RPR CARBON ANTIGEN TEST

IMMUNOPAK

Slide Test for Reagins (Flocculation)

Last update 04-2023

Ref. IS-RPR.077, 50 Test
IS-RPR.77U, 100 Test
IS-RPR.77V, 10 ml (500 Test)

INTENDED USE

Qualitative and semi-quantitative slide flocculation test for the detection of Treponema Pallidum antibodies in Serum/Plasma.

INTRODUCTION

Syphilis is caused by the infection of spirochetes *'Treponema pallidum'*: It is most commonly transmitted sexually and by direct or indirect contact, sometimes through minute lesions on the skin or mucous membrane. In response to the infection, the host forms treponemal antibodies. It also forms non-treponemal antibodies against the lipoidal material released from the damaged host cells. These antibodies are called "Reagins".

The RPR (Rapid Plasma Reagin) carbon 18 mm Circle Card test as the name suggests, is based on the detection of these "reagins".

PRINCIPLE

A suspension of modified cardiolipin coated on microparticulate carbon is used as an antigen against the "Reagin" (antibodies). The antigen reacts with "Reagin" in the sample to form black clumps or floccules indicating a positive test.

PRESENTATION

All the reagents to be stored at 2-8°C	Pack Size 50 Test/100 Test/ 10 ml (500 test)
• RPR Carbon Antigen	1
• Positive Control	1
• Negative Control	1
• Mixing Stick • Plastic dropper with rubber teat • Plastic Slides • Antigen delivery dropper with rubber teat	Provided as per Pack Size

PRECAUTION

1. RPR reagents are for *IN-VITRO* diagnostic use only.
2. Use clean and dry glass wares.
3. Include positive and negative controls for greater proficiency in interpretation of results.
4. The slide should be tilted back and forth gently to avoid disturbance to the reaction pattern.
5. Avoid drying of reaction mixture.

All reagents and controls have been tested negative for HBsAg and anti-HIV antibodies. However they should be handled as if they are potentially infectious.

REAGENT STORAGE AND STABILITY

Store reagent at 2-8°C (DO NOT FREEZE).

RPR reagent is stable until the expiry date printed on the label at 2-8°C.

SPECIMEN COLLECTION

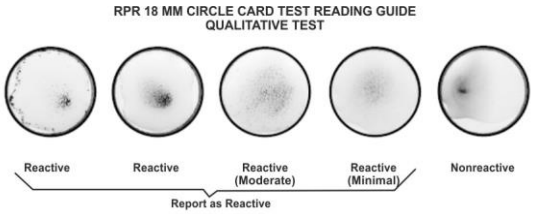
Fresh serum or plasma collected using EDTA, heparin or oxalate as an anticoagulant can be used. The sample may be stored at 2-8°C for 5 days or at -20°C for 4 weeks.

TEST PROCEDURE

Allow the reagent and sample to attain room temperature before use.

QUALITATIVE SLIDE TEST

1. Clean the slide provided in the kit and place it on a flat surface.
2. Place one drop of test sample and controls into separate reaction circles, using the plastic droppers provided.
3. To each of this add one drop of RPR Carbon reagent using the needle dropper provided in the kit. Do not contaminate the dropper with any sample.
4. Mix the reagent and sample in the respective circles using separate mixing sticks. Spread the mixture uniformly over the circle.
5. Start the stop-watch.
6. Rotate the slide gently either manually or using a mechanical rotor at 100 rpm.
7. Observe test results at 6 minutes.
8. Check for presence of flocculation or black clumps under a strong source of light.



(Diagram is just for illustration)

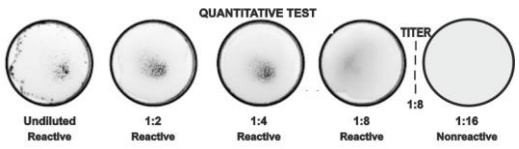
INTERPRETATIONS OF RESULTS

Observe the test slide under a strong source of light.

	Observation	Interpretation
1.	Black floccules or clumps against white back ground	Reactive/Positive
2.	Uniform greyish suspension with no floccules	Non-reactive/ Negative

SEMI QUANTITATIVE TEST

1. Any sample showing positive result in the qualitative test may be subjected to the semi-quantitative test.
2. Prepare serial dilutions of the positive test sample as 1: 2, 1: 4, 1: 8, 1: 16, 1:32 and so on.
3. Perform the qualitative test as mentioned above using each of the diluted sample as a test sample.
4. The titer is reported as the reciprocal of the highest dilution which shows a positive reaction.



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Quality Control

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's Standard Quality Control procedures. It is recommended that the user should refer to pertinent CLSI (formerly NCCLS) guidance and CLIA regulations for appropriate Quality Control practices.

LIMITATIONS FOR INTERFERENCE

1. The RPR Carbon antigen test is basically a screening test.
2. False negative results can occur because of failure to recognize prozone reactions, which may occur in 1% to 2% of patients with secondary syphilis.
3. False negative results are also seen in incubating primary and late syphilis.
4. Biological false positive reactions may be reported in diseases such as mononucleosis, leprosy, malaria, lupus erythematosus, vaccinia, virus pneumonia, Collagen diseases, Measles and Rubella.
5. False positive reactions may also be found in pregnancy, narcotic addiction and autoimmune disease patients.

REFERENCES

1. Pang Bom, Mary C., Isolation and purification of serologically active phospholipid from Beef heart, J. Biol, Chem., 143:247, 1942.
2. J. Venereal Disease inform., 27 : 169, 1946.
3. Mc Grew B. E. et al., American Journal of Clinical Pathology, 50 : 52, 1968.