OXALIS
Diagnostics Pvt. Ltd.

Rapichek
Rapid Syphilis Antibody Test (Device)

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

INTENDED USE

Rapid Syphilis Antibody Test device is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to Treponema pallidum in human blood/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 addition of the serum or plasma or whole blood sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Treponema pallidum specific antigens (15,17,47 kDA) and Rabbit IgG. If the sample contains detectable levels of the Treponema pallidum antibodies, it reacts with the gold conjugated recombinant Treponema pallidum specific antigens to form a complex. This complex moves further and Treponema pallidum specific antibodies conjugate complex reacts with recombinant Treponema pallidum specific antigens (15,17,47 kDA) test line on the nitrocellulose membrane area to form 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.

CONTENTS OF KIT

1. Tests Individually sealed in aluminium pouches with silica gel pouch and sample applicator/dropper.
2. Package Insert

MATERIALS NEEDED BUT NOT PROVIDED

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 test if 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 device 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

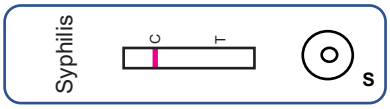
1. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
2. **BLOOD SPECIMEN:** For Whole Blood, collect blood into suitable anti-coagulant tube (EDTA, Heparin or Oxalate) and use the freshly collected blood.
3. **PLASMA SPECIMEN:** Collect blood into suitable anti-coagulant tube (EDTA, Heparin or Oxalate) and centrifuged the tube to obtain plasma specimen.
4. **SERUM SPECIMEN:** Collect the venous whole blood in the commercially available plain tube, not containing any anti-coagulant as mention above and leave to settle about 30 minutes for blood coagulation and then centrifuge to obtain serum specimen.
5. Repeated freezing and thawing of specimen should be avoided.
6. Do not use hemolyzed, clotted, contaminated, viscous/turbid specimen.
7. Refrigerated specimen must be brought to room temperature before testing.
   Note: Testing should be performed as early as possible after collection. Do not leave Serum/Plasma/Whole blood at room temperature for prolonged periods.

TEST PROCEDURE

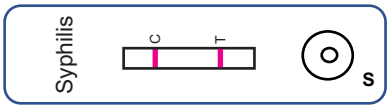
1. Allow the sample and test pouch to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Open the pouch and remove the test Device, plastic dropper and desiccant pouch.
3. Check the Silica Gel pouch color, It should be blue. If it has turned colorless or pink, discard the test and use another test. Once open the device must be used immediately.
4. Label the device with specimen identity.
5. Add two drops of serum/plasma or three drops of blood sample in well 'S'.
5. Start the timer.
6. Read the result at 15 minutes.
7. Do not read the result after 20 minutes.

INTERPRETATION OF REULTS

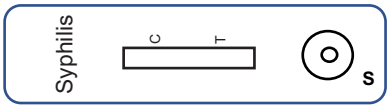
Negative: If colored line appears at the control region 'C' only.



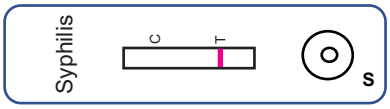
Positive: A distinct colored line appears at the control region 'C' and at the test region "T".



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.



NOTE: The intensity of the color in the test line region (T) will vary depending on the levels of the Treponema pallidum antibodies in the specimen. However, neither the quantitative value nor the rate of increase in Treponema pallidum antibodies in the specimen can be determined by this qualitative test. Depending on the levels of Treponema pallidum antibodies in the specimen. Read the result at 15 minutes. Do not read the result after 20 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:
In an in-house study, total 250 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 80/80) and the relative specificity was 100 % (I. e. 170/170)

The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Syphilis Antibody Test- Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Syphilis Antibody Positive Serum Samples	40	40	0	100	-
Syphilis Antibody Positive Plasma Samples	20	20	0	100	-
Syphilis Antibody Positive Whole Blood Samples	20	20	0	100	-
Syphilis Antibody Negative Serum Samples	100	0	100	-	100
Syphilis Antibody Negaitive Pasma Samples	35	0	35	-	100
Syphilis Antibody Negative Whole Blood 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