ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HSCD

PRATHAM®

HIV & TP Combo Test

INTENDED USE

PRATHAM® HIV & TP Combo Test is a one step, qualitative and differential detection of antibodies specific to HIV 1, HIV 2 and Syphilis (Treponema Pallidum) in human serum, plasma or whole blood. For in-vitro diagnostic and self / professional use only.

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 tumors 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 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. Treponema Pallidum (TP) is the causative agent of venereal disease Syphilis, TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. After infection, host forms non-treponemalanti lipodial antibodies to specific antibodies. Diagnosis of syphilis depends on the correlation clinical date with the non-treponema tests (VDRL, RPR, etc) are generally used for screening and treponema tests (TPHA, FTA-ABS) are used as confirmatory tests. Rapid treponema antibody tests are gaining importance as screening and conformity tests, as they detect the presence of antibodies specific to Treponema Pallidum.

TEST PRINCIPAL

PRATHAM® HIV & TP Combo Test utilizes the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane. Cocktail of highly purified antigens-gp41 / gp120 & gp36 representing HIV 1&2 are coated on the nitrocellulose membrane as an assay control reagent (Goat anti rabbit IgG) is coated as Control line-C. The Conjugate pad contains colloidal conjugate containing corresponding antigens of HIV, TP and rabbit IgG. When the test is performed, the highly specific HIV-antigens-colloidal gold conjugate complexes / TP-antigens-colloidal gold complexes with the TP specific antibodies in the specimen an travels on the membrane due to capillary action along with the rabbit IgG-colloidal gold conjugate. The complex moves further on the membrane to the test line region (T), where it is immobilized by the HIV and TP antigens coated on the presence of colored band (s) in the test regions (T) indicates the presence of antibodies to HIV-1&2 in the and (T) indicates the presence of antibodies to TP (Syphilis) in the test specimen.

The unreached conjugate and unbound complex, if any, along with rabbit IgG gold conjugate moves further on the membrane and are subsequently immobilized by goat anti-rabbit IgG antibodies coated at the control line region 'C' forming a colored band. This control band acts as an internal control and serves to validate the result.

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® HIV & TP Combo 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 & muse be protected from exposure to humidity and direct sunlight.

SPECIMEN COLLECTION AND STORAGE

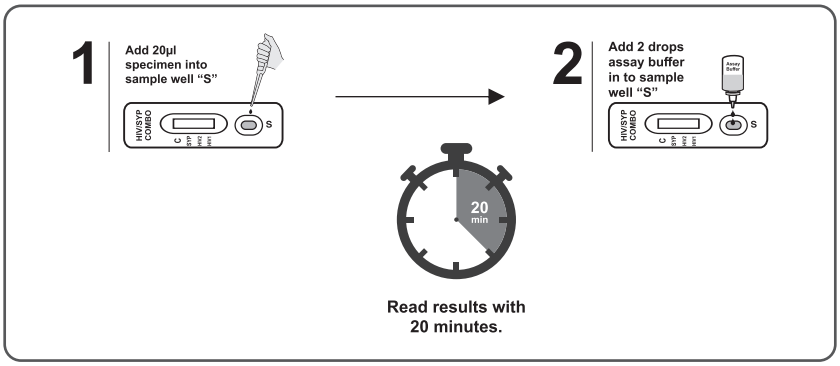
1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored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

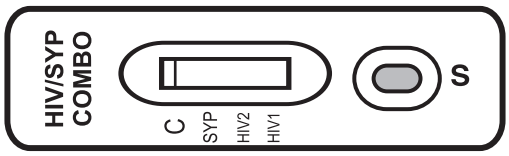
TEST PROCEDURE

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.

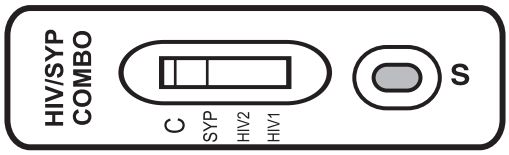


INTERPRETATION OF RESULTS

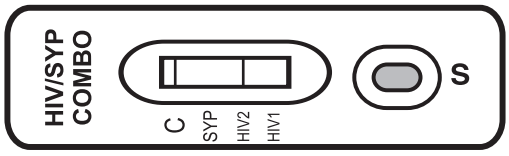
Negative:
Appearance of one pink / purple line in front of 'C' and no line in front of Syphilis & HIV2, HIV1 indicates that specimens is non-reactive result.



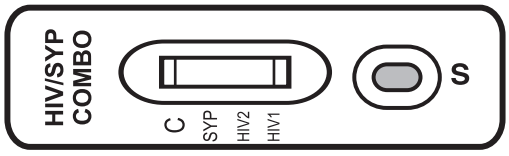
Positive Syphilis:
Appearance of pink / purple line in front of 'C' and 'STP', indicates that specimen has positive for syphilis.



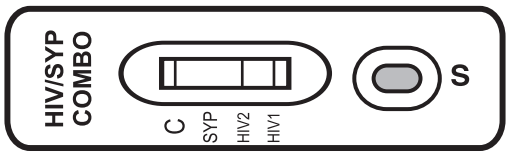
Positive HIV-2:
Appearance of pink / purple lines in front of 'C' and 'HIV-2', indicates that specimen has positive for HIV2.



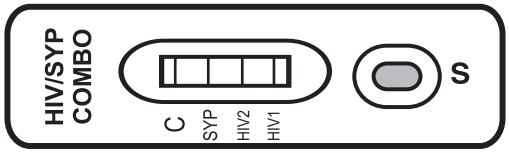
Positive HIV-1:
Appearance of pink / purple lines in front of 'C' and 'HIV-1', indicates that specimen has positive for HIV1.



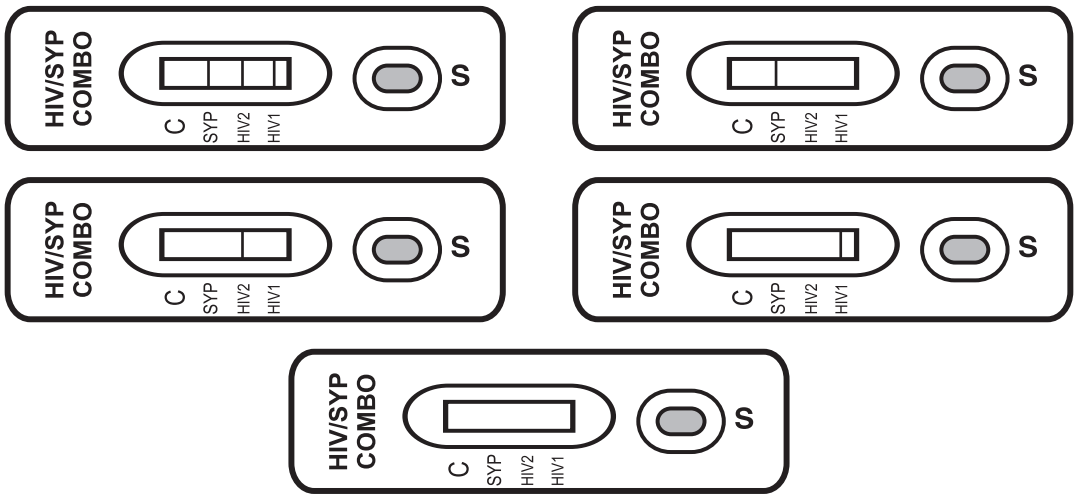
Positive HIV-1 & HIV-2:
Appearance of pink / purple lines in front of 'C' and 'HIV-1, HIV-2', indicates that specimen has positive for HIV1 and HIV2.



Positive Syphilis, HIV-1 & HIV-2:
Appearance of pink / purple lines in front of 'C' and SYP 'HIV-1, HIV-2', indicates that specimen has positive for SYP, HIV1 and HIV2.



Invalid:
No visible band at the control region, Repeat with a new test device.



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.

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.
Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
For feedback/queries contact customer care : 011-27358101

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