

**Quantitative determination of C-Reactive Protein in Serum
Only for *In Vitro* Diagnostic use**

ORDER INFORMATION

REF	CONT
TCRP 25	1 x 25 ML
TCRP 50	1 x 50 ML

CLINICAL SIGNIFICANCE

CRP is an acute phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and viral infection, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections .The CRP concentration can raise up to 300 mg/L in 12-24 hr.

PRINCIPLE

CRP-turbilatex is quantitative latex based turbidimetric test for the measurement of C - reactive protein (CRP) in human serum. Latex particles coated with specific anti-human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change dependent upon the CRP contents of the patient samples that can be quantified by comparison from a calibrator of known CRP concentration.

REAGENT COMPOSITION

Reagent I : Tris buffer 20 mmol/l,pH 8.2 Sodium Azide 0.95 g/L
 Reagent II : Latex particles coated with goat IgG anti-human CRP, pH 8.2,
 CRP-CAL : C-reactive protein concentration is stated on the Vial label.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the CRP Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum: Stable for 7 days at 2-8°C or 3 months at -20°C.
 Samples with presence of fibrin should be centrifuged before testing.
 Do not use highly hemolysed or lipemic sample.

REAGENT PREPARATION AND STORAGE

Working reagent: swirl the latex vial gently before use. Prepare the necessary amount as follows.

9 ml Reagent 1 + 1 ml Reagent 2

CRP calibrator: Ready to use value mention on vial in mg/L.

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

Working reagent: Stable for 30 days at 2-8°C

AUTOMATED PARAMETERS	
Wavelength	540 (530-550) nm
Cuvette	1 cm light path
Reaction Temperature	37°C
Measurement	Against Distilled water
Delay Time	10 Sec
Reaction	2 point kinetics
Reaction Direction	Increasing
Sample / Reagent Ratio	1 : 100
Linearity	150 mg/l.

ASSAY PROCEDURE

PIPETTE INTO TEST TUBES

	CAL	SAMPLE
Sample	-	10 µl
Standard	10 µl	-
Reagent	1000 µl	1000 µl

Mix well, and read the absorbance immediately A1 and after 2 minutes A2 of the sample addition.

CALCULATION

$$\text{CRP (mg/L)} = \frac{(\text{A2}-\text{A1}) \text{ Sample}}{(\text{A2}-\text{A1}) \text{ Calibrator}} \times \text{calibrator concentration}$$

LINEARITY

The method is linear up to a concentration of 150 mg/l.
 If the concentration exceeds this value, the sample should be diluted with 0.9% saline solution and re-assayed.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

REFERENCE INTERVAL

Normal value: up to 6mg/L

BIBLIOGRAPHY

1. Alouf Jodeph E.Pharma Ther 1980;11:661-717.
2. M Fasani et al eur J Lab Med 1994;Vol 2 no 1-67.
3. Todd E W J Exp Med 1932;55-267-280.



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