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C-reactive Protein (CRP) Latex

Qualitative and semi-quantitative determination of CRP

For Slide agglutination

For professional in vitro diagnostic use only.

INTENDED USE

Slide agglutination test for the qualitative and semi-quantitative determination of CRP (C-reactive Protein) in human serum.

GENERALITIES

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise by more than 300 mg/L in 12-24 hours.

TEST PRINCIPLE

CRP is a slide agglutination test for the qualitative and semi quantitative detection of CRP in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated, when mixed with samples containing CRP.

The CRP-latex Reagent has been standardized to detect serum CRP levels at or above 6 mg/L which is considered the lowest concentration of clinical significance. When the latex suspension is mixed with serum containing elevated CRP levels on a slide, clear agglutination is seen within 3 minutes. The presence or absence of a visible agglutination indicates the presence or absence of CRP in the specimen.

REAGENT COMPOSITION

CRP Latex Reagent	
Latex particles coated with monoclonal goat anti-human CRP IgG, pH 8,2	
Sodium azide	0.95 g/L
CRP Positive Control (Optional)	
Human serum containing CRP	> 20 mg/L
Sodium azide	0.95 g/L
CRP Negative Control (Optional)	
Animal serum	
Sodium azide	0.95 g/L

STORAGE AND SHELFLIFE

Reagent up to the expiration date, when stored tightly closed and contamination is prevented during use and stored at 2-8 °C. Always store vials vertically. If the position is changed, the reagent must be mixed up to dissolve any aggregates present. Close immediately after use. Do not freeze! Frozen reagents could change the functionality of the test.

Reagent spoilage: visible particles and turbidity after vertexing.

SAMPLE COLLECTION AND PREPARATION

Use fresh serum obtained by centrifugation of clotted blood.

The specimen may be stored at 2-8 °C for 7 days before performing the test. For longer periods of time the serum must be frozen for a maximum of 3 months (once only). Hematic, lipemic or contaminated serum must be discarded. Samples containing fibrin should be centrifuged before use.

MATERIALS REQUIRED

Mechanical rotator adjustable to 80-100 rpm.

Vortex mixer.

Pipettes with disposable tips.

General laboratory equipment.

TEST PROCEDURE

A. Qualitative Procedure

1. Bring reagents and samples to room temperature (18-25°C). The sensitivity of the test may be reduced at low temperatures.
2. Place one drop of the Negative CRP Control onto a circle of the agglutination slide.
3. Place one drop of the Positive CRP Control onto an adjacent circle of the agglutination slide
4. Using the pipette, place one drop of serum specimen (40 µL) onto the remaining circle of the agglutination slide.
5. Shake gently and re-suspend the CRP latex reagent.
6. Add one drop next to each drop of controls and serum on the agglutination slide.
7. Stir with individual stirrers and spread mixture over the entire area of the test circle.
8. Place the slide on a mechanical rotator at 80-100 rpm. Interpret results in three minutes. False positive results can appear if the test is read after >3 minutes

B. Semi-quantitative method (titration) procedure:

The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the specimen in saline as follows:

1. Prepare dilutions in test tubes:

Dilutions	**1:2**	**1:4**	**1:8**	**1:16**
Saline	100 µL	50 µL	75 µL	87.5 µL
Specimen	100 µL	50 µL	25 µL	12.5 µL
Mix both drops with a disposable mixing stick, spreading the liquid over the entire surface of the test field. Use different sticks for each sample.				
Place the slide on a mechanical rotator at 80-100 rpm for 3 minutes. False positive results can appear if the test is read after >3 minutes.				
Calculate the result as follows:				
6 x Nº of dilution	6 x 2	6 x 4	6 x 8	6 x 16
Results:	12 mg/L	24 mg/L	48 mg/L	96 mg/L

INTERNAL QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

All results different from the negative control result will be considered positive.

INTERPRETATION OF TEST RESULTS

Examine macroscopically the presence or absence of visible agglutination after 3 minutes immediately after removing from the rotator. The presence of agglutination indicates a CRP concentration ≥ 6 mg/L. In the semi-quantitative method, the titer is defined as the highest dilution showing a positive result.

PERFORMANCE

Analytical Sensitivity: 6 mg/L (under the described assay conditions).

No prozone effect was detected up to 90 mg/L.

Diagnostic Specificity: 96.2%.

Diagnostic Sensitivity: 95.6%.

TRACEABILITY

Sensitivity is calibrated against the reference material ERM-DA 472/IFCC.

EXPECTED VALUES

Reference range: < 6 mg/L. It is recommended that each laboratory establishes its own normal range.

LIMITATIONS

High CRP concentrations in the samples may give negative results (prozone effect). It is recommended to retest these samples with 20 µL of the samples.

The strength of agglutination is not indicative for the CRP concentration in the samples tested.

Clinical diagnosis should not be made on findings of a single test result but should integrate both clinical and laboratory data.

INTERFERENCES

Rheumatoid Factors: 100 IU/mL.

No interference up to:	
Hemoglobin	10 g/L
Lipemia	10 g/L
Bilirubin	20 mg/dL

Other substances may interfere.

LITERATURE

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USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
Σ	Contains Sufficient for <N> Tests