PCR Latex Test

IVD CE

Latex card test for the detection of C Reactive Protein in human serum, without sample predilution.

Technical sheet

ORDERING INFORMATION

Form	Code	Composition
Kit 100 test	**REF CSA087027**	**n° 1 fl. x 5 ml** (CRP Reagent) **n° 1 fl. x 1 ml** (Positive Control) **n° 1 fl. x 1 ml** (Negative Control)

INTENDED USE

In vitro diagnostic medical device for the execution of the rapid latex agglutination test for qualitative research, and / or semi-quantitative dosage, of C-reactive protein in human serum. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

C-Reactive Protein (PCR) is present in the serum during the onset of inflammatory processes, of both infective and non-infective origin. The determination of this protein is of great diagnostic and prognostic importance because it is associated with numerous diseases (septic and aseptic inflammation, myocardial infarct, malignant tumors, rheumatic diseases, rheumatoid arthritis, senile vascular diseases, etc.) as a probable consequence of tissue degeneration; this parameter is considered even more specific than the erythrosedimentation rate (ESR).

PRINCIPLE

CRP Latex reagent is a polistyrene latex suspension coated with goat IgG anti-human CRP. When CRP is present in the sample, agglutination shows a CRP content of at least 6 mg/L **(without sample pre-dilution).**

Storage and stability

= Storage temperature 2-8 °C

Store the reagent and controls closed at 2-8°C, avoiding direct light. Do not freeze. If stored as recommended the reagent is stable until the expiration date printed on the label.

CONTENTS OF THE KIT AND PACKAGING

CRP Reagent	Ready to use. Suspension of latex particles coated with goat IgG anti human CRP *Contains preservative*
Reagent 2 (Red Cap)	Positive Control containing at least 20 mg/L of CRP*. Human serum. *Contains preservative*
Reagent 3 (Blu Cap)	Negative Control. Normal Serum *Contains preservative*

*Warning: biohazard. Human sera used in control sera have been tested and found to be negative for the presence of HBsAg and HCV and anti-HIV antibodies. However, handle cautiously as potential infectious human material (Biosafety Level 2).

16 x 6	Six circles' Slides, black screen
n. 50	Disposable stirrers for mixing the reaction mixture

OTHER REQUIRED MATERIALS, BUT NOT SUPPLIED

- 50 µl micropipettes; Isotonic saline

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials.
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.
10. Laboratory standards for protection against infection shall be used.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

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.

CALIBRATION

The sensitivity of PCR latex test is calibrated on Reference Material ERM-DA-474/IFCC

REAGENT PREPARATION

Reagents are liquid and ready to use. Swirl gently Reagent CRP before using (no aggregates must be visible)

PREPARATION AND STORAGE OF SAMPLES

Use fresh sera obtained by centrifugation of coagulated blood. Centrifuge for 10-15 minutes at 2500 g. Samples can be stored at 2-8°C for 48h before testing. For longer time of storage samples must be frozen (-20°C). Highly hemolyzed, lipemic or contaminated samples can't be used. Samples with the presence of fibrin should be centrifuged before testing. Do not dilute sample before testing.

PROCEDURE

Qualitative test

1 - Allow the reagent and samples to reach room temperature before use.
2 - Transfer one drop of control or undiluted sample serum (50 µl) to different test circle on the slide (Do not use dropper different than that supplied in the kit)
3 - Mix the Latex reagent to obtain a homogeneous suspension, then, using the dropper provided, add one drop of reagent (50 µl) to the test circle (placing the dropper perpendicularly to the slide surface)
4 - By using a disposable stirrer, mix and spread the drops on the surface of test circle.
5 - Rotate the slide for two minutes. Examine macroscopically the presence or absence of visible agglutination immediately after two minutes. Aspecific agglutination could appear if the test is read later than two minutes.

Semi-Quantitative technique

Make serial two-fold dilutions of the sample in 9 g/L NaCl solution (ex 1:2; 1:4; 1:8; 1:16). Proceed for each dilution as in the qualitative method. CRP concentration can be calculated as follow: $\frac{6 \times \text{CRP titer}}{} = \text{mg/L}$

CRP titer is the reciprocal of the last positive dilution.

READING: Observe for the presence or absence of agglutination within two minutes: agglutination evident on clear liquid background, indicates a positive result; an absence of change in appearance of the latex suspension is indicative of a negative result. The CRP Latex method is able to detect positive samples with a titer higher or equal than 6 mg / L. With lower titles a negative result is obtained. Agglutinations occurred after two minutes are to be considered as non-specific.

REFERENCE VALUES

Adults <6 mg/L

Each laboratory should establish its own reference range. CRP is a protein that increase significantly in serum in acute phase after the most forms of tissue injuries, bacterial and viral infections, inflammation and malignant neoplasia. It was described the presence of this protein in normal people in concentration lower than 6 mg/L. However, the increase occurs aspecifically in different disease as malignant neoplasia, rheumatic fever, myocardium infarct, inflammations, etc. and can rise up to 300 mg/L in 12-24h.

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. *Diagnostics Sensitivity*: 95.6%
4. *Diagnostics Specificity*: 96.2%

INTERFERENCES

Hemoglobin (< 10g/L), bilirubin (< 20mg/dL) and e lipemia (< 10g/L) do not interfere. Reumathoid Farctor (>100IU/ml) interferes. Other substances may interfere

LIMITATION OF PROCEDURE

The incidence of false positive is about 3-5%. Patients suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results. Diagnosis has to be integrated with RF latex test results and clinical tests.

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

Bibliography

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Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
D	10-2022	Modified for IVDR Compliance

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