

Syphilis Antibody Test- Dipstick

For In-Vitro Diagnostic Use Only
Store at 4°C to 30°C

INTENDED USE

Rapid Syphilis Antibody test (Device) is an immunoassay for the rapid and visual detection of antibodies to *Treponema pallidum* in human serum or plasma used in the diagnosis of Syphilis.

1. PRINCIPLE

After placing the dipstick in a container with serum or plasma, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant *Treponema pallidum* antigens (15KDA, 17KDA, 47KDA) and mouse IgG. If the sample contains detectable levels of the syphilis antibodies it reacts with the gold conjugated recombinant *Treponema pallidum* antigens (15KDA, 17KDA, 47KDA) to form a complex. This complex moves further and reacts with the respective recombinant *Treponema pallidum* antigens (15KDA, 17KDA, 47KDA) testline on the nitrocellulose membrane area to form a colored band. The unbound complex and the mouse IgG conjugated colloidal gold particles move further to the goat-anti mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

3. CONTENTS OF KIT

1. Test Strip 2. Package Insert 3. Desiccant pouch

4. OPTIONAL MATERIAL REQUIRED

1. Timer 2. Sample container 3. Disposable gloves 4. (12 X 75) mm test tube

5. PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

6. SPECIMEN COLLECTION

Rapid Syphilis Antibody Test can be performed using serum or plasma. Testing should be performed immediately after the specimens have been collected. Do not leave the specimen at room temperature for prolonged periods. Specimens may be stored at 2 to 8°C for up to 3 days. For long term storage, specimens should be stored below -20°C.

1. Bring specimen to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimen should not be frozen and thawed repeatedly.

7. TEST PROCEDURE

1. Before opening the foil pouch allow the test strip and sample to reach room temperature (20°C to 30°C)
2. Remove the Test strip and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has

turned colorless or pink, discard the strip and use another test.

3. Take the (12X75) mm test tube. Take approximately 1 ml of sample.

3. With arrows pointing toward the sample, immerse the test strip vertically in sample.

4. Start the timer

5. Read the result at 15 minutes. Do not read the result after 20 minutes.

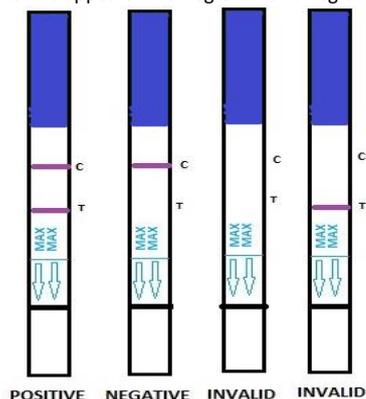
8. INTERPRETATION OF RESULTS

Negative: Only one colored line appears on the control region 'C' only.

Positive: A distinct colored line appears on the control region 'C' and on the test region 'T'.

Invalid: The test should be considered invalid if

No line appears in 'C' region and 'T' region



9. LIMITATIONS

1. This test provides presumptive diagnosis of Syphilis. A confirmed syphilis diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. This test strip is not reusable.
3. **10. DISCLAIMER**

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

11. REFERENCES

1. World Health Organization Technical Report Series. No.674 (1982) Treponemal infections.
2. Center for Disease Control. Recommendations for diagnosing and treating syphilis in HIV infected patients. MMWR Morb. Mortal Wkly Rep. 1988;37:601.
3. Marx AR. Crack, sex and STD, sexually Transmitted Disease, 1991;18:92-101.
4. Wasserheit JN. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Disease 1992; 19:61:77

Manufactured By:

Sidak life care Pvt. Ltd

Plot no. 1113, M.I.E. Ph. 1,
Bahadurgarh, Haryana-124507, INDIA

Mail-info@sidakcare.com