



Store at: +2+8°C.

Presentation:
Cod. SE013 125 Test.
Cod. SE014 250 Test.

Procedure

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

Carbon	Carbon particles coated with a lipid complex, cardiolipin, lecithin and cholesterol in phosphate buffer 20 mmol/L. Preservative. pH 7.0
Control (+)	Artificial serum with a reagin titer $\geq 1/8$.
Control (-)	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

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 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.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8° C. Do not use reagents over the expiration date.

CALIBRATION

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

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 haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment

TEST PROCEDURE

Preparation

RPR-carbon: Shake 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.

Qualitative method

1. Allow the reagents and sample to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 μ L of the sample and one drop of each Positive and Negative control 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 a drop of this reagent next to the sample to be tested.
5. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
6. Rotate the slide with a mechanical rotator at 80-100 r.p.m. for 8 minutes (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 the 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.

REFERENCE VALUES

It is suggested that each laboratory establish its own reference range.

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-.

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 $\geq 1/128$.
- Diagnostic sensitivity: 100%.
- Diagnostic specificity: 100%.

INTERFERING SUBSTANCES

Interferences:

- 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.

NOTES

1. 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.

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.

BIBLIOGRAPHY

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4. Joseph Earle Moore et al. Gastrointestinal Haemorrhage 1952; 150(5): 467-473. Association 1990: 1-192.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

