ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HSCD

PRATHAM®

HIV Ag-Ab Rapid Test (4th Generation)

INTENDED USE

PRATHAM® HIV Ag-Ab Rapid Test is a rapid test for qualitative and differential detect HIV antigen and antibodies to HIV-1 & 2 in human whole blood / serum / plasma as an aid in the diagnosis of HIV infection. For in-vitro diagnostic and self / professional use only.

INTRODUCTION

Worldwide, acquired immunodificiency syndrome (AIDS) is caused by two retroviruses, 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. Presence of specific anti-HIV1 and / or HIV-2 virus antibodies in blood, serum and plasma indicates the exposure of an individual to HIV-1 and/ or HIV-2 virus, is of great value for clinical diagnosis. Antibodies to HIV-1 core protein p24, transmembrane protein (gp 41) and/or antibodies to HIV-2 transmembrane protein (gp36) are tracer reagent allows detection of all subtypes (IgG, IgA, IgM) of antibodies. In addition, p24 antigen is detected by using a combination of monoclonal antibodies to p24 antigen in a sandwich assay which further reduces window period.

TEST PRINCIPAL

PRATHAM® HIV Ag-Ab Rapid Test is based on the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane. Each device has test strip composed of absorbent pad, nitrocellulose membrane, conjugate pad and sample pad. Highly purified antigens-qp41/gp120 representing HIV-1 and gp36 representing HIV-2 and monoclonal anti p24 is coated on the nitrocellulose membrane as test lines and Goat anti-rabbit / mouse IgG) as control line protein. Conjugate pad contains colloidal gold conjugated with recombinant proteins of gp41, gp120, gp36, anti-p24 and rabbit / mouse IgG. When a specimen (human whole blood /serum / plasma) containing HIV antigen or antibody is applied in the sample well (S) along with assay buffer, it binds and make an immune complex with colloidal gold conjugated with recombinant proteins / anti p24 of HIV. The immune complex migrates chromatographically on the membrane to the test line region, where it is immobilized by the recombinant antigens or anti p24 coated as test lines, this leads to the formation of coloured bands. The presence of coloured bands in the test regions (1&2) indicates the presence of antibodies to HIV-1&2 and or p24 antigen in the specimen. The unreacted conjugate and unbound complex, if any, moves further on the membrane and are subsequently immobilized by protein coated at the control line region 'C' forming a coloured band. This control band acts as an internal control and serves to validate the results. The test should be considered invalid of control line does not appear and test should be repeated using another test card.

KIT COMPONENTS

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

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

PRATHAM® HIV Ag-Ab Rapid Test device should be stored at 2-40ºC 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.

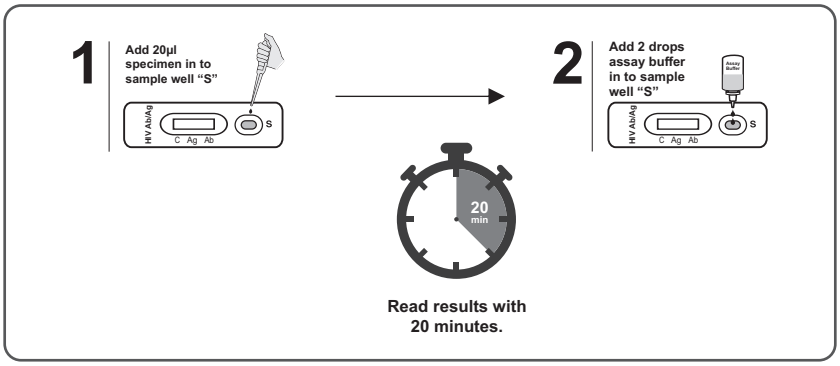
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20ºC or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination)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

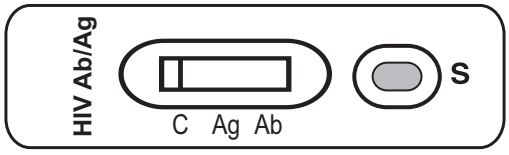
TEST PROCEDURE

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 (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.



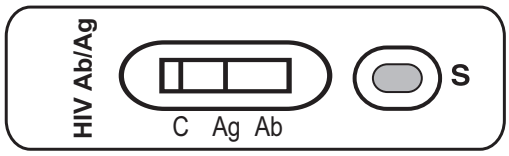
INTERPRETATION OF RESULTS

Negative:
Appearance of pink / purple lines in front of 'C' only indicates that specimens has negative for HIV antigen and Antibody.



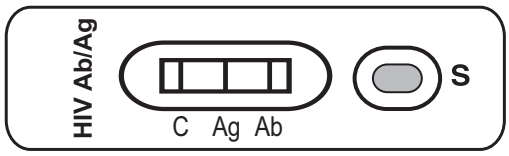
Positive HIV P24 Antigen:

Appearance of pink / purple lines in front of 'C' and 'P24 Antigen', indicates that specimen has detectable level of HIV P24 antigen and HIV Antibody should be considered positive / reactive for HIV P24 antigen.



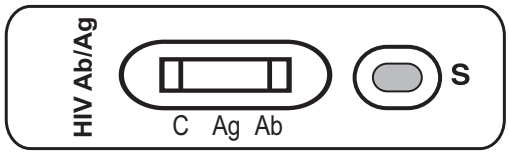
HIV P24 Antigen & HIV Antibody:

Appearance of pink / purple lines in front of 'C' and 'P24 Antigen' & 'HIV Antibody', indicates that specimen has detectable level of HIV P24 Antigen & HIV Antibodies and should be considered positive / reactive for HIV P24 antigen & HIV antibodies.



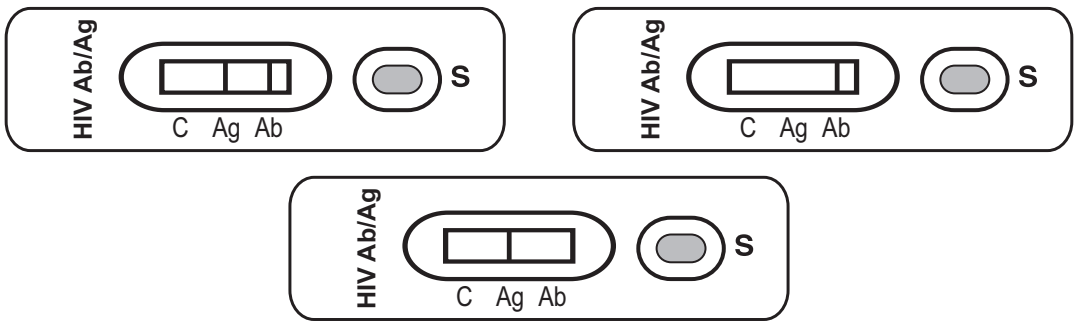
HIV Antibody:

Appearance of pink / purple lines in front of 'C' and 'HIV Antibody', indicates that specimen has detectable level of antibody of HIV 1 and 2 and should be considered positive / reactive for HIV antibodies.



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

Analytical Sensitivity:

The sensitivity of the has been determined for p24 Antigen using WHO international standard: HIV-1 p24 antigen NIBSC Code No. 90/636 and it is equal to 1000 IU/ml.

In-house Evaluation:

In-house evaluation of the product was done using well known specimens with other approved competitor rapid test kits commercially available in market.

Type of Specimen	Number of Specimen	In-house evaluation			
		Pratham HIV Ag Ab Test (4th Generation)		HIV Ag Ab Test kit (Commercial kit)	
		Negative	Positive	Negative	Positive
Positive for Ab to HIV 1 and 2	20	0	20	0	20
Positive for p24 antigen to HIV	5	0	05	0	05
Negative for HIV	250	0	250	0	250

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
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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