



RPR CARBON

Presentation:

125 Test Ref.: 40130
250 Test Ref.: 40131
Store: 2 - 8° C.

RPR CARBON
Slide agglutination

Diagnostic reagent for qualitative measurement of Plasma reagins.

Only for in vitro use in clinical laboratory (IVD)

TEST SUMMARY

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

REAGENTS COMPOSITION

- RPR Carbon** Ref.40130-2,5 mL. Ref.40131- 5 mL. Carbon particles coated with a lipid complex, cardiolipin, lecithin and cholesterol, in phosphate buffer 20 mmol/L. Preservative. pH, 7.0.
- Control (+)** Ref.40132 - 1 mL. Artificial serum with a reagin titer ≥ 1/4.
- Control (-)** Ref.40134 - 1 mL. Animal serum. Preservative.

PRECAUTIONS

Control +: H319- Causes serious eye irritation.
Follow the precautionary statements given in MSDS and label of the product.

REAGENT PREPARATION AND STABILITY

RPR-carbon: Homogenize the reagent before use. Place the needle to the plastic dispenser vial, open the RPR-carbon vial and aspirate the required amount of reagent. Once the test is finished, return the reagent to the original vial and rinse the needle and dispenser with distilled water.
Mix reagents gently before use.

Do not freeze; frozen reagents could change the functionality of the test.

Reagents deterioration:

- Presence of particles and turbidity.

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use.
Do not use reagents over the expiration date.

CALIBRATION

The sensitivity is calibrated against the International Reference WHO (1st Standard Human Syphilitic Serum, ref. 05/132).

SPECIMEN

Fresh serum or plasma. Stable 7 days at 2-8° C or 3 months at -20° C.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolysed or lipemic samples.

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment

TEST PROCEDURE

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. Homogenize the reagent before using. Invert the dispenser vial and press lightly to remove air bubbles.
4. Place the dispenser vial together with the needle in a vertical position and perpendicular to the slide, and add one drop (20 µL) of reagent together with each of the samples and controls.
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.

READING AND INTERPRETATION

Reading: 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.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

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 regains, -antibodies against these fragments-.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- **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 %.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL), haemoglobin (10 g/L) and lipids (10 g/L), do not interfere. Rheumatoid factors (300 IU/mL) interfere.
Other substances may interfere⁵.

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.

NOTES

1. During the 8 minutes of reaction time do not expose the slide to a source of heat or intense light in order to reduce evaporation. Such evaporation could cause a false agglutination and therefore false positive results.

BIBLIOGRAPHY

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5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.



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Rev.11 - 03/05/21