BIOLABO

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CRP-LATEX

Latex agglutination slide test for qualitative and semi-quantitative determination of C Reactive Protein (CRP) in human serum.

REF 097100 (100 tests) **R1** 1 x 4.0 mL **R2** 1 x 0.5 mL **R3** 1 x 0.5 mL

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CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1) (2) (3) (4)

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 cells sedimentation rate.

CRP lacks diagnostic value when the patients illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases.

It is routinely found in cases of bacterial infection (2), active rheumatic fever (3) and many malignant diseases and is often seen in association with cases of rheumatoid arthritis, viral infections and tuberculosis. CRP has also been detected in patients following blood transfusions and surgical operations (4) as well as in patients with burns, pemphigus vulgaris and other bullaous lesions.

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

PRINCIPLE (2) (3)

The CRP-latex particles are coated with antibodies to human CRP.
The CRP-latex Reagent has been standardised 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 2 minutes.
The presence or absence of a visible agglutination indicates the presence or absence of CRP in the specimen.

REAGENTS

-- Reusable agglutination slide and disposable stirring pipettes.

Vial R1 **CRP-Latex**

Suspension of polystyrene latex particles coated with anti-CRP antibodies (goat origin).

Vial R2 **Positive Control**

Human serum containing CRP.

Vial R3 **Negative Control**

Human serum free of CRP.

REAGENTS PREPARATION

Reagents are ready for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1.Semi-quantitative test: micropipettes and test tubes.
2.Saline (0.9 % NaCl)

STABILITY AND STORAGE

Store at 2-8°C away from light

DO NOT FREEZE.

- When free from contamination, stored in the original vial and used as described in this technical data sheet, reagents are stable until expiry date stated on the label of the kit.
- Discard any reagent if contaminated or do not demonstrate correct activity with controls.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin and eyes, thoroughly wash affected areas with plenty of water.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Controls contain human serum. Human serum used have been tested and found to be negative for HIV, HCV and HbsAg. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- For further information, Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

SPECIMEN COLLECTION AND HANDLING (5)

Use fresh serum obtained by centrifugation of clotted blood.
The specimen may be stored at 2-8° C for 72 hours before performing the test.
For longer periods of time the serum must be frozen for a maximum of 6 months (once only).
Haematic, lipaemic or contaminated serum must be discarded.

INTERFERENCES (6)

Haemoglobin: no interference up to 10 g/L.

Bilirubin : no interference up to 20 mg/dL.

Lipemia : no interference up to 10 g/L.

Rheumatoid factors: positive interference above 100 IU/mL.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S..

QUALITY CONTROL

Positive and Negative CRP control included in this kit.
External quality control program.
It is recommended to control in the following cases :

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.

If control is is not correct, apply following actions :

1. Repeat the test with the same control.
2. If control is still not correct, try again with a new vial of control(s).
3. If control is still not correct, try again with a new vial of reagent.
4. If control is still not correct, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (1)

IFCC Value: < 5 mg/L

These values are applicable only to adults between 20 and 60 years of age

Each laboratory should establish its own normal ranges for the population that it serves..

PERFORMANCES CHARACTERISTICS

Analytical Sensitivity: 6 (5-10) mg/L

Prozone effect: No effect detected up to 1600 mg/L

Diagnostic Sensitivity: 95.6 %

Diagnostic Specificity: 96.2 %

Above 1600 mg/L, high CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a sample drop of 20 µL.

MANUAL PROCEDURE

QUALITATIVE METHOD

1. Allow each component to reach room temperature before use.
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-stirrers provided, place one drop of serum specimen(s) onto the remaining circle(s) 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 pipette-stirrers and spread mixture over entire area of the test circle.
8. Gently rock the agglutination test slide for two minutes and observe the test circles for agglutination. Interpret results at two minutes. Extended incubation may result in evaporation and erroneous results.
9. At the end of the test rinse the slide with distilled water and dry on air.

SEMI-QUANTITATIVE DETERMINATION

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

Prepare dilutions in test tubes :

Dilutions	1/2	1/4	1/8	1/16
Saline	100 µL	100 µL	100 µL	100 µL
Specimen	100 µL	-	-	-
	→	100 µL →	100 µL →	100 µL →
Transfer onto a circle of a test slide :				
Diluted Specimen	50 µL	50 µL	50 µL	50 µL
Reagent (vial R1)	50 µL	50 µL	50 µL	50 µL
Calculate the result as follows :				
6 x N° of dilution	6 x 2	6 x 4	6 x 8	6 x 16
Results : mg/L	12	24	48	96

INTERPRETATIONS OF RESULTS

QUALITATIVE METHOD

Agglutination indicates a level of CRP equal or ≥ 6 mg/L.

Positive:
Agglutination appears within 2 minutes

Negative:
No agglutination appears within 2 minutes

No agglutination indicates a level of CRP equal or ≤ 6 mg/L.

SEMI-QUANTITATIVE METHOD

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination:
e.g. if this occurs in dilution 1/4, the titre is 4 x 6 = 24 mg/L.

REFERENCES

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(2) Tillet, W.S., and Francis, T., J. Exp. Med. 52:561 (1930)
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(4) Anderson,H.C., and McCarthy, M., Am. J. Med. 8:445 (1950)
(5) Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (1995) p.178 - p.181
(6) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-184 to 3-185
(7) Crockson, R.A., at al., Clin. Chrim. Acta 14: 435 (1966)
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Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with