SeroMAX RF

(Latex Slide Agglutination Method)

ORDERING INFORMATION

Ref. No.	Pack Size
AVRAF-25	25 Tests
AVRAF-50	50 Tests
AVRAF-100	100 Tests

INTENDED USE

Kit is use for the Qualitative and Semi-Quantitative determination of Rheumatoid Factors in Human Serum.

PRODUCT FEATURES

1. Detects RF (Rheumatoid Factors) as low as 12 IU/ml. (Cut off Sensitivity 12 IU/ml).
2. Uniform and Homogenous Latex Particles ensure clear Agglutination.
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 unlike conventional procedures.
7. Do not use a magnifying lens for interpretation of results.
8. Avid Agglutination ensures proper discrimination between positive and negative results.
9. Cut off sensitivity 12 IU/ml is determined in correlation with Quantitative Turbidometry.
10. Latex Reagent Sensitivity 12 IU/ml is calibrated against WHO calibrators.
11. Optimum Human Gamma Globulin concentration coated on to the Latex particles overcomes immunological interferences like Prozone Effect and Hook Effect.

INTRODUCTION

Rheumatoid Arthritis (RA) is a Chronic Systemic Disease of unknown etiology. It is frequently characterized by Swelling, Pain in the joints, Inflammatory and regenerative processes involving Cartilage, Synovial membrane or Muscle tissue.

Rheumatoid factors (RF) are group of proteins present in the Blood and in Synovial fluid of individual having Rheumatoid Arthritis. It is believed that RF are Auto Antibodies produced by human body against RF self or against Human Gamma Globulin. The presence of these Auto Antibodies serve as credible marker of the disease.

The clinical significance of RA determination consists of differentiation between Rheumatoid Arthritis in which RF have been demonstrated in the serum of approximately 80% of the cases examined and Rheumatic Fever, in which RF are almost always absent.

PRINCIPLE :

The Latex particles are coated with Human Immunoglobulin G (IgG). The specimen containing RF on mixing with Latex Reagent agglutinates showing the Positive test result. If RF are absent there will be no agglutination which is the Negative test result.

REAGENTS

1. SeroMAX-RF reagent (latex): A uniform suspension of polystyrene latex particles coated with suitably modified Fc fraction of IgG (agglutinating sera). The reagent is standardised to detect »10 IU/ml of RF or more. The standardization of detection limit of SeroMAX-RF is traceable to the W.H.O., 1st International Reference Preparation of Rheumatoid Arthritis Serum.
2. Positive control, reactive with the SeroMAX-RF reagent.
3. Negative control, non-reactive with the SeroMAX-RF reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

STORAGE & STABILITY :

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the labels. When opened contamination must be avoided.

KIT CONTAINS

Name of Reagent	AVRAF-25	AVRAF-50	AVRAF-100
Reagent 1 Latex Reagent	1.0 ml	2 x 1 ml	2 x 2 m
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 :

Glass Slide (Black 4 Circles)	1 No.	1 No.	1 No.
Disposable Sample Droppers	25 Nos	50 Nos.	100 Nos.
Disposable Mixing Sticks	25 Nos	50 Nos.	100 Nos.

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.
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. Shake the Latex Reagent Vial properly to get the homogenous Latex Particles before testing.
2. Do not freeze the Latex Reagent.
3. Cap the vial properly after use to avoid drying of the Latex Reagent.
4. Drying of the Samples and Latex Reagent mixture at the periphery of the circle could lead to erroneous results.

SPECIMEN :

Fresh Serum is the preferred Specimen.
Plasma or Hemolysed / Lipaemic Serum should not be used.

TEST PROCEDURE :

A. QUALITATIVE TEST :

1) Bring the Latex Reagent, Controls and Specimens to room temperature before use. Shake the Latex Reagent gently to ensure Homogenous Suspension.
2) Place one drop (Approximately 40-50µl) each of Specimen, Positive Control & Negative Control into the separate circle of glass slide using a separate disposable sample dropper provided in the kit.
3) Add one drop Latex Reagent in each of these circles.
4) Mix the contents of each circle separately by the disposable mixing sticks provided and spread it in the entire circle.
5) Rock the slide gently for 2 minutes and look for agglutination.
6) Results should be read at a normal reading distance in good light.
7) Do not read results after 2 minutes

INTERPRETATION OF RESULTS:

Agglutination with Positive Control and no agglutination with Negative Control validates test results. Distinct agglutination indicates RF content of more than 12 IU/ml. Sera with Positive results should be retested in the Semi-Quantitative test. Agglutination within 2 minutes is a positive test and indicates presence of RF in the test specimen. No agglutination up to two minutes is a negative test, and indicates absence of RF in the test specimen.

B. SEMI QUANTITATIVE TEST :

1) Dilute the specimen serially 1 : 2, 1 : 4, 1 : 8, 1 : 32, 1 : 64 using Normal Saline.
2) Place one drop each of diluted serum sample using sample droppers in each circle of glass slide & proceed further as in Qualitative Test (A).

INTERPRETATION OF RESULTS :

The highest dilution which shows clear cut agglutination within two minutes indicates the RF titre. The approximate RF concentration can be obtained by multiplying titre by Sensitivity of the test.

RF in IU/ml=D x S

D = Highest dilution showing clear cut agglutination.

S = Sensitivity of the test - 12 IU/ml.

PERFORMANCE CHARACTERISTICS

The performance characteristics of SeroMAX RF were 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 RF		Total
	+Ve	-Ve	
RF + Ve samples	16	0	16
RF - Ve samples	0	70	70
	16	70	86

Sensitivity: 100% Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of RF negative and RF 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) Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
2) As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
3) In addition to Rheumatoid Arthritis,.positive result may also be found in Syphilis, Systemic Lupus Erythematosus, Hapatitis, Hypergammaglobulinemia.
4) The source material used in the manufacture of Positive and Negative Controls is tested for HBsAg & HIV antibodies, and is found to be Negative. However, for better safety, these controls should be handled as if they are potentially dangerous.
5) Do not read results after 2 Minutes.

REFERENCES:

1. Amy. M. Wasserman et.al, Diagnosis and Management of Rheumatoid Arthritis, American Family Physician , Vol 84, No. 11. Dec 1, 2011 , pgs 1245-1252.
2. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 810-813
3. Data on file: Tulip Diagnostics (P) Ltd.

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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Manufactured in India by :

AVECON Healthcare Pvt. Ltd.

Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576

Ver. : 4/04-23