

IVD
Store at 2 - 8°C.

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



RPR-CARBON

RPR-carbon
Slide agglutination

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

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 antibodies present in persons suffering from syphilis. These antibodies are called "Luetic 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 +: Human serum with reagin titre 1/4 ± 1 two-fold dilution. Sodium azide 0.95 g/L

Control -: Animal serum. Sodium azide 0.95 g/L

PRECAUTIONS

Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagent by flushing with large amounts of water to prevent azide buildup.

The positive and negative controls were prepared from human sera, which have been tested and are found to be non-reactive for HbsAg, HCV and antibodies to HIV (1/2). However, no test method can offer complete assurance that infectious agents are absent. Therefore all human specimens should be considered potentially infectious.

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!

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 over the full surface of the circle.
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 rotor 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 gray 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 %.

Langdorp, 11.2011