RPR Carbon

IVD CE

Rapid Plasma Reagins Card Test

PRODUCT CODE
SL004

INTENDED USE
The RPR-carbon is a non-treponemal flocculation 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.

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.

PRINCIPLE
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 – Green Cap	Animal serum, preservative

ACCESSORIES
Disposable slides, Mixing pipettes, Dropper bottle with needle
Accessories of Ref.:SL004 0500 (500 Test) will be provided in separate pouch.

ADDITIONAL REQUIREMENTS
Mechanical rotator with adjustable speed at 80-100 rpm

STORAGE AND STABILITY
All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC 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.

CALIBRATION
The sensitivity is calibrated against the International Reference WHO (1st standard human syphilitic Serum, ref .05/132).

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.

PRECAUTIONS
Reagent components of human origin have been tested and found to be negative for the presence of antibody to HIV (1/2) as well as for HBsAg and HCV antibody. However, handle cautiously as potentially infectious.
The reagent and controls contain less than 0.1% sodium azide.

SPECIMEN AND SAMPLE PREPARATION
Fresh serum or plasma, stable 7 days at 2-8ºC or 3 months at –20ºC. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

PROCEDURES

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 control into separate circles on the slide test.
3- Mix the RPR-CARBON reagent rigorously or on a vortex mixer. Invert the dropper assembly and press gently to remove air bubbles from 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.

INTERPRETATION OF RESULT
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.

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.

PERFORMANCE CHARACTERISTICS
1- ***Analytical sensitivity*:** Accurate titer determination of the Reference Material, under the described assay conditions (see calibration).
2- ***Prozone effect*:** No prozone effect was detected up to titers ≥1/128.
3- ***Diagnostic sensitivity:*** 100 %.
4- ***Diagnostic specificity:*** 100 %.

INTERFERENCES
Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere[5].

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

LIMITATION OF THE PROCEDURE
1. 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.
2. 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.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

1- George P. Schimid. Current Opinion in Infectious Diseases 1994; 7: 34-40.
2- Sandra A Larsen et al. Clinical Microbiology Reviews 1995; 8 (1): 1-21.
3- Sandra Larsen et al. A manual of Test for Syphilis American Public Health
4- Joseph Earle Moore et al. Gastrointestinal Haemorrhage 1952; 150(5): 467-473.
5- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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