CRP LATEX

Slide Agglutination

PRODUCT CODE
SL002

INTENDED USE
CRP slide test is a convenient and specific slide agglutination assay for the qualitative and semi quantitative detection of C-Reactive Protein (CRP) in human serum

No prozone effect detected up to 1600 mg/L. -Rapid procedure, only 2 minutes test. -Excellent clarity, clear agglutination.

CLINICAL SIGNIFICANCE
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 up to 300 mg/L in 12-24 hours.

PRINCIPLE
The CRP-latex is a slide agglutination test for the qualitative and semi-quantitative detection of C-Reactive Protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP.

REAGENTS

Latex	Latex particles coated with goat IgG anti-human CRP, pH 8.2, Preservative
Control + Red Cap	Human serum with CRP concentration > 20 mg/L
Control – Green Cap	Animal serum, preservative

ACCESSORIES
Reaction slide, Mixing pipettes

ADDITIONAL REQUIREMENTS
Mechanical rotator with adjustable speed at 80-100 rpm

STORAGE AND STABILITY
All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
Reagents deterioration: Presence of particles and turbidity.

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

SPECIMEN AND SAMPLE PREPARATION
Fresh serum, Stable 7 days at 2-8°C or 3 months at –20°C.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

PROCEDURES

Qualitative Method

1- Allow the reagents and samples to reach room temperature. The Sensitivity of the test may be reduced at low temperatures.
2- Place 40 ul of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3- Swirl the CRP - Latex reagent gently before using and add one drop (40 ul) next to the sample to be tested.
4- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5- Place the slide on a mechanical rotator at 80 - 100 r.p.m for 2 minutes. False positive results could appear if the test is read later than 2 minutes.

Semi-Quantitative Method

1- Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2- Proceed for each dilution as in the qualitative method.

INTERPRETATION OF RESULT
Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a CRP concentration equal or greater than 6mg/L. (Note2 and 3)
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS
The approximate CRP concentration in the patient sample is calculated as follows:
6 x CRP Titer = mg/L

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 result different from the negative control result, will be considered as a positive.

REFERENCE VALUES
Up to 6 mg/L. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
1. *Analytical sensitivity*: 6 (5-10) mg/L, under the described assay conditions
2. *Prozone effect*: No prozone effect was detected up to 1600 mg/L.
3. *Diagnostic sensitivity:* 95.6 %.
4. *Diagnostic specificity:* 96.2 %.

INTERFERENCES
Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere[7].

NOTES
1- High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
2- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
3- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

1- Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2- M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3- Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144
4- Yoshitsugy Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5- Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6- Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138: 309 – 318.
7- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany