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Turbilatex CRP CE IVD

Product name: Infinite Turbilatex CRP

INTRODUCTION

- Infinite Turbilatex CRP is a reagent set for quantitative determination of C-Reactive Protein in human serum based on Turbidimetric method.
- Infinite Turbilatex CRP is a two liquid reagent system using one step procedure.
- Infinite Turbilatex CRP can be determined in just 2 minutes.
- Infinite Turbilatex CRP is linear up to 150 mg/L.
- Infinite Turbilatex CRP can be used on any Spectrophotometer, Discrete semi- automated and automated analyser.

PRINCIPLE

Infinite Turbilatex CRP contain latex particles coated with specific anti-human CRP which reacts with CRP in the sample resulting in agglutination. Agglutination causes change in absorbance, measured at 540 nm (530- 550 nm) & is proportional to the concentration of CRP in the sample.

PREPARATION OF WORKING STABILITY

Swirl the latex vial gently before use and prepare working solution buy mixing Reagent R1 and Reagent R2 in the ration 9:1 as per the requirement.

Calibrator: Calibrator has to be purchased separately, for calibrator preparation follow the instruction as mentioned in the IFU of calibrator.

REAGENT STORAGE, STABILITY AND HANDLING

- The reagent kit should be stored at 2-8ºC and is stable till the expiry date indicated on the label. It is recommended to store the reagents at 2-8ºC, tightly closed after use.
- The working solution (9R1 + 1R2) is stable for 30 days at 2 – 8ºC.

DO NOT FREEZE THE REAGENTS. Frozen Latex or Diluent could change the functionality of the test.

- Contamination of the reagents should be strictly avoided.
- Reconstituted calibrator is stable for 1 month at 2-8ºC or 3 months at -20ºC

COMPONENTS & CONCENTRATION OF WORKING SOLUTION

R1: Tris Buffer > 15 mmol/L - 45 ml
R2: Latex Particles coated with anti-CRP antibody -5 ml

SPECIMEN COLLECTION AND PRESERVATION

Fresh serum sample is preferred. Samples with presence of fibrin should be centrifuged before testing. CRP in serum is stable for 7 days at 2 – 8oC and for 3 months at -20oC. Sample should be brought to room temperature before use.
Do not use highly haemolysed or lipemic samples.

PROCEDURE

- Reaction Type: Fixed time
- Reaction direction: Increasing
- Wavelength: 540 nm
- Flowcell temperature: 37oC
- Zero setting with: Distilled Water
- Delay Time: 5 sec
- No. of readings : 2
- Interval : 120 sec
- Sample volume: 5µl
- Working section volume (9R1+1R2): 1 ml
- Linearity : 150 mg/L

MANUAL ASSAY PROCEDURE

Perform the assay as given below:

Reagents	Calibrator	Sample
Working Solution	SD %	SD %
	0.078	0.152

Mix & aspirate the assay mixture. The first reading should be recorded at 5 seconds (A1) followed by a second reading after 120 seconds (A2) interval at 540 nm.

CALCULATION

$$\text{Factor} = \frac{\text{Concentration of Calibrator}}{\text{(A2-A1) Calibrator)}}$$

CRP(mg/L) = (A2- A1) Sample X Factor

EXPECTED VALUES

Up to 6 mg/L
Expected range varies from population to population. It is therefore recommended that each laboratory should establish its own normal range.

PROCEDURE LIMITATIONS

- Linearity limit: If the CRP concentration exceeds 150 mg/L, dilute the specimen with normal saline and repeat the assay. The result obtained should be then multiplied with the dilution factor to obtain correct CRP concentration.
- Detection limit: Values less than 2 mg/L give non-reproducible results.
- Prozone effect: No prozone effect was detected up to 800 mg/L.

• Bilirubin (20 mg/dl), lipemia (10 g/L) and rheumatoid factors (300 IU/ml) do not interfere. Haemoglobin (>5 g/L) interferes

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each batch should include normal and abnormal commercial reference control serum. It should be realised that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

REFERENCES

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Accurex Biomedical Pvt. Ltd.
Plant: G-54/55, MIDC Tarapur, Boisar, Thane - 401 506, India.

Call us on: +91 7400453000