CHRONOLAB

CE
IVD

# RPR-carbon

Slide agglutination

Qualitative determination of plasma reagins

***PACKAGING***

| | |
|---|---|
| Ref.: 101-0426 | Cont.: 250 tests |
| Ref.: 101-0220 | Cont.: 500 tests |
| Ref.: 101-0431 | Cont.: 250 tests (latex only) |

Store at 2 - 8º C.

***CLINICAL SIGNIFICANCE***

Reagins are a group of antibodies against some components of the damage tissues from patients infected by *Treponema pallidum*, the agent which causes the syphilis.This microorganism produces some damage to the liver and heart, releasing some tissue fragments. Immunological patient system reacts producing reagins, antibodies against these fragments.

The assay is useful to follow the antibiotic therapy answer.

***PRINCIPLE OF THE METHOD***

The RPR-carbon is a non-treponemal slide agglutination test for the qualitative and semi-quantitative detection of plasma reagins in human serum. Carbon particles coated with a lipid complex are agglutinated when mixed with samples containing reagins of patient affected by syphilis.

***REAGENTS***

| | |
|---|---|
| **RPR-carbon** | Carbon particles coated with a lipid complex, cardiolipin, lecithin and cholesterol in phosphate buffer 20 mmol/L. Preservative. pH, 7.0. |
| **Control +** Red cap | Artificial serum with reagin titer ≥ 1/4. |
| **Control -** Blue cap | Animal serum. Preservative |

***CALIBRATION***

The reagent sensitivity is calibrated against the "Human Reactive Serum" from CDC (Center of Disease Control of Atlanta) and compareable to the RPR reagent from BD (Becton Dickinson).

***PREPARATION***

**RPR-carbon:** Swirl the reagent gently to disperse the carbon particles before use. Open the RPR-carbon vial, place the micropipette to the dispensing vial and draw by suction the required volume of RPR-carbon. Once the test is completed, return the reagent to the original vial and rinse the micropipette and vial with distilled water.

***STORAGE AND STABILITY***

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2 - 8º C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.

**Reagents deterioration:** Presence of particles and turbidity.

***ADDITIONAL EQUIPMENT***

- Mechanical rotator with adjustable speed at 80 - 100 r.p.m.
- Humid store.
- Vortex mixer.
- Pippetes 50 µL.

***SAMPLES***

Fresh serum or plasma. Stable 7 days at 2 - 8º C or 3 months at –20º C.

The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

***PROCEDURE***

**Notes:**

High temperature may cause test components to dry on the slide giving an agglutination aspect that can be interpreted as false positive results. It is recommended to place the slide under a humidifying cover.

**Qualitative method**

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the RPR-carbon reagent vigorously or on a vortex mixer 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 rotator at 80-100 r.p.m. for 8 min (Note 1). False positive results could appear if the test is read later than 8 minutes.

**Semi-quantitative method**

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

**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.

***READING AND INTERPRETATION***

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide test from the rotator. Rotate the slide twice by hand before reading.

**Interpretation**

| Agglutination | Reading | Report |
|---|---|---|
| Medium or large clumps | R | Reactive |
| Small clumps | W | Weakly reactive |
| No clumping or very slight "roughness" | N | Non Reactive |

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

***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.

All result different from the negative control result, will be considered as a positive.



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***PERFORMANCE CHARACTERISTICS***

**Analytical sensitivity:** Accurate titer determination of the Reference Material, under the described assay conditions (see calibration).

**Prozone effect:** No prozone effect was detected up to titers ≥1/128.

**Diagnostic sensitivity:** 100%

**Diagnostic specificity:** 100 %.

***INTERFERENCES***

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].

***BIBLIOGRAPHY***

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