CRP - TURBILATEX

METHOD – LATEX - TURBIDIMETRY
PRODUCT CODE – LC08

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for quantitative determination of C-Reactive Protein (CRP) by using Latex Turbidimetric method.

CLINICAL SIGNIFICANCE

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

PRINCIPLE

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

REAGENTS

Diluent (R1) - 1 x 40 ml.
Latex Reagent (R2) - 1 x 10 ml.
CRP-CAL - 1 vial (Lyophilized. Add DW as per vial label before use).

PREPARATION, STORAGE & STABILITY

Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent prior to use. Do not shake vigorously. Working reagent is stable for 1 month at 2-8 ^{0}C. Do not freeze. Frozen latex and diluent could change the functionality of the test. CRP calibrator is stable for 1 month at 2-8 ^{0}C or 3 months at -20 ^{0}C after reconstitution. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

TEST PARAMETERS

Name	CRP Turbi	Reagent Volume	1000 µl
Reaction Type	Kinetic (↑)	Sample Volume	5 µl
Wavelength Primary	540 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	10 sec.
Blank setting	D/W	Read Time	120 sec.
Blank Abs Limit	-	Factor	-
Linearity	150 mg/L	Calibrator Conc.	On Vial

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	5 µl
Mix the reagent and sample in the above mentioned ratio	
Aspirate the reaction mixture into the flowcell and record the absorbance at 10th and 130th sec.	

CALCULATION

$$\text{CRP (mg/L)} = \frac{\Delta \text{ Abs. of sample x Conc. of calibrator.}}{\Delta \text{ Abs. of calibrator.}}$$

SPECIMEN COLLECTION & PRESERVATION

Fresh serum should be used for testing. Serum is stable for 7 days at 2-8 ^{0}C or 3 months at -20 ^{0}C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipaemic samples.

REFERENCE VALUES FOR NORMAL PEOPLE

Adults: Upto 6 mg/L.

PERFORMANCE CHARACTERISTICS

1. Linearity limit is upto 150 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5th in normal saline and retested again. The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivily of the test will be proportionally decreased.
2. Values less than 2 mg/L give non-reproducible results.
3. No prozone effect was detected up to 800 mg/L.
4. Sensitivity: Δ 4.2 mA. mg/dL.

QUALITY CONTROL

Inclusion of a normal value and abnormal value Scontrol serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for CRP. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

INTERFERENCES

Bilirubin (20 mg/dl), rheumatoid factors (300 IU/mL), lipaemia (10 g/L) do not interfere. Hemoglobin (≥ 5 g/L), interferes. Other substances may interfere.

SYMBOLS: Read Instruction for use | IVD In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

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