Ana-Chek® CRP - TURBILATEX

METHOD – IMMUNOTURBIDIMETRY
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

Ana-Chek® 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.

KIT COMPONENTS

Diluent (R1)	1 x 40 ml.
Latex Reagent (R2)	1 x 10 ml.
CRP Calibrator	1 vial

REAGENT 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. Swirl the latex reagent gently before use. Do not shake vigorously. Working reagent is stable for 1 month at 2-8 ^{0}C. Do not freeze the reagent, Frozen latex and diluent could change the functionality of the test. 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	Two point Kinetic	Sample Volume	10 µl
Wavelength Primary	540 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	10 sec.
Blank setting	Distilled Water	Read Time	120 sec.
Linearity	150 mg/L	Calibrator Conc.	On Vial

PRECAUTIONS & HANDELING

For in vitro diagnostic use only. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the Ana-Chek® CRP Turbilatex Reagent Material Safety Data Sheet. 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. The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. Don't freeze the reagent. Do not shake the reagent vigorously. Do not use the reagent after the expiration date printed on the kit. Handle the calibrator cautiously as potentially infectious material.

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

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 hemolyzed or lipemic samples.

ASSAY PROCEDURE

	Calibrator	Test
Reagent	1000 µl	1000 µl
Calibrator	10 µl	NA
Sample	NA	10 µl
Aspirate the reaction mixture into the flow cell and record the absorbance at 10th and 130th sec.		

CALCULATION

$$CRP(mg/L) = \frac{(A2-A1)Sample}{(A2-A1)Calibrator} \; X \; Calibrator\ Concentration$$

REFERENCE VALUES FOR NORMAL PEOPLE

Adults: Upto 6 mg/L.

Note: We recommend each laboratory to establish their own reference range.

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 sensitivity 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.

QUALITY CONTROL

Inclusion of a normal value and abnormal value control 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), lipemia (10 g/L) do not interfere. Hemoglobin (≥ 5 g/L), interferes. Other substances may interfere.

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.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE

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