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# C REACTIVE PROTEIN (CRP)

REF: K-9510M

## MONOREAGENT PROCEDURE

In vitro diagnostic reagents for the quantitative determination of C Reactive Protein (CRP) in serum by means of particle-enhanced turbidimetric immunoassay.

## Diagnostic Relevance

C- reactive protein (CRP) is one of the acute phase proteins being synthesised by hepatocytes. The serum concentration of CRP increases during acute stages of diverse diseases associated with inflammation and tissue injury. Elevated CRP has been demonstrated in nearly all bacterial and fungal infections. In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery.

The diagnosis usefulness of CRP is based on the velocity and on the magnitude of its increase. Serum concentrations are raised within hours of disease onset and the increase can be as much 2000-fold. A rapid fall of CRP levels indicates recovery.

## Principle

This CRP test is based upon the reactions between C reactive protein (CRP) and latex-covalently bound antibodies against human CRP. CRP values are determined photometrically.

## Reagents

Each CRP kit contains:

**A**.- Buffer - 45 mL of TRIS buffer, pH: 8.2, and 0.09 % sodium azide as preservative.

**B**.- Latex reagent – 5 mL of Polystyrene particles (0.5%) coated with goat antibodies anti-human-CRP serum in a glycine buffer (0.1 M, pH: 8.2), containing NaCL (0.15 M) and bovine serum albumin (0.5%). Preservative: Sodium azide 0.075%

**C**.- Calibrator – 1 mL. Human - based reference fluid. Preservative: sodium azide, 0.075 %. All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

## Reagent Preparation

Working Reagent is prepared with 1 part of Latex Reagent and 9 parts of Buffer Reagent. Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.

## Calibration Curve and Controls

Analytical Range up to 90 mg/L.

| | |
|---|---|
| Calibrator 1 | 100 µl of Biolatex CRP Calibrator* |
| Calibrator 2 | 100 µl of Calibrator 1 + 100 µl of Saline Solution |
| Calibrator 3 | 100 µl of Calibrator 2 + 100 µl of Saline Solution |
| Calibrator 4 | 100 µl of Calibrator 3 + 100 µl of Saline Solution |
| Calibrator 5 | 100 µl of Saline Solution |

(*) See values on the label or on the insert. Multiply by the appropriate factor.

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

## Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at +2 - +8ºC. Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at +2 - +8ºC after use. Do not freeze reagents.

The CRP latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

The CRP buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

WR is stable for up to one month at 4ºC. **It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.**

## Precautions

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can

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form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

## Materials required

Spectrophotometric analyser. Saline solution. Controls.

## Specimens

Fresh or deep frozen serum. CRP remain stable for 8 days at +2 to +8ºC. If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolysed or contaminated samples.
Heavily lipaemic sera and turbid frozen serum samples must be cleared with a delipidating agent. Delipidation of samples do not affect the results of CRP in serum samples. The cleared patient serum sample must be used on the same day, as turbidity may reoccur.

## Procedure

| | | | |
|---|---|---|---|
| Wavelength | | 550nm | |
| Temperature | | 37ºC | |
| Cuvette | | 1cm light path | |
| Measurement against distilled water blank. | | | |
| Bring the reagents at 37ºC and pipette: | | | |
| | Calibrator | Sample | Blank |
| Calibrator | 3 µl | --- | --- |
| Sample | --- | 3 µl | --- |
| Distilled Water | --- | --- | 3 µl |
| Work. Reagent | 500 µl | 500 µl | 500 µl |
| Mix and measure absorbance immediately (A1) incubate 2 min (37ºC), after incubation read absorbance (A2). | | | |

## Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A2-A1) in the calibration curve.

If is an one point calibration:

$$\frac{(A2-A1)_{sample} - (A2-A1)_{blank}}{(A2-A1)_{calibrator} - (A2-A1)_{blank}} x Calibrator Concentration$$

## Specific Performance Characteristics

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, the data must be calculated by each instrument.

## Reference Values

Values < 6 - 8 mg/L are within the normal range. Each laboratory should establish an expected range for the geographical area in which it is located.

## Literature

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**Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fecha de Caducidad<br>Expirate Date<br>Date de Péremption<br>Data di Scadenza<br>Data Expiração<br>Verwendbar bis | Temperatura de almacén<br>Storage Temperature<br>Temperature de Conservation<br>Temperatura de Conservazione<br>Temperatura de Conservação<br>Lagertemperatur | Número de Lote<br>Lot Number<br>Número de Lot<br>Numero di Lotto<br>Número de Lote<br>Chargen-Nr | Para Diagnóstico In Vitro<br>For In Vitro Diagnostic<br>Usage In Vitro<br>Per Uso Diagnostico In Vitro<br>Utilizar em Diagnostico In Vitro<br>In Vitro Diagnosticum | REF<br>Número de catálogo<br>Catalog Number<br>Numéro de catalogue<br>Numero di catalogo<br>Número de catálogo<br>Katalognummer | Conformidad Europea<br>European Conformity<br>Conformité aux normes européennes<br>Conformità europea<br>Comformidade com as normas europeias<br>CE-Konformitätskennzeichnung | Fabricado por<br>Manufactured by<br>Fabriqué par<br>Fabbricato da<br>Fabricado por<br>Hergestellt | REAG<br>Reactivo<br>Reagent<br>Réactif<br>Reagenti<br>Reagente<br>Reagenz | CAL<br>Calibrador<br>Calibrator<br>Calibrateur<br>Calibradore<br>Calibrador<br>Kalibrator | Buffer<br>Tampón<br>Buffer<br>Tampon<br>Tampone<br>Buffer<br>Puffer | LYOPH<br>Liofilizado<br>Lyophilised<br>Lyophilisé<br>Liofilo<br>Liofilizado<br>Lyophilisiert | Conc.<br>Concentración<br>Concentration<br>Concentration<br>Concentrazione<br>Concentraçao<br>Konzentration | Control H / Control L<br>Control Alto / Control Bajo<br>Control High / Control Low<br>Contrôle élevé / Contrôle Bas<br>Controllo Alto / Controllo Basso<br>Controlo Alto / Controlo Baixo<br>Kontrolle Hoch / Kontrolle Niegrid |

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