



Rapid Latex agglutination slide test for the qualitative and semi quantitative in-vitro determination of C-Reactive Protein in sample

Presentation

Pack size	CRP latex reagent (R1)	CRP positive control (R2)	CRP negative control (R3)
25T	0.9ml	0.3ml	0.3ml
50T + 10T	2x1.1ml	0.3ml	0.3ml

Summary

C-Reactive Protein is a non-specific acute phase-reactive protein, which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cell sedimentation rate.

CRP levels get elevated in conditions where there is tissue destruction. CRP tests can help in determining post surgical complications.

Principle

CRP test is based on latex agglutination test. Specially selected polystyrene particles are coated with antibodies to C-Reactive Protein. When a serum sample, positive for C-Reactive Protein is mixed with the latex reagent, a positive reaction is indicated by a distinctly visible agglutination of the latex particles in the test cell of the slide. In serum sample, negative for C-Reactive Protein, the latex remains as a smooth suspension in the test cell.

Contents, reagents and material provided

1. CRP latex reagent. Mix gently before use. Suspension of polystyrene latex particles, coated with antibodies to C-Reactive Protein.
2. Positive control, reactive with CRP latex reagent.
3. Negative control, non reactive with CRP latex reagent.
4. 1 glass slide
5. Disposable plastic droppers with rubber teat.
6. Disposable mixing sticks.

Storage & Stability

Latex reagent & control sera are stable up to the expiry date printed on the labels when stored at 2-8°C. Do not freeze

Specimen

Use fresh serum specimen. However the same may be stored at 2-8°C up to 24 Hrs. and at -20°C up to 4 weeks.

Plasma should not be used because fibrinogen may cause non specific agglutination of the latex particles.

Do not use lipaemic, haemolysed or contaminated specimen.

Precautions & Notes

1. Kit reagents are for in-vitro diagnostic use only.
2. Strictly follow the instructions mentioned in the product insert.
3. Bring specimens & reagents to room temperature before use.
4. Mix latex reagent gently before use.
5. Interpret results exactly at 2 minutes.
6. Accessories provided with the kit only must be used for optimum results.
7. The reagents contain Sodium azide as a preservative. Do not swallow. Avoid contact with skin & mucous membrane.
8. All reagents of human source have been tested negative for HbsAg & anti-HIV antibodies and found to be non-reactive.
9. CRP is found to be present after the first trimester of pregnancy & persists until delivery.
10. CRP levels increase in women who are on oral contraceptives.
11. In cases where increase of CRP levels is suspected. But the screening test shows a negative result, semiquantitation must be done to rule out prozone effect.

Procedure

A. Qualitative analysis

Bring latex reagent, controls and serum specimens to room temperature. Mix the latex reagent thoroughly prior to use.

Drop on to separate cells of the slide, using disposable plastic droppers provided with the kit:

Serum specimen	1 drop
Positive control	1 drop
Negative control	1 drop
CRP latex reagent, on to all the sample & control cells of the slide in use.	1 drop

Do not let the dropper tip touch the liquid on the slide Mix with separate mixing sticks and spread the fluid over the entire area of the particular cell. Tilt the slide back & forth for 2 minutes so that the mixture rotates slowly inside the cells or place the slide on an automated rotator at 100 rpm. Observe for agglutination at the end of 2 minutes.

Interpretation of results

Observation	Conclusion
Agglutination within 2 minutes	CRP positive
Smooth Suspension/ No agglutination	CRP Negative

B. Semi Quantitative analysis

Prepare 0.9% saline solution. Then dilute specimen with saline solution as under until the last dilution giving distinct agglutination.

Dilution	CRP (mg/dl in undiluted specimen)
1+1 (1:2)	1.2
1+3 (1:4)	2.4
1+7 (1:8)	4.8
1+15 (1:16)	9.6
1+31 (1:32)	19.2

Continue test as described in Qualitative analysis

Interpretation of results

Titre is the highest dilution giving visible agglutination.

Sensitivity

The reagent is standardised to detect CRP concentrations greater than 0.6 mg/dl

Quality Control

The positive and negative control serum may be used for routine performance check.

References

1. Anderson H.C., Mc. Carthy M, Am. J. Med., 8,445(1950)
2. Kidmark, C.O.(1972) Scand J.Clin.Invest.29, 407.
3. Fisher C.L., Nakamura R., Am. J. Path., 66,840 (1976)

