LORNE LABORATORIES LTD.

GREAT BRITAIN

SYPHILIS SEROLOGY REAGENT

DIRECTIONS FOR USE

RPR Carbon Antigen: For Serodiagnosis Of Syphilis.

SUMMARY

Syphilis is a venereal disease caused by the spirochaete micro-organism *Treponema pallidum.* This organism cannot be cultured on artificial media and so the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. There are two different techniques for detection of syphilis. TPHA tests, which detect antibodies to *Treponemal pallidum*, and non-treponemal serologic tests, which detect an antibody-like substance in infected people called Reagin.

INTENDED PURPOSE

The reagent is a test reagent intended to be used to qualitatively determine the presence or absence of Reagin (antibodies against Syphilis) in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

When used by the recommended techniques, the reagent will aggregate (clump) in the presence of reagin. No aggregates (no clumping) generally indicate the absence of reagin (see **Limitations**).

KIT DESCRIPTION

Lorne RPR (Rapid Plasma Reagin) Carbon Antigen is a non-treponemal test for the serodiagnosis of syphilis. The RPR carbon antigen contains micro particulate carbon to aid macroscopic reading of results. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. The reagent is supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMENS

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8ºC for 7 days or for up to 3 months at or below –20ºC. Specimens must be free from bacterial contamination, fibrin, haemolysis and lipaemia.

PRECAUTIONS

1. The kit is for *in-vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagent has been processed to reduce the bio-burden, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
5. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that known positive and negative specimens are tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Make sure RPR Carbon Antigen reaches 18-25ºC before use.
3. Shake the RPR Carbon Antigen well before use to ensure homogeneity.
4. Use of reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the kit is in use.
5. The user must determine the suitability of the kit for use in other techniques.

KIT COMPONENT SUPPLIED

1. RPR Carbon Antigen (5 mL): Particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

1. RPR Positive Control.
2. RPR Negative Control.
3. Pipette capable of accurately delivering 50 µl.
4. Dispensing bottle.
5. Dispensing needle capable of dispensing 20 µl.
6. Mechanical rotating table capable of rotating at 80-100 rpm.

QUALITATIVE TECHNIQUE

1. Allow the reagent and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample into a circle on the slide.
3. Swirl the RPR-carbon reagent gently before using. Invert the dropper assembly and press gently to remove air bubbles from the micropipette.
4. Place the micropipette in a vertical position and perpendicular to the slide, and add one drop (20 µL) of this reagent next to the samples to be tested.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample
6. Place the slide on a mechanical rotating table at 80-100 r.p.m. for 8 min. False positive results could appear if the test is read after more than 8 minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Reactive:** Visible agglutination (medium to large clumps) constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
2. **Weak-Reactive:** Weak agglutination (small clumps) around the periphery of the test area constitutes a weak positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
3. **Negative:** No agglutination constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of reagin.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 8-minute rotating period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
2. A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.
4. Bilirubin (≤ 20 mg/dL), hemoglobin (≤ 10 g/L) and lipids (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 300 IU/mL), interfere. Other substances may interfere[5].

5. False positive or negative results may also occur due to:
   a) Not expelling air from end of needle
   b) Not maintaining dispensing bottle and needle in a vertical position when dispensing the antigen.
   c) When transferring the specimen from the collecting tube some of the specimen being drawn up in to the teat
   d) Contamination of test materials
   e) Improper storage of test materials or omission of reagents
   f) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne RPR Carbon Antigen is tested by the **Recommended Techniques** to ensure suitable reactivity.

DISCLAIMER

1. User is responsible for performance of the kit by any method other than those mentioned in **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
100 Tests Per Kit	045005A

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