ASTAM DIAGNOSTICS

PRODUCT INSERT

REF SYPD

PRATHAM® ONE STEP SYPHILIS ANTIBODY TEST DEVICE

A lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG/IgM and IgA) to Treponema pallidum (TP) in human serum/plasma/whole blood.

INTENDED USE

PRATHAM® One Step Syphilis Antibodies Test Device is an in vitro diagnostic rapid test based on the principle of immunochromatography on a membrane, for qualitative determination of antibodies (IgG/ IgM/ IgA) to *Treponema pallidum* (TP) a marker for diagnosis of Syphilis. For professional use only.

INTRODUCTION

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 –treponemal anti lipodial antibodies to the lipodial material released from the damaged host cells as well as treponema specific antibodies. Diagnosis of syphilis depends on the correlation of clinical data with the non-treponemal and treponemal assays. Non-treponemal tests (VDRL, RPR, etc) are generally used for screening and treponemal 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® One Step Syphilis Antibodies Test Device is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. As the test sample flows through the membrane assembly of the device, the colored recombinant antigen of TP -colloidal gold conjugate complexes with the anti TP in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant antigen of TP coated on the membrane leading to formation of a colored band.

Which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex moves further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region, forming a colored band. This control band serves as an internal control to validate the test results.

KIT COMPONENTS

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

MATERIAL REQUIRED BUT NOT PROVIDED

Blood collection tubes, syringes, lancing device, lancets, swabs, gloves and timer etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

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 -200C or below. Do not freeze whole blood sample. 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 to use.

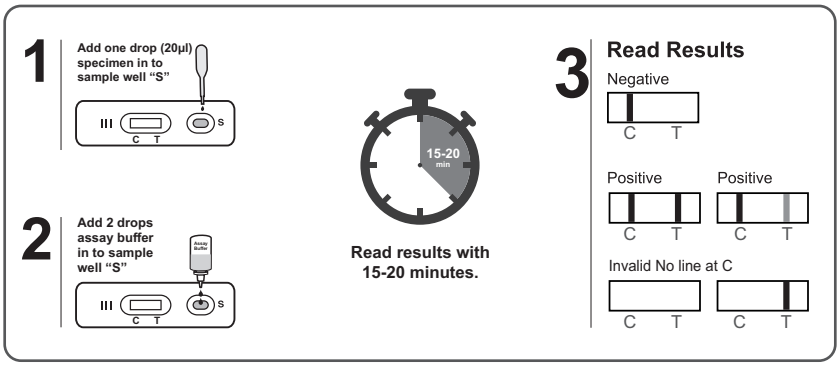
WARNING AND PRECAUTIONS

- For professional use only, not to be used by the general public.
- The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
- Bring all reagents and specimen to room temperature before use.
- Do not pipette any material by mouth.
- Do not eat, drink or smoke in the area where testing is done.
- Use protective clothing and wear gloves when handling samples.
- Use absorbent sheet to cover the working area.
- Immediately clean up any spills with sodium hypochlorite.
- Dispose of all the reagents and material used as if they contain infectious agent.
- Neutralize acid containing waste before adding hypochlorite.
- Do not use kit after the expiry date.
- Do not mix components of one kit with another

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.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 15-20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:

Appearance of only one colored band at control line region 'C'. The result should be considered negative.

Positive:

Appearance of two colored bands, one at test region 'T' and other at control line region 'C'. The result should be considered positive.

Invalid:

Appearance of no colored band at the control region 'C', the result should be considered as invalid. Repeat the test with a new test card.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A coloured 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

1. **Sensitivity:** Syphilis / TP Test Device was evaluated in various laboratories for sensitivity. The result was found to be 99.9% sensitive in serum /plasma/whole blood specimens.
2. **Specificity:** Normal healthy men and women do not have detectable levels of antibodies to TP. Homologous and other potentially interfering substances did not cross react with Syphilis / TP Test Device.
3. **Accuracy:** The results obtained by Syphilis/TP Test device correlated very well when run in parallel with other commercially available tests, using known positive and negative specimens. Relative Sensitivity: 99.9% Relative Specificity: 99.5%
4. **Precision:** Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive samples. No variations were found in the outcome of the different tests.

LIMITATION OF THE TEST

1. **PRATHAM® One Step Syphilis Antibodies Test Device** is for professional in vitro diagnostic use, and should only be used for the qualitative detection of TP antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
2. **PRATHAM® One Step Syphilis Antibodies Test Device** will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the existence of TP antibodies in blood, as antibodies may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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

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2. Claire M. Fraser. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998; 281 July: 375-381
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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:
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