

C REACTIVE PROTEIN (CRP) Turbi Latex

REF: 560 001 100 test REF: 560 002 200 test

R1 Diluent	2 x 20 ml	R1 Diluent	4 x 20 ml
R2 Latex	1 x 10 ml	R2 Latex	2 x 10 ml
Calibrator	1 Vial	Calibrator	1 Vial

Intended Use

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

Background

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.

Test Principle

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

Reagents

R1 Diluent

TRIS buffer 20 mmol/L, pH 8.2, and 0.95 g/L sodium azide.

R2 Latex reagent

Latex particles coated with goat IgG anti-human CRP, pH 7.3 and Sodium azide 0.95 g/L.

Calibrator

CRP concentration is stated on the vial label.

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









Precautions and Warnings

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

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 °C). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize stability. 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 diluent 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 4°C. It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

Reagent Preparation & Stability

Working Reagent is prepared with 1 part of Latex Reagent and 4 parts of Buffer Reagent . Prepare a fresh WR based on its workload. Shake gently the reagents before pipetting.
e.g. 400 µl Buffer Reagent + 100 µl Latex Reagent.

stability : 1 month at at 2 - 8 °C.

CRP Calibrator: Reconstitute with 1 ml distilled water. mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at at 2 - 8 °C or 3 months at at -20 °C

Specimen Collection and Preparation

Fresh or deep frozen serum. CRP remain stable for 8 days at (2 - 8 °C). 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. The cleared patient serum sample must be used on the same day, as turbidity may reoccur.

Procedure

1 - Bring the reagents and the photometer to 37°C

2 - Assay conditions:
Wavelength 540 nm (530 -550 nm)
Temperature 37°C
Cuvette 1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

Working Reagent	500 µl
Calibrator or Sample	5 µl

5.Mix and read absorbance immediately (A₁) and after 2 min (A₂) of the sample addition.

Calculation

$$\frac{(A_2-A_1)_{\text{sample}}}{(A_2-A_1)_{\text{calibrator}}} \times \text{Calibrator concentration} = \text{mg/L CRP}$$

Sensitivity

2 mg/L

Linearity

Up to 150 mg/L.
specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Quality Controls

Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Expected Values

Values < 6 mg/L are within the normal range.

Each laboratory should establish an expected range for the geographical area in which it is located.

References

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Hessian PA, Palmer DG. The presence and possible significance of C-Reactive protein in rheumatoid inflammation. J Rheumatol 1985 1985; 12:871-5.

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ORDERING INFORMATION	
CATALOG NO.	QUANTITY
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560 002	200 test



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