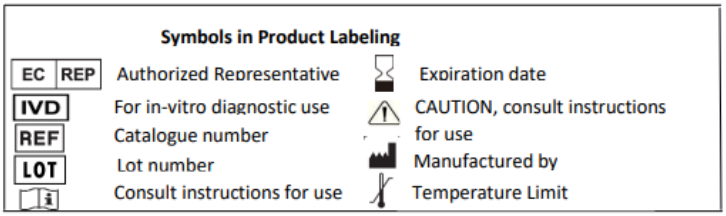
GENESIS

Instructions For Use

CRP Latex (Agglutination Method)

Cat no.	Test
3102 101	100 Test
3102 201	50 Test
3102 301	100 Test + Controls
3102 401	50 Test + Controls



INTENDED USE
CRP Latex Reagent (Agglutination-Test) is intended for Qualitative and Semi quantitative Determination of C - reactive protein in human serum.

DIAGNOSTIC CHARACTERISTICS
C-reactive protein (CRP) is a serum protein, which is synthesized in the liver. Its rate of synthesis and secretion increases within hours of an acute injury or the onset of inflammation and may reach as high as 20 times the normal levels.
Elevated serum concentration of CRP is an unequivocal evidence of an active tissue damage process and CRP measurement thus provides a simple screening test for organic disorders. Apart from indicating inflammatory disorders,CRP measurement helps in differential diagnosis, in the management of neonatal septicaemia and meningitis where standard microbiological investigations are difficult.
Its use in postoperative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7-10 days. Absence of this fall is indicative of possible septic or inflammatory postoperative complications.
Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and Creatinine phosphokinase (CPK).

PRINCIPLE OF THE METHOD
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.

COMPOSITION

Latex Reagent
-particles coated with goat IgG anti-human CRP -pH 8.2 -Sodium azide 0.95 g/L
(+)Control
-Human serum with CRP concentration > 20 mg/L -Sodium azide 0.95 g/L.
(-)Control
-Animal serum,Sodium azide 0.95 g/L

STORAGE
Store at 2-8ºC.
Reagent and Controls are stable until the expiry date shown on the vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION
Reagent and Controls are provided ready to use.

ADDITIONAL EQUIPMENT
Stop watch, Test tubes, A high intensity direct light source, physiological saline.
Note: For latex.
sample dispensing pipette and mixing sticks would be require additionally.

SAMPLES
1. Fresh serum. Stable 7 days at 2-8ºC or 3 months at < –20ºC.
2. Samples with presence of fibrin should be centrifuged before testing.
3. Do not use highly hemolysed or lipemic samples.

PRECAUTIONS AND WARNING
All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive.
No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

PROCEDURE
Bring reagent and samples to room temperature before testing.

Qualitative Method
1. Pipette one drop (40 µl) of test specimen (serum) on the latex slide using disposable pipette.
2.Add one drop of GENESIS-CRP latex reagent to one drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3.Using a mixing stick, mix the test specimen and latex reagent uniformly over the entire circle.
4.Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at two minutes.

Semi Quantitative Method
1.Using physiological saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2, 1:4, 1:8,1:16, 1:32, 1:64 and so on.
2.Pipette one drop (40 µl) of each dilution of the test specimen onto separate reaction circles.
3.Add one drop of GENESIS-CRP latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
4.Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
5.Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at two minutes.

INTERPRETATION OF RESULTS

Qualitative Method

-Agglutination is a positive test result and indicates presence of detectable levels of CRP in the test specimen.

-No agglutination is a negative test result and indicates absence of detectable levels of CRP in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of CRP in mg/l present in the test specimen.

Concentration of CRP can be calculated as follows:

CRP (mg/dl) = S x D

Where, S = Sensitivity of the reagent i.e. 6 mg/l.

D = Highest dilution of serum showing agglutination

REFERENCE VALUES

Up to 6 mg/L

METROLOGICAL CHARACTERISTICS

	Total	+Ve	-Ve
CRP + ve samples	33	33	0
CRP - ve samples	80	0	80
total	113	33	80

* Sensitivity: 100%
* Specificity: 100%.

Interferences:

Hemoglobin (up to 10 g/L), bilirubin (up to 20 mg/dL) and lipemia (up to 10 g/L) do not interfere. Rheumatoid factors (>100IU/mL) interfere.Other substances may interfere

BIBLIOGRAPHY

1. Andersen H.C., McCarthy M., Am. J. Med., 8, 445 (1950).
2. Ward A. N., Cooper E. M., Clin. Chem. Acta, 81, 75(1977).
3. Fisher C. L., Nakamura R., Am. J. Clin. Path., 66, 840 (1976).).

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