#### 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.
- 3. Infinite Turbilatex CRP can be determined in just 2 minutes.
- 4. Infinite Turbilatex CRP is linear upto 150 mg/L.
- Infinite Turbilatex CRP can be used on any Spectrophotometer, Discrete semi-automated and automated analyzer.

#### **PRINCIPLE**

**Infinite** Turbilatex CRP contain latex particles coated with specific antihuman 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 SOLUTION

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

Lyophilized calibrator should be reconstituted by adding 1.0 ml of distilled or deionized water. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake. Let stand for 20 minutes at room temperature before use.

### REAGENT STORAGE, STABILITY & HANDLING

The reagent kit should be stored at  $2 - 8^{\circ}$ C and is stable till the expiry date indicated on the label. It is recommended to store the reagents at  $2 - 8^{\circ}$ C, tightly closed after use.

The working solution (9R1 + 1R2) is stable for 30 days at 2 -  $8^{\circ}$ C.

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 -  $8^{\circ}$ C or 3 months at -  $20^{\circ}$ C.

## COMPONENTS & CONCENTRATION OF WORKING SOLUTION

R1 : Tris buffer > 15 mmol/L - 45 ml
R2 : Latex particles coated with anti - CRP antibody - 5 ml
R3 : CRP Calibrator (Value mentioned on vial label) - 1 ml

# & 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 - 8° C and for 3 months at -20° C. Sample should be brought to room temperature before use.

Do not use highly haemolyzed or lipemic samples.

#### **PROCEDURE** □ Reaction type ......Fixed-Point □ Reaction direction ......Increasing □ Wavelength ......540 nm. □ Flowcell temp......37°C □ Zero setting with ......Distilled Water □ Delay time ......5 sec □ No. of readings ......2 □ Interval ......120 sec $\Box$ Sample volume ......5 $\mu$ l □ Working solution volume (9R1+1R2) ......1.0 ml □ Linearity ......150 mg/L **Manual Assay Procedure** Perform the assay as given below: Calibrator Reagents Sample 5 µl 5 µl **Working Solution** 1.0 ml 1.0 ml Mix & aspirate the assay mixture. The first reading should be recorded at 5 seconds (A1) followed by second reading after 120 seconds (A2) interval at 540 nm. **CALCULATION:**

#### **EXPECTED VALUES**

Conc. of Calibrator

(A2 - A1) Calibrator

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

Factor =

Upto 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 then be multiplied with the dilution factor to obtain correct CRP concentration.
- Detection limit: Values less than 2 mg/L give non-reproducible results.
- 3. 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. Hemoglobin (> 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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IVD	<i>In Vitro</i> Diagnostic Use	<u>~</u>	Date of Manufacturing
(II)	Consult Instructions for use	Ω	Use by (YYYY-MM-DD)
REF	Catalogue Number	1	Temperature Limitation
LOT	Batch Code	w	Manufacturer

AR. NO. I 96 TLC1-2018-02-003





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