IVD
Store at 2 - 8°C.

Ref. 22152-500 RPR carbon Kit
500t – 2 x 5 ml RPR carbon
pos control 1 ml
neg control 1 ml
50 x 10 disposable slides
2 x Dispensing siringe with needle

Ref. 22152S RPR carbon 5 ml
5 ml RPR carbon

CE

RPR-Carbon

Slide agglutination

Non treponemal test for syphilis based on luetic reagin detection by flocculation on slide

INTENDED USE

The RPR carbon test is a non-treponemal testing procedure for the detection of syphilis in human serum and plasma.
For in vitro diagnostic use only.
For professional use only

CLINICAL SIGNIFICANCE

Syphilis is a chronic infection, caused by the spirochaete Treponema pallidum, which progresses through distinct stages of infection: primary, secondary, tertiary and quaternary. These stages produce diverse clinical symptoms, typically producing initial chancres then syphilitic rash followed by long periods of dormancy and may eventually lead to cardiovascular problems and neurosyphilis.
Tests for syphilis fall into four categories: direct microscopic examination; treponemal antibody tests; non-treponemal antibody tests and direct antigen tests. Non-treponemal test are important to follow up antibiotic therapies. If the therapy is efficient, non treponemal titers will significantly decrease. RPR carbon is one such test.

PRINCIPLE OF THE METHOD

The RPR carbon reagent is a stabilized suspension of cholesterol crystals coated by cardiolipin lecithin added to adjust the sensitivity and charcoal particles to improve the reading of the reaction. The reagent acts as antigen against certain non treponemal antibodies present in persons suffering from syphilis. These antibodies are called "Luetic reagins". The RPR carbon reagent agglutinates when mixed with samples containing these reagins.

REAGENTS

RPR-carbon:	Carbon particles coated with a lipid complex, cardiolipin, lecithin and cholesterol- in phosphate buffer 20 mmol/L. Sodium azide 0.95 g/L.
Control +:	Artificial serum with reagin titre 1/4 ± 1 two-fold dilution.
Control -:	Animal serum. Preservative.

PRECAUTIONS

Control +: H319: Causes serious eye irritation. P280: Wear eye protection, face protection, protecting clothing, protective gloves. P501: Dispose of contents in an appropriate container observing applicable local regulations.
EUH032: Contact with acids liberates very toxic gas.

PREPARATION AND STABILITY

Shake the RPR carbon reagent before use. After that it must be uniform and without visible clumping. The reagent has to be dispensed with the dispensing syringe through the needle (supplied), or by an automatic pipette adjusted to 20µl. Place the syringe/pipette in a vertical position and perpendicular to the slide surface. Any variation in this way will modify the result of the reaction.
The reagent and controls have to be stored at 2°-8°C. Do not freeze!

ADDITIONAL EQUIPMENT, NOT INCLUDED

- Mechanical rotator with adjustable speed at 100rpm
- Pipettes 50 µl
- Plastic stirrers

SAMPLES

Use fresh serum or plasma. The sample may be stored at 2° - 8°C for 8 days before performing the test. For longer periods of time (up to 3 months) the sample must be frozen at –20°C. The samples with presence of fibrin should be centrifuged before testing. Haematic, lipaemic or contaminated sera may cause erroneous results.

PROCEDURE

Qualitative method

1. Bring reagents and specimens to room temperature before use.
2. Gently shake the reagent to disperse the particles.
3. Place a drop (50µl) of UNDILUTED sample onto a circle of the slide.
4. Place a drop (50µl) of each Positive and Negative controls onto separate circles of the slide.
5. Spread the samples/controls with a stirrer over the full surface of the circle. Use different stirrers for each sample.
6. Add 1 drop of the RPR carbon reagent through the dispensing syringe and needle, or pipette measuring 20 µl, into each sample/control.
7. Rotate the slide on a mechanical rotator at 100 rpm for 8 minutes.
8. Read the presence or absence of visible agglutination immediately after removing the slide from the rotator under direct light. A brief rotation and tilting of the card by hand must be made this to aid differentiating non-reactive from minimally reactive results.
   Unspecific agglutination could appear if the test is read later than this period of time.

Semi-quantitative method

Will be performed in the same way as the qualitative test but using serial two fold dilutions of the serum sample in saline (NaCl 9g/l.).

READING AND INTERPRETATION

Presence of black clumps on a clear background will represent a positive result. The lack of flocculation in a uniform grey color mixture represents a negative result in the sample.
The titre of the serum, in the semi-quantitative method, is the highest dilution that exhibits a positive reaction.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of procedure, as well as a comparative pattern for a better result interpretation.

NORMAL LEVELS

Syphilis is a sexually transmitted disease caused by Treponema pallidum.
Positive result indicates the presence of "Luetic reagins" and is detected through non treponemal luetic serology.

PERFORMANCE CHARACTERISTICS

1. *Analytical sensitivity*: Accurate titre determination of the Reference Material, under the described assay conditions. The reagent sensitivity is calibrated against the "Human Reactive Serum" from CDC (Centre for Disease control).
2. *Prozone effect*: No prozone effect was detected up to titres 1/256.
3. *Sensitivity:* 100%.
4. *Specificity:* 100 %.

LIMITATIONS OF THE PROCEDURE

- 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.
- 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.
- False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.

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