SeroMAX RPR

(Slide Agglutination Method)

ORDERING INFORMATION

Ref. No.	Pack Size
AVRPR-50	50 Tests
AVRPR-100	100 Tests
AVRPR-500	500 Tests

INTENDED USE :

Kit is use for the Qualitative and Semi-Quantitative determination of Reagin Antibodies in Human Serum and Plasma

INTRODUCTION

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 OF THE METHOD

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.

REAGENT

1. SeroMAX RPR reagent: A particulate carbon suspension coated with lipid complexes.
2. Positive control, reactive with the SeroMAX RPR reagent.
3. Negative control, non reactive with the SeroMAX RPR reagent. SeroMAX RPR detects antilipoidal antibodies in serum or plasma. As against the conventional V.D.R.L. reagents, test samples do not require heat inactivation. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE & STABILITY:

All reagents are stable at 2-8°C till the expiry date mentioned on the labels.
Do not freeze the reagents

KIT CONTAINS

Name of Reagent	AVRPR-50	AVRPR-100	AVRPR-500
Reagent 1 RPR Antigen	1.0 ml	1 x 2 ml	2 x 5 ml
Reagent 2 Positive Control	0.4 ml	0.4 ml	0.4 ml
Reagent 3 Negative Control	0.4 ml	0.4 ml	0.4 ml

ACCESSORIES :

Disposable Slids	7 Nos.	2 x 7 Nos	10 x 7 Nos.
Disposable Sample Droppers	50 Nos	100 Nos.	500 Nos.
Disposable Mixing Sticks	50 Nos	100 Nos.	500 Nos.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.
1. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Glass slides, Test tubes, Pasteur pipettes, Isotonic saline (0.9% NaCl Solution), Centrifuge, Timer, Mixing sticks, Sodium Hypochlorite (1%).

PRECAUTIONS:

1. Avoid use of turbid or hemolysed specimens.
2. Bring reagents and specimen to room temperature before use.
3. Avoid drying of reagents on the card as it may lead to erroneous results.
4. Swirl RPR antigen before use and add holding the dropper vertically.
5. Rinse the RPR antigen dropper with distilled water and dry it after use.

SPECIMEN:

Unhemolysed Plasma / Serum
The samples should be free from contamination.
Inactivation of specimen is not required.

NOTES:

1. In the early and latent stages of the disease, there may be false negative results.
2. Acute or chronic infections such as leprosy, lupus erythromatosus, infectious mononucleosis, viral pneumonia and rheumatoid arthritis may lead to false positive results.
3. All reagents of this kit have been tested for HBsAg and HIV antibodies and shown to be negative.
4. As with all diagnostics procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.
5. For accuracy of results, the procedure has to be followed meticulously.

TEST PROCEDURE:

(A) QUALITATIVE TEST

1. Place one drop (50 µl) each of positive control (2), negative control (3) and sample in separate circles of the Disposable Test Card.
2. Shake well the RPR Antigen and add one drop (20µl) using the Antigen dropper provided in the kit.
3. Mix well and spread the reaction mixture in the entire area of the test circle.
4. Tilt the card gently back and forth for 8 minutes and observe results.

Interpretation of Results:

No agglutination	Negative Result
Black aggregates seen within 8 minutes	Positive Result

Positive samples should be retested in the semi-quantitative tests.

(B) SEMI QUANTITATIVE TEST:

1. Prepare serial dilutions of the positive specimen using normal saline as shown below:
   1:2, 1:4, 1:8, 1:16, 1:32 etc.
2. Proceed as in qualitative Test (A)

Interpretation of Results:

The highest dilution showing agglutination indicates the titre of the specimen.

PERFORMANCE CHARACTERISTICS

The performance characteristics of SeroMAX RPRwere evaluated using known positive and negative serum samples. The known serum samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

Specimen	SeroMAX RPR		Total
	+Ve	-Ve	
RPR + Ve samples	35	0	35
RPR - Ve samples	0	70	105
	35	70	105

Sensitivity: 100% Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of RPR negative and RPR positive
serum samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

REMARKS

1. Uniform, Homogenous, Micronised Activated Carbon Particles coated with Cardiolipin Antigen ensure clear agglutination.
2. Cardiolipin Antigen coated on to the Carbon Particles is suspended in a aqueous base to give consistent results. (Unlike Volatile Alcohol base which tends to give inconsistent results because of evaportaion of Alcohol).
3. Qualitative and Semi Quantitative procedures included in the same kit.
4. Positive and negative controls are provided for the proper validation of the kit.
5. Positive and negative controls provided in the kit are free from HIV & HbsAg.
6. Sample dilution is not required .
7. Sample Inactivation is not required.
8. Avid aggulation ensures proper discrimation between positive and negative controls
9. Optimum Cardiolipin Antigen Concentration coated on to the charcoal particles overcomes immunological interferences like prozone effect and hook effect.
10. Incorporates Six Sigma methodologies throughout the manufacturing processes wherein the product under goes various stringent process checks like Defining, Measuring, Analyzing, Improving and Controlling. (DMAIC)

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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse	Σ	Contains sufficient no. of test

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Transforming Research into Innovations

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