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C-Reactive Protein (TURBI-LATEX)

Turbi-latex reagent for in-vitro diagnostic determination of CRP present in human serum.

REF: BS.1/CRT1.050.0050	50 tests	REF: BS.1/CRT1.100.0100	100 tests

CLINICAL SIGNIFICANCE [1-2]

Tissue-damaging associated with inflammatory diseases, infection and neoplasms are associated with a major acute phase response of the C-reactive protein (CRP) and other acute phase reactants. The CRP response frequently precedes clinical symptoms, including fever. Measuring changes in the concentration of CRP provides useful diagnostic information about how acute and how serious a disease is. It also allows the assessment of complications during the disease and judgment about the disease genesis.

METHOD PRINCIPLE

BioScien CRP turbidimetric immunoassay for the determination of CRP in human serum is based on the principle of agglutination reaction. The test sample is mixed with activation buffer (R1), latex reagent (R2) and allowed to react. Presence of CRP in the test sample results in the formation of an insoluble complex producing a turbidity, which is measured at 540 nm.

REAGENT COMPOSITION

Reagents:	Composition
R1: BUFFER REAGENT	Tris buffer 20 mmol/l, PH 7.0
R2: LATEX REAGENT	A suspension of polystyrene latex particles coated with anti- CRP antibodies.
CALIBRATOR	equivalent to the stated amount of CRP on a mg/L

Both reagents contain 0.9 g/L Sodium azide as a preservative.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the CRP reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien CRP reagent is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows: 4 ml Buffer+ 1 ml Latex Reagent.
Calibrator: Reconstitute with 1 ml distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
Stability: 1 month deep freezed

Deterioration
The ***BioScien*** CRP reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION [2]

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8°C in case of delay in testing up to 72 hours.
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.

SYSTEM PARAMETERS

Wavelength	540 nm (530 – 550 nm)
Optical path	1 cm
Assay type	Turbidimetric
Temperature	37 ˚C

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

1. Bring the working reagents and the photometer (cuvette holder) to 37° C.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

R1: Buffer Diluent	400 µl
R2: Latex Reagent	100 µl
Calibrator or Sample	5 µl

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

CALCULATION

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

QUALITY CONTROL

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. For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	10	10	10	10
Mean mg/dl	135	372	135	372
SD.	3.4	5.9	13.2	17.8
CV. %	2.5	1.6	5.9	4.8

Analytical sensitivity: 4.2 mg/dl
Analytical linearity: up to 110 mg/l
The linearity limits depends on the sample / reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Prozone effect: No prozone effect was detected up to 80mg/dl.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL) and lipemia (10/g/dL) and rheumatoid factors (300 IU/ml),do not interfere. Hemoglobin (≥ 5g/L) interferes, other substances may interfere7.

LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. 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 cautiously as potentially infectious.
4. Do not use damaged or leaking reagents.
5. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.
6. After usage the antigen suspension should be immediately recapped and replaced at 2-8 C.

EXPECTED VALUES

Up to 6 mg/L
Each laboratory should establish its own reference range.

REFERENCES

1.Halbert, SP. Ann. N.Y. Acad. Sci., 103, 1027:1051; 1963.
2.Klein GL, Applied Microbiology, 21:999, 1971.
3.Klein GC: Manual of Clinical Immunology ASM 264-273:1976.
4.Müller M, Mierau R, Wohltmann D. Interference of IgM rheumatoid factor with nephelometric C-reactive protein determinations. J Immunol Methods 1985; 80: 77-90.
5.Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24,1952.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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