RPR CARBON ANTIGEN KIT

IVD *For In-Vitro and professional use only*
Store at 2- 8°C

INTENDED USE

RPR Carbon Antigen Kit is intended to be used to detect Reagin antibodies present in serum or plasma of syphilitic persons by utilizing carbon particles coated with cardiolipin antigen to cause aggregation of the carbon particles which appear as dark clumps against a white background.

INTRODUCTION

Syphilis is a disease caused by infection of the spirochete Treponema pallidum. The disease is characterised by periods of latency and is caused by a systemic infection. Serological techniques play a major role in the diagnosis and follow-up of treatment for syphilis since T pallidum cannot be isolated in culture.

Syphilis is categorized by an early primary infection that causes non-specific symptoms and, in some cases, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to T pallidum reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by T pallidum) may help to differentiate between active and past syphilis infection. The Rapid Plasma Reagin (RPR) assay is able to detect nontreponemal antibodies, which is often positive during active infection and negative after therapy or in late/latent types of syphilis.

PRINCIPLE OF THE TEST

RPR uses carbon particles coated with cardiolipin antigen to detect Reagin antibodies in syphilitic patients' serum or plasma.

Aggregation of the carbon particles will form in the specimens that contain Reagin antibodies which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

SAMPLES COLLECTION AND HANDLING

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

STORAGE AND STABILITY

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.

MATERIALS

MATERIALS PROVIDED

1. RPR carbon antigen reagent: Contains less than 0.1% sodium azide.
2. Positive Control: Contains less than 0.1% sodium azide.
3. Negative control: Contains less than 0.1% sodium azide
4. RPR test cards (Optional).
5. Plastic stirring sticks.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

1. Rotator (100rpm).
2. Timer.
3. Pipettes.

PROCEDURES

QUALITATIVE PROCEDURE

Mix well the RPR reagent before use.

1. Allow the reagents and samples to reach room temperature.
2. Dispense **50 µL of each sample** into a separate circle on the card. Use a separate tip for each sample.
3. Dispense **1 drop of each of positive and negative controls** into two additional circles.
4. Gently shake the RPR Reagent vial and slightly press to remove air bubbles from the tip so the drop size obtained is correct.
5. Dispense **1 drop (~18 µl) of RPR antigen reagent** to each circle next to the sample/control to be tested.
6. Mix the reagent with the sample using the stirring sticks and spread the mixture over the entire area of the circle.
7. Place the card on a mechanical rotator and rotate at 100 r.p.m. for **8 minutes**.
8. Observe macroscopically for agglutination formed within a minute after removing the card from the rotator.

SEMI-QUANTITATIVE PROCEDURE

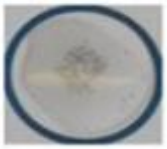
Mix well the RPR reagent before use.

1. Make doubling dilutions from Undiluted sample to 1:16 using normal saline solution.
2. Place 50 µl of each dilution into a separate circle on the test card.
3. Continue as per the Qualitative procedure from step 4 to step 7. The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

INTERPRETATION OF TEST RESULTS

1. **Strong Reactivity:** Large clumps of carbon particles formed with a clear background.

2. **Reactive:** Large clumps of carbon particles formed somewhat more disperse than Strong Reactive pattern.



3. **Weak Reactivity:** Small clumps of carbon particles formed with light grey background.

4. **Trace Reactivity:** Carbon particle clumping that appears as a button of aggregates in the centre of the test circle or distributed along the test circle's edge.

5. **Non-Reactive:** In the centre of the test circle, there is usually a smooth grey pattern or a button of non-aggregated carbon particles.

PERFORMANCE CHARACTERISTICS

1. ***SENSITIVITY***
   100%.

2. ***SPECIFICITY***
   100%.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after expiration date.
3. Do not eat, drink, or smoke in the area where the specimens or kits are handled.
4. Always use a fresh pipette tip for every test.
5. Handle all negative and positive specimens as potentially biohazard samples as they might contain other infectious agents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7. The used test should be discarded according to local regulations.
8. Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.

REFERENCES

1. Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.

VeroTest Sdn. Bhd.
Unit G-E-2A, Enterprise 4, Technology Park Malaysia,
Bukit Jalil, 57000 – Kuala Lumpur – Malaysia
RSPA044N
Rev 1.0 (26.04.2022)

REF	Catalogue Number		Temperature limit		Manufacturer fax number		Fragile, handle with care
IVD	*In Vitro* diagnostic medical device		Caution		Manufacturer telephone number		Use-by date
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)		Keep away from sunlight		Date of Manufacture
LOT	Batch code		Manufacturer		Do not use if package is damaged		Keep dry