ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HIVD

PRATHAM® *HIV-1 & HIV-2 Antibody Test Device*

One Step rapid immunochromatographic test for the differential detection of total antibody (IgM/IgG/IgA) to HIV in human serum / plasma / whole blood.

INTENDED USE

PRATHAM® One Step HIV-1 / HIV-2 Test is a rapid and immunochromatographic assay used for the qualitative and differential detection of antibodies to HIV-1 and HIV-2 in human serum / plasma / whole blood. It is intended for professional use as an aid in diagnosis of HIV infections.

INTRODUCTION

Human immunodeficiency virus infection/acquired immunodeficiency syndrome (HIV/AIDS) is a disease of the human immune system caused by the human immunodeficiency virus (HIV). During the initial infection a person may experience a brief period of influenza-like illness. This is typically followed by a prolonged period without symptoms. As the illness progresses it interferes more and more with the immune system, making people much more likely to get infections, including opportunistic infections, and tumours that do not usually affect people with working immune systems. The virus is transmitted by sexual contact, exposure to infected blood certain bodily fluids or tissues, and from mother to fetus or child during the prenatal period. The clinical diagnosis of HIV has been done by detection of HIV-1and HIV-2 antibodies in human/plasma/serum, or venous/capillary whole blood by immunoassay. HIV-1 and HIV-2, collectively referred to as HIV-1/2. Both HIV-1 and HIV-2 virus can elicit strong immune response including the production of anti-virus antibodies.

TEST PRINCIPAL

Pratham® One Step HIV-1/HIV-2 Test is an antibody-capture immunochromatographic assay, detecting the presence of HIV-1/2 antibodies in blood samples. Highly purified antigens - gp41 / gp120 representing HIV-1 and gp36 representing HIV-2 are coated on the nitrocellulose membrane as two separate test lines. An assay control reagent (Goat anti rabbit IgG) forms the third band 'Corresponding antigens (gp41 / gp120 / gp36) and rabbit IgG are conjugated to colloidal gold. When serum/plasma/whole blood is added the highly specific HIV-1&2 antigens colloidal gold conjugate complexes with the HIV-1&2 specific antibodies in the specimen and travels on the membrane due to capillary action along with the rabbit IgG-colloidal gold conjugate. The antigen-antibody-gold complex will migrate towards the test window until the test zone ("1" and "2") where they will be captured by immobilized antigens, forming a visible pink line (Test band) indicating positive results. If HIV-1/2 antibodies are absent in the sample, no pink line will appear in the Test Zone ("1" and "2").

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micro Pipette, Tips & Centrifuge etc.

STORAGE AND STABILITY

PRATHAM® One Step HIV-1 / HIV-2 Test device should be stored at 2-30ºC in the cool & driest place. Once the pouch is opened, test card must be used immediately. The kit should not be frozen & must be protected from exposure to humidity and direct sunlight.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.

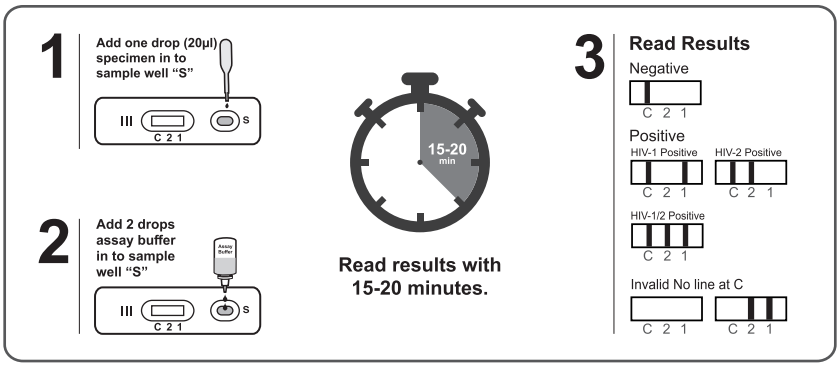
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20ºC or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior of use.

WARNING AND PRECAUTIONS

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any where discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add one drop (20µl) of serum / plasma / whole blood into the sample well with the help of provided dropper in the kit or micro pipette.
5. Add 2 drops of assay / running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.



TEST PROCEDURE & INTERPRETATION OF RESULTS

Negative:

A pink colored band appears only at the control region "C", indicating a negative result for HIV infections.

Positive:

Along with the control band, if the "1" band appears, the specimen is infected with HIV-1. If "2" band appears, the specimen is infected with HIV-2. If both "1" & "2" band appears, the specimen is infected with both HIV-1 and HIV-2.

Invalid:

No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

IN-HOUSE EVALUATION

In an in-house study, the performance of device was evaluated using a panel of thirty known positives (of varying reactivity) and five hundred seventy five known negative specimens in comparison to licensed Competitor HIV-1&2 rapid test. The results of the evaluation are as follows:

Results					
Types of specimens	**Numbers**	**Pratham HIV-1/HIV-2 Test**		**Competitor HIV 1&2 test**	
		Positive	Negative	Positive	Negative
Positive	30	30	0	30	0
Negative	575	1	574	575	575
Sensitivity		100%			
Specificity		99.8%			

LIMITATION OF THE TEST

1. 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.
2. A negative result does not eliminate the possibility of HIV-1 / HIV-2 infection. The specimen may contain low levels of antibodies to HIV-1 /HIV-2.
3. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
4. Although the test demonstrates superior accuracy in detecting HIV-1/2 infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. A non-reactive result does not eliminate the possibility of HIV-1 or HIV-2. The specimen may contain low levels of antibodies to HIV-1 or HIV-2 not detectable at the stage of testing or may have some blocking agent's high suspicious non-reactive samples may be tested for p24 Ag, High sensitivity method such as PCR etc.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Eve M. Lackritz, M.D. Glen A. Satten, Ph.D, etc.: Estimated risk of transmission of the Human Immunodeficiency virus by screened blood in United States. journal of medicine, Volume 333, November.
2. Coffin J. Hasse, Levy JA: What to call the AIDS virus. Nature 321:10, 1986. M.S.Saac, M. Holodniy, D.R. Kurtizhes, etc.: HIV viral load markers in clinical practice. Nature medicine, Volume2. November 6, June 1996.
3. Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982;31:507.
4. Popvic, M., et.al. Detection Isolation and continuous production of Cytopathic Retro viruses (HTLV-lll) from patients with AIDS and pre-AIDS. Science 1984;224:497.

SYMBOLS

 Read instructions for use	 Name of Manufacturer	 For single use only
 No. of test	 Expiry Date of Kit.	 Date of manufacturing of IVD Kit
 In-vitro diagnostic use	 Keep away from Sunlight	 Reference Catalogue Number
 Storage Condition		

Manufactured By:
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