OXALIS
Diagnostics Pvt. Ltd.

Rapichek

Rapid Syphilis Antibody Test (Dipstick)

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

INTENDED USE

Rapid Syphilis Antibody Test Dipstick is a chromatographic immunoassay for the qualitative detection of antibodies to Treponema pallidum in human serum/plasma . It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of infection with Treponema pallidum. Alternative test method(s) should be considered to confirm the test result obtained by this device.

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 (15,17, 47kDA) and rabbit IgG. If the sample contains detectable levels of the syphilis antibodies it reacts with the gold conjugated recombinant Treponema pallidum antigens (15,17, 47kDA) to form a complex. This complex moves further and reacts with the respective recombinant Treponema pallidum antigens (15,17, 47kDA) test line on the nitrocellulose membrane area to form a colored band. The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat-anti rabbit 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.

CONTENTS OF KIT

1. Tests Individually sealed in aluminium pouches with silica gel pouch.
2. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Timer
2. Disposable golves

STORAGE AND STABILITY

Store in original packing between 4°C to 30°C. Material provided are stable up to the expiration date printed on pouch/kit.

WARNING AND PRECAUTIONS

1. Please read the instruction carefully before performing the test.
2. For In Vitro Diagnostic use only.
3. Do not reuse the test.
4. Do not use the test after the expiration date.
5. Do not freeze, keep away from direct sunlight.
6. Do not use cassette if cassette pouch is torn or damaged.
7. Use appropriate Personal Protective Equipment. Avoid direct skin contact.
8. Immediately carry out the test after removing the test dipstick from the pouch.
9. Do not eat the Silica Gel in the package.
10. Keep away from children.
11. Do not mix or interchange the specimen sample.
12. Handle all specimen as if potentially infectious. Follow Standard Biosafety Guidelines during handling and disposal of materials to avoid the risk of infections.
13. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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.

TEST PROCEDURE

1. Allow the sample and test pouch to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Collect approximately 1 ml of specimen in a clean test tube (12 X 75 mm).
3. Bring the sealed pouch to room temperature, open the pouch and remove the dipstick (taking care not to touch the membrane area), and desiccant pouch.
4. Check the color of the desiccant it should be blue, if it has turned colorless or pink, discard the dipstick and use another dipstick. Once opened, the dipstick must be used immediately.
5. With arrows pointing toward the sample specimen, immerse the test strip vertically in the test tube containing sample specimen (Approx. 1 ml).
   NOTE: Dip the test strip in sample up to the MAX line mentioned on strip.
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

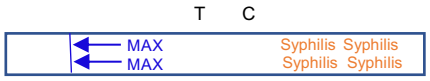
INTERPRETATION OF RESULTS

Negative: If colored line appears at the control region 'C' only.

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

Invalid: The test should be considered invalid if,

A) No line appears at 'C' and 'T' region



B) No line appears at 'C' region and line appear only at 'T' region.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 195 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 60/60) and the relative specificity was 100 % (i. e. 135/135). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Syphilis Antibody Test- Dipstick		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Syphilis Antibody Positive Serum Samples	40	40	0	100	-
Syphilis Antibody Positive Plasma Samples	20	20	0	100	-
Negative Human Serum Samples	100	0	100	-	100
Negative Human Plasma Samples	35	0	35	-	100

LIMITATIONS

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.

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. 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.

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

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An ISO 13485:2016 and ISO 9001:2015 Certified Company

Expiry Date | IVD In Vitro Diagnostic Use | 4°C 30°C Storage | Mfg. Date | LOT Batch Number | See Package Insert | Keep Dry | Keep Away from Sun Light | Do not re use