# Syphilis Ab Rapid Test (WB,S,P)

Labgene biotech

## INTENDED USE

Labgene Syphilis Ab rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection of antibodies against *Treponema pallidum (Tp)* in human Whole blood, serum, and plasma.

## ORDER INFORMATION AND MATERIALS PROVIDED

| Cat No. | Test Devices | Assay Buffer | Dropper & Sillica Gel | Lancets & Alcohol Swabs |
|---|---|---|---|---|
| LG006-10T | 10 | 1 X 2 mL | 01 in an individual pouch | - |
| LG006-25T | 25 | 1 X 3 mL | | |
| LG006-30T | 30 | 1 X 3 mL | | |
| LG006-40T | 40 | 2 X 2 mL | | |
| LG006-50T | 50 | 2 X 3 mL | | |
| LG006-100T | 100 | 4 X 3 mL | | |
| LG006LS-10T | 10 | 1 X 2 mL | | 10 |
| LG006LS-25T | 25 | 1 X 3 mL | | 25 |
| LG006LS-30T | 30 | 1 X 3 mL | | 30 |
| LG006LS-40T | 40 | 2 X 2 mL | | 40 |
| LG006LS-50T | 50 | 2 X 3 mL | | 50 |
| LG006LS-100T | 100 | 4 X 3 mL | | 100 |
| *IFU: O1 in an individual carton box | | | | |

## INTRODUCTION

Syphilis is a disease caused by Spirochaete bacterium called *Treponema pallidum (TP).* If untreated the organism moves throughout the body and can cause damage to many organs, making syphilis a life-threatening disease, People who have been infected with syphilis experience different symptoms during the 3 stages of the disease. Early, this is defined by the presence of the chancre at the site of inoculation. Syphilis may be further divided into primary, secondary, and early latent syphilis; late syphilis includes late latent and the various forms of tertiary syphilis. The serological response to syphilis involves production of antibodies to a wide range of antigen, including non-specific antibodies and specific anti-TP antibodies. The first detectable response to infection is the production of specific anti-treponemal IgM, which can be detected within 4 to 7 days after the chancre appear and until the end of the second week of infection; anti treponemal IgG appear at about four weeks later. By the time that symptoms develop, most patients have detectable IgG/IgM and IgA.

## PRINCIPLE

Labgene Syphilis Ab Rapid test lateral flow chromatographic immunoassay contains: 1) A nitrocellulose membrane strip containing a test band (T) and Control band (C) . The T band is pre-coated with recombinant Treponema antigen (Tp15, Tp17, Tp47) of *Treponema pallidum (TP).* on test band region (T). 2) A conjugate pad containing Tp antigen-colloidal gold conjugate.

When adequate amount of sample and buffer is added to sample well the colloidal gold conjugate and sample moves along the membrane chromatography to test region (T) and Control region (C) and forms a visible band as the antigen- antibody-antigen gold particle complex forms. The development of a coloured band in the test region (T) indicate the presence of Tp antibodies in the specimen. The unreacted gold conjugate and unbound complex move further on membrane and are subsequently immobilized by the control reagent coated on the membrane at the control region (C), forming a coloured band. Control band is used for procedural control and should always appear if the procedure is performed correctly.

## MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

## PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

## STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

## SPECIMEN COLLECTION AND PREPARATION

The Syphilis Ab Rapid Test can be performed using either serum, plasma or whole blood.

**Plasma** :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

**Serum :**

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

**Whole Blood :**

**Venipuncture:**

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

**Collection using a lancet:**

- Clean the area to be lanced with the alcohol swab
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

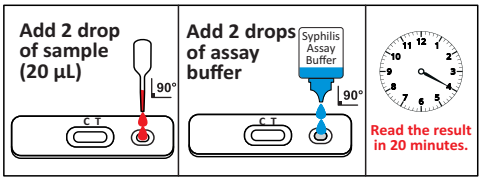
## PROCEDURE

Follow the same procedure for serum/plasma and whole blood.

1. Allow the kit component and specimen to attain room temperature prior to testing.
1. Remove the test cassette from foil pouch and place it on flat dry surface.
2. With disposable dropper draw **serum/plasma or whole blood** specimen and dispense **2 drops (20 µL)** or with **micropipette dispense 20 µL into the sample well.**
3. Add **2 drops of Assay buffer into the well**. Wait for 20 minutes and read the results.

⚠ **Do not read the result after 25 minutes, as it can give false results.**

## WHOLE BLOOD/SERUM/PLASMA:

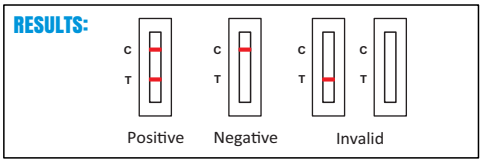



## INTERPRETATION OF RESULTS

**Positive Result:** If the control (C) and Syphilis test band (T) are developed, the test indicate for the presence of Treponema pallidum antibodies in the specimen, the result is Positive.

**Negative Result:** If only the control (C) band is developed, the test indicate that no detectable Treponema pallidum antibodies are present in the specimen, the result is negative.

**Invalid Result:** If control (C) band is not visible in the result window after performing the test, the result in considered invalid. The specimen must be tested using a new test device.




## LIMITATIONS

1. This assay is intended as an aid for the clinical diagnosis. Conduct this assay in conjunction with clinical examination, patient's medical history and other test results.
2. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result. A negative result does not preclude the possibility of Syphilis infection. This assay is a screening assays and any positive result should be confirmed by Western Blot method or other confirmatory methods.
3. As with all diagnostic assays, all results must be interpreted together with other clinical information available to the physician.

## PERFORMANCE CHARACTERISTICS

**Internal Evaluation**

Sensitivity and Specificity studies were carried out using clinical samples confirmed by Dengue ELISA and Lateral Flow test. The correlation between these two systems was found to be 100%.

| Status | Positive | Negative | Total |
|---|---|---|---|
| Positive | 50 | 00 | 50 |
| Negative | 00 | 300 | 300 |
| Total | 50 | 300 | 350 |

Relative Sensitivity: 100%, Relative Specificity: 100%

**External Evaluation**

The external performance evaluation of the Syphilis Ab rapid test has been done by National Institute of Biologicals (NIB), India. The results are shown in following table:

| | |
|---|---|
| Sensitivity | 98% |
| Specificity | 100% |

## CROSS REACTIVITY WITH OTHER INFECTIOUS DISEASES

| Specimen | Sample Size | Syphilis Ab Reactivity |
|---|---|---|
| HBsAg Positive Serum | 10 | Negative |
| HIV Positive Serum | 10 | Negative |
| HCV Positive Serum | 10 | Negative |

## REFERENCES

1. Fraser CM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete. Science (1998); 281 July: 375-381.
2. Center for Disease Control. Recommendations for diagnosing and treating Syphilis in HIV-infected patients. MMWR Morb. Mortal Wkly Rep. (1988); 37: 601.
3. Johnson PC. Testing for Syphilis. Dermatologic Clinic (1994); 12 Jan: 9-17.

## INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
| REF | Product Reference No. | ISO 13485 | International Organization or Standardization |
| | Manufacturer | | Keep out of Sunlight |
| | Expiry date | IVD | For invitro diagnostic use only |
| LOT | Lot (batch) number | | Read product insert before use. |
| 2°C 30°C | Store between 2-30°c | | Do not use if package is damaged |
| | Do not reuse | | Keep Away From Moisture |
| | Contains sufficient for test | ART/IFU-006-04 | |

**Manufactured by:**

**LABGENE BIO-TECH PVT. LTD.**
GF, Plot no 13, 14, Kamla Amrut Inditech Park,
Chhatral- Kadi Road, Indrad, Kadi, Mahesana, Gujarat 382715
Mobile : +91 97 27 37 9000
Email: info@labgene.in
Web: www.labgene.in

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