SeroMAX CRP

(Latex Slide Agglutination Method)

ORDERING INFORMATION

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

INTENDED USE:

Kit is use for the Qualitative and Semi-Quantitative determination of C-Reactive Protein in Human Serum.

PRODUCT FEATURES

1. Detects CRP as low as 0.6 mg/dl.(Cut off Sensitivity 0.6 mg/dl)
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 and are safe to use.
6. Sample dilution is not required unlike conventional procedures.
7. Avid Agglutination ensures proper discrimination between positive and negative results.
8. Cut off sensitivity 0.6 mg/dl is determined in correlation with Quantitative Turbidometry.
9. Latex Reagent Sensitivity 0.6 mg/dl is calibrated against WHO calibrators.
10. Optimum Anti CRP Antibody concentration coated on to the Latex particles overcomes Prozone Effect.

INTRODUCTION

C-Reactive Protein (CRP) is a Normal Alpha Globulin, which increases in Inflammatory Processes. The name CRP is derived from the fact that this protein has the capacity to precipitate the somatic C-carbohydrate of Pneumococcus. Elevated CRP levels are usually observed in a variety of infections and inflammatory conditions where there is tissue destruction.

The CRP level measurement is useful in differential diagnosis of Neonatal Septicaemia and Meningitis. CRP levels are always elevated after Myocardial Infarction and Surgery. The CRP test can also help in determining Post-Surgical complications.

PRINCIPLE:

Uniform Latex particles are coated with Anti-Human CRP. The specimen containing CRP on mixing with Latex Reagent agglutinates, showing a positive test results. If CRP is absent, there will be no agglutination, indicating a negative test result.

REAGENTS

1. SeroMAX-CRP reagent: A uniform suspension of polystyrene latex particles coated with agglutinating sera for CRP. The reagent is standardized to detect CRP concentrations greater than 0.6 mg/dl. The standardization of detection limit of SeroMAX-CRP is traceable to the W.H.O., International reference Standard (85/506) for Human C-reactive protein.
2. Positive control, reactive with SeroMAX-CRP reagent.
3. Negative control, non-reactive with SeroMAX-CRP 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 stable at 2-8°C till the expiry date mentioned on the labels.

KIT CONTAINS

Name of Reagent	AVCRP-25	AVCRP-50	AVCRP-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. Do not read results after 2 Minutes.
2. Bring all the reagents to RT before use.
3. Do not freeze the Latex Reagent.
4. Do not use Hemolysed or Turbid Specimen.
5. The Latex Reagent (1) should be shaken well before use to ensure a homogeneous suspension of latex particles.
6. The source material used in the manufacture of Positive and Negative Controls is tested for HBsAg and HIV antibodies and are found to be negative. However, for better safety these controls should be handled with proper care as If they are potentially dangerous.
7. While dispensing Latex Reagent, hold the Latex dropper vertically to ensure uniform drop size.

SPECIMEN :

Only Serum Is the preferred specimen. In case of a delay In testing, store the specimen at 2-8°C. Plasma or Hemolysed/ Lipaemic Serum Samples should not be used.

PROCEDURE:

A) QUALITATIVE TEST:

1. **Place one drop (Approximately 40-50**µl) of specimen, Positive Control and Negative Control in separate circles of the glass slide by using the Sample droppers provided.
2. Add one drop of Latex Reagent in each of these circles with the Latex dropper.
3. Mix the content of each circle separately and spread it in the entire circle with the mixing sticks provided in the kit.
4. Rock the slide gently for 2 minutes and look for any agglutination.
5. Do not read results after 2 Minutes.

INTERPRETATION:

Agglutination with Positive Control and no agglutination with Negative Control validate the test results. Agglutination within 2 minutes is a positive test and indicates presence of CRP in the test specimen. No agglutination up to 2 minutes is a negative test and indicates absence of CRP in the test specimen.

Do not observe results after 2 minutes.

B) SEMI QUANTITATIVE TEST:

1) Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline.
2) Place one drop each of diluted serum samples using sample droppers in each circle of the glass slide and proceed further as in Qualitative Test (A).

INTERPRETATION:

The highest dilution, which shows clear-cut aggulination within 2 minutes, indicates the CRP titre. the approximate CRP concentration can be obtained by multiplying titre by sensitivity of the test.

CRP in mg/dl = D x S

D = Highest dilution showing clear cut aggulation.

S = Sensitivity of the test 0.6 mg/dl.

PERFORMANCE CHARACTERISTICS

The performance characteristics of SeroMAX CRP 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 CRP		Total
	+Ve	-Ve	
CRP + Ve samples	33	0	33
CRP - Ve samples	0	80	80
	33	80	113

Sensitivity: 100% Specificity: 100%

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

REMARKS

1. Do not read results after 2 Minutes.
2. Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
3. Improper mixing and drying of reagents may lead to erroneous results.
4. Contaminated sera and a longer reaction time after 2 minutes may lead to false positive results.
5. As with all diagnostics tests, the final diagnosis should be based on correlation of test results with other clinical symptoms and findings.
6. Non specific positive reaction may occur if plasma is used or serum is highly lipemic or hemolysed.
7. For accuracy of results, the procedure has to be followed meticulously.

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.

REFERENCES:

1. R.D. Eastham et.al.,C-Reactive Protein in Rheumatic Heart Disease, Am. Rheum. Dis. (1958), 17 pgs 314-318
2. Clinical Laboratory by Lothar Thomas , M.D., 1st edition, 1988, TH-Books, Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 700-706.
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		Contains sufficient no. of test

Manufactured in India by :

AVECON Healthcare Pvt. Ltd.

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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

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