# LordsMed Syphilis Rapid Test

(Wholeblood/Serum/Plasma)

| Catalog No. | Pack Size | Specimen Type |
|---|---|---|
| SYPLMR01 | 25 Test Device | WholeBlood/Serum/Plasma |
| SYPLMR02 | 50 Test Device | WholeBlood/Serum/Plasma |
| SYPLMR03 | 25 Test Device | Serum/Plasma |
| SYPLMR04 | 50 Test Device | Serum/Plasma |

**INTENDED USE**

LordsMed Syphilis Rapid test is an immunoassay for the rapid and visual detection of antibodies to Treponema pallidum in human serum, plasma or whole blood to aid in the diagnosis of Syphilis. It is intended for professional use.

**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 (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 (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. 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.

**MATERIALS PROVIDED**

1. Test device
2. Desiccant
3. Sample dropper
4. Package Insert

**MATERIALS NEEDED BUT NOT PROVIDED**

1. Timer

**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 2°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.

**PRECAUTION**

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment
4. Dispose of hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat blood samples and used devices as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

**SPECIMEN COLLECTION**

1. Test should be performed with freshly collected serum, plasma or whole blood.

2.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, serum/plasma should be stored below -20°C.

3.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.

**PROCEDURE**

**For LordsMed Syphilis Rapid Test :**

1. Before opening the foil pouch allow the test device & specimen to reach room temperature (20-30°C).
2. Remove the Test device and desiccant pouch from the pouch.

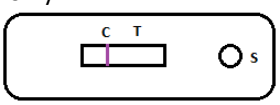
3(a). **Serum/Plasma:** Add 2 drop (approx. 60 µl) of serum, plasma in sample well "S"

3(b). **Wholeblood:** Add 3 drops (approx.. 90 µl) of wholeblood sample in well "S".

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

**TEST INTERPRETATION ( REFER TO FIGURE)**

**NEGATIVE**: Only one purplish pink colored line appears on the control region 'C' only.

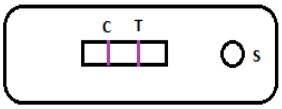



**POSITIVE**: Two purplish pink colored line appears on the control region 'C' and on the test region "T".

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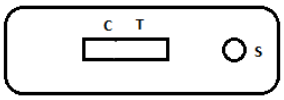
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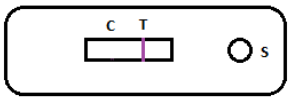



**INVALID:** The test should be considered invalid if,

- No purplish pink colour line appears in 'C' region and 'T' region




- No purplish pink colour line appears in 'C' region and line appear only in 'T' region




**NOTE:** The intensity of the purplish pink 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, positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 15 minutes

**LIMITATION**

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 with confirmatory test.
2. This test strip is not reusable.

**PERFORMANCE CHARACTERISTICS**

As per National Institute of Biologicals – Noida, (NIB) the sensitivity is 87% and specificity is 100%

**AS PER NABL LAB SENSITIVITY & SPECIFICITY**

| | Positive sample | Negative sample | Rate |
|---|---|---|---|
| Positive sample | 46 | 00 | 99.2% (Sensitivity) |
| Negative sample | 01 | 28 | 100% (Specificity) |
| Total | 47 | 28 | 99.56% (Total accuracy) |

**BIBLIOGRAPHY**

1.World Health Organization Technical Report Series.No.674 (1982) Treponemal infections.

2.Clair FM. Complete genome sequence of Treponema pallidum, the syphilis spirochete, Science 1998; 281 July375-381.

3. Centre for Disease Control. Recommendations for diagnosis and treating Syphilis in HIV - infected patients, MMWR Morb. Mortal Wkly Rep. 1998, 37: 601.

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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|---|---|---|---|
| REF | Catalog No | | Attention Caution |
| LOT | Batch No. | | Instruction for use |
| | Manufacturing Date | IVD | *In-vitro* Diagnostics |
| | Expiry Date | | Storage temperature |
| | Manufacturer | Σ | No. of Tests |

IFU/SYP/01 Rev No .: 01 Dated.:15/07/2024

Lord's Mark Industries Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website:www.lordsmed.com