results.
7. The kit works best when used with fresh samples and when all the kit components are at room temperature (25±5° C). Samples which have been frozen and thawed several times contain particulates which can block the membrane, hence resulting in improper flow of reagents and high background colour which may make the interpretation of results difficult.
8. Optimum test performance depends on strict adherence to the test procedure as described in this manual. Any deviation from test procedure may lead to erratic result

## REFERENCES


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**BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL**

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|---|---|---|---|---|---|
| 2℃ 8°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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