Cromatest

LINEAR

CRP-Latex CE

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REF	2410005 2410010	CRP-Latex CRP-Latex	50 Tests 100 Tests
For *in vitro* diagnostic use only			

CRP-Latex

Determination of C-reactive protein

SLIDE TEST

PRINCIPLE

CRP-Latex Test is a rapid slide agglutination procedure based on a modification of the latex fixation method[1], developed for the direct detection and semi-quantitation of C-reactive protein (CRP) in serum.
The assay is performed by testing a suspension of latex particles coated with anti-human CRP antibodies against unknown serum. The presence of a visible agglutination indicates an increase of the CRP level above the upper limit of the reference interval in the samples tested.

REAGENT COMPOSITION

R — **CRP-Latex Reagent**. Suspension of polystyrene latex particles coated with specific anti-human C-reactive protein antibodies in a buffered saline solution. Contains 0.95 g/L of sodium azide.

CONTROL + Human serum with a CRP concentration > 15 mg/L. Contains 0.95 g/L of sodium azide.

CONTROL - Animal serum with a maximum concentration of human CRP of 1 mg/L. Contains 0.95 g/L of sodium azide.

Precautions: Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
Warning: The reagents in this kit contain sodium azide. Do not allow contact with skin or mucous membranes.

PACKAGING CONTENTS

REF 2410005, kit 50 tests.
1 vial CRP-Latex Reagent, 1x1 mL Positive control, 1x1 mL Negative control, 3 Test cards and 1x50 disposable stirrers.

REF 2410010, kit 100 tests.
2 vials CRP-Latex Reagent, 1x1 mL Positive control, 1x1 mL Negative control, 3 Test cards and 2x50 disposable stirrers.

STORAGE AND STABILITY

Store at 2-8ºC. Do not freeze. Frozen reagents could change the functionality of the test.
Reagent and Controls are stable until the expiry date stated on the label.

REAGENT PREPARATION

Reagent and Controls are ready to use.

SAMPLES

Fresh, clear serum.
After the clear serum has been separated it may be stored at 2-8ºC for upto one week or longer periods at –20ºC.

MATERIAL REQUIRED

- Automatic pipettes.
- Saline solution (0.9% NaCl, only for semi-quantitation procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURE

I. Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Mix the Reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 1 drop (50 µL) of the serum under test into one of the circles on the card. Dispense 1 drop of positive control serum and 1 drop of negative control serum into two additional circles.
4. Add 1 drop of CRP-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide means of a mechanical rotator (100 r.p.m.) for a period of **2 minutes** (Note 2).
7. Observe immediately under a suitable light source for any degree of agglutination.

Reading
Nonreactive: Smooth suspension with no visible agglutination, as shown by negative control (Note 3).

Reactive: Any degree of agglutination visible macroscopically (Note 4).

II. Semi-quantitative Test

1. Dilute sample with NaCl 9 g/L following the 2-fold dilutions procedure as follow:

Dilution	1/2	1/4	1/8	1/16	1/32
Sample (µL)	100				
ClNa 9 g/L (µL)	100	100	100	100	100
Transfer (µL)		100	100	100	100
CRP (mg/L) non-diluted sample	12	24	48	96	192

2. Test each dilution as described in Qualitative Test.

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Reading
Same as in Qualitative Test. The titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative.
If the highest dilution tested is reactive repeat the test starting with a preliminary 1:32 dilution. Use a 1:50 dilution of negative control in NaCl 9 g/L solution to the replace the NaCl 9 g/L solution in the new 2-fold dilution series.
The approximate CRP level (mg/L) present in the sample may be obtained multiplying the titer of the last positive dilution by the minimum detectable unit (analytical sensitivity).

e.g. titer 1/16
CRP concentration = 6 x16 = 96 mg/L

QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the reagent.
The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

EXPECTED VALUES[2-5]

While the C-reactive protein concentration is generally below 5 mg/L in the sera of healthy adults, in a number of disease states these values often exceeded within 4 to 8 hours after an acute event and reach levels up to 500 mg/L. Since an elevated CRP level is always associated with pathological changes, determination of CRP is of great value in diagnosis, treatment and monitoring of inflammatory conditions.

CLINICAL SIGNIFICANCE[6-8]

C-reactive protein 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. CRP contributes to non-specific defense by complement activation and accelerating phagocytosis.
CRP testing has a high diagnostic value on a tentative diagnosis made on the basis of case history and clinical findings.

ANALYTICAL PERFORMANCE

- The minimum detectable unit (analytical sensitivity) is of approximately 6 mg/L (5-10 mg/L), tested against a Reference Material CRM 470/RPPHS.
- Diagnostic specificity: 96.2%.
- Prozone effect: No prozone effect was detected up to 160 mg/L.
- Results obtained with this reagent did not show significant differences when compared with reference reagents. Details of the comparison experiments are available on request.
- Hemoglobin (<10 g/L), bilirubin (<20 mg/dL) and lipemia (<10 g/L) do not interfere. Rheumatoid factors (>100 IU/mL) interfere. Other substances may interfere[9].

LIMITATIONS OF PROCEDURE

- The presence of rheumatoid factors (RF) in a serum sample may cause false positive reactions.
- Weak or negative reactions may occur with marked antigen excess (prozone effect).

NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25ºC.
2. Delays in reading the results may result in over-estimation of the CRP concentration.
3. When CRP contents of the serum is in excess, prozoning effect may result in false negative reactions with undiluted serum. The test may be repeated using 10 µL of sample. In case of positivity, use the titration procedure above.
4. The strength of the agglutination reaction is not indicative of the CRP concentration in the samples tested.

SOURCES OF ERROR

- Bacterial contamination of controls and specimens as well as freezing and thawing of the latex reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The CRP-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the suspension.

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