Reactivos GPL

Barcelona, España

CE

- RPR CARBON -

RPR CARBON
Slide agglutination

Store at: +2+8ºC.

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

Procedure

Diagnostic reagent for qualitative measurement of plasma regains.

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. Sodium azide 0.95 g/L. pH, 7.0.
Control (+)	Human serum with a reagin titer ≥ 1/8. Sodium azide 0.95 g/L.
Control (-)	Animal serum. Sodium azide 0.95 g/L.

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY
All the reagents are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
Signs of reagent deterioration: If appear particles and turbidity do not use.

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

CALIBRATION
The reagent sensitivity is calibrated against the "Human Reactive Serum" from CDC (Centre for Disease Control).

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

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 µL of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Shake the RPR-carbon reagent gently 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.

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 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).

1. *Prozone effect:*

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

2. *Diagnostic sensitivity:*

86 % (primary syphilis) and 100% (secondary syphilis).

3. *Diagnostic specificity*: 98 %.

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 interfere[5].

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.

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