RPR
AGGLUTINATION TEST

INTENDED USE
Kit for qualitative and semi-quantitative determination of Reagin Antibodies in human serum. This is for professional use only.

TEST PRINCIPLE
Micronized Activated Carbon Particles coated with Rapid Plasma Reagin Antigen. RPR Antigen reacts with the Reagin Antibodies present in the specimen to produce agglutination which indicates positive test result. If Reagin Antibodies are absent there will be no agglutination observed which indicates negative test result.

MATERIALS PROVIDED
1. Reagent 1: RPR Antigen
2. Reagent 2: Positive Control
3. Reagent 3: Negative Control
4. Disposable test cards with drawn circles
5. Disposable mixing sticks
6. Disposable specimen droppers
7. Antigen dropper
8. Instruction for use (IFU)

MATERIALS REQUIRED BUT NOT PROVIDED
1. Normal saline
2. Micropipettes
3. Micro tips
4. Micro centrifuge tubes
5. Vortex mixer
6. Marker/pen
7. Stop watch

WARNING AND PRECAUTIONS
1. Firmly shake the RPR antigen vial properly to get the homogenous suspension before testing.
2. Do not freeze the antigen reagent.
3. Cap the vial of reagents properly after use.
4. Drying of specimens and antigen reagent mixture at the periphery of the circle could lead to erroneous result.
5. Positive and negative controls are ready to use & provided for the validation of kit.
6. Do not use expired test kit.
7. Bring all components to room temperature (15-300C) before use.
8. Do not use the components of any other type of test kit as a substitute for the components in the kit.
9. Do not use if the product has been exposed to excessive heat.
10. Do not smoke, drink or eat in areas where specimens or kit is being handled.
11. Apply standard biosafety precautions for handling and disposal of potentially infective material:
    - Handle all specimens as potentially infectious.
    - Wear gloves while handling specimens and performing the test.
12. Dispose off all materials used to perform the test as biohazardous waste.
13. Instructions must be read completely before performing the test. Failure to follow the instructions may give inaccurate test results.
14. Rinse the RPR Antigen dropper with distilled water and dry it after use.

STORAGE AND EXPIRATION
- Please refer to the outer box for details.
- The kit components are stable up to expiry date indicated on the component label.

SPECIMEN COLLECTION AND HANDLING
- Fresh serum is the preferred specimen.
- Plasma or haemolysed / lipaemic serum should not be used.

TEST PROCEDURE

A. QUALITATIVE TEST
1. Bring all the reagents and specimens to room temperature before use. Shake the antigen reagent gently to ensure homogenous suspension.
2. Vertically place one drop (30-40 μl approximately)of each specimen, positive control and negative control into separate circles of test card using separate disposable sample droppers provided in the kit.
3. Vertically add one drop of antigen in the circle of specimen, positive control and negative control by using the antigen dropper provided in the kit.
4. Mix the contents of each circle by using separate disposable mixing sticks provided in the kit and spread in the entire circle.
5. Switch on the timer.
6. Move the test card gently to and fro for 8 minutes and observe for agglutination.
7. Result should be read at a normal reading distance in good light.
8. Do not examine for agglutination after 8 minutes. Do not use magnifying lens.

INTERPRETATION OF RESULT
- Agglutination with positive control and no agglutination with negative control validate the test result.
- Agglutination indicates positive test result and no agglutination indicates negative test result.
- Specimen with positive result should be retested in the semi-Quantitative test.

A. SEMI-QUANTITATIVE TEST
1. Serially dilute the specimen by using normal saline in tubes (1:2, 1:4…….1:64, etc.)
2. Vertically place one drop (30-40μl approximately) of diluted serum specimen from each tube using sample droppers in different circles of the test card.
3. Vertically add one drop of antigen in each circle and further repeat the steps 4 to 8 of Qualitative test.

INTERPRETATION OF RESULT
The last dilution which shows clear agglutination within 8 minutes indicates the RPR titer.

PERFORMANCE CHARACTERISTICS

1. Evaluation
- RPR test evaluated by NIB (National Institute of Biologicals) India as per their protocol and results obtained by them are as follows:

Sr.No.	Test(s) Conducted	Results
1	Sensitivity	≥ 96%
2	Specificity	≥ 100%

- RPR test is standardized against WHO standards for sensitivity test which have been calibrated against standard material equivalent to WHO reference preparation.

2. Interference
Bilirubin (20 mg/dl), Haemoglobin (20 mg/dl), Triglycerides (1000 mg/dl) and RF positive specimens do not interfere in RPR test result.

LIMITATIONS
- Individuals suffering from infectious mononucleosis, viral pneumonia and lupus erythematosus may lead to false positive result.
- In early and late stages of the disease, there may be false negative result.

REFERENCES

1. Protnoy, J.et.al. (1962); U.S. Publ. Health report, 77, 645.
2. Stevens, R.W. and storeable; E.J.(1970); Clin. Path. 53, 32.

DISCLAIMER
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of his product, the product is used outside of the control of the Manufacture and Distributor and the result may accordingly be affected by environmental factors and user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Instructions for use		Storage temperature
IVD	For in-vitro diagnostic use		Expiry date
	Do not reuse	REF	Ref. / Catalogue number
	Keep away from sunlight		Manufactured by
	No. of tests		Manufacturing date

Manufactured by:
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