ORDER INFORMATION

CODE : ASH1033- R1- 1X40mL
R2-1X10 ML

CRP TURBILATEX

TURBIDIMETRY

INTENDED USE

Diagnostic reagent for quantitative measurement of CRP. Only for in vitro use in clinical laboratory (IVD).

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 by more than 300 mg/L in 12-24 hours.
Clinical diagnosis should not be made on a single test result. It should integrate clinical and other laboratory data.

PRINCIPLE

The CRP-Turbilatex is a quantitative turbidimetric test for measurement C-reactive protein (CRP) in human serum or plasma. Latex particles coated with specific human anti-CRP 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.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum.Stable for 7 days at 2 - 8°C or 3 months at -20°C. The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized orlipemic samples.

REAGENTS COMPOSITION

1. Buffer(R1)
2. Latex (R2)
3. Calibrator Ready to use

REAGENT PREPARATION AND STABILITY

Shake gently the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 4 mL Diluent
The reagent kit should be stored at 2 - 8°C and is stable till the expiry date indicated on the label.
Working Reagent: Stable for 1 month at 2 - 8º C. But it is recommended to prepare a fresh Working Reagent based on its workload.
Particles and turbidity indicates contamination or reagents deterioration.
All the reagents of the kit are stable upto the end of the indicated month of the expiry. Do not use reagents over the expiration date.
Do not freeze; Frozen reagents could change the functionally of the test

SYSTEM PARAMETERS

Pre warm at 37ºC the required amount of working solution before use.

Reaction Type	Two Point Kinetic
Wavelength Main / sub	540 nm (530 – 550)
Reaction Slope	Increase Slope
Blank –Zero Setting	Against Distilled Water
Reaction Temp.	37ºC
Cuvette Path	1 cm length path
Delay or LagTime	10 second
Interval Time or Measuring Time	120 second
Sample Volume	10µl
Reagent volume	R_1 800µl + R_2 200 µl
Calibrator Concentration	As mention on Calib.
Low Normal at 37ºC	0.0 mg/L
High Normal at 37ºC	6.0 mg/L
Linearity at 37ºC	150 mg/L

ASSAY PROCEDURE

Pre warm at 37ºC the required amount of working solution before use.
PIPETTE INTO TEST TUBES

	Calibrator	Test
Reagent (R_1)	800 µl	800µl
Reagent (R_2)	200µl	200µl
Calibrator	10µl	10 µl

Mix and read the absorbance immediately at 10 Seconds (A1) and at 120 Seconds
minutes (A2) of the sample addition.
Multipoint Calibration:

1. Calculation of sample concentration is against interpolation of the absorbance (A_2- A_1) in the calibration curve.
2. Calibration curves are stable for 10 days, after which a new curve must be generated.

The assay is calibrated to the Reference Material CRM 470/RPPHS.
The use of other commercially available CRP calibrators is not recommended.

CALCULATION

One point Calibration:
Serun CRP mg/L

$$= \frac{\text{Abs of Sample (A2- A1)}}{\text{Abs of Calibrator (A2 - A1)}} \text{ X Calibrator concentration}$$

REFERENCE NORMAL RANGE at 37ºC

Serum : 0.0 to 6.0 mg/L at 37ºC.
It is suggested that each laboratory establish its own reference range .The results of the performance characteristics depend on the used analyzer.

LINEARITY

Linearity limit: Up to 150 mg/L

1. Linearity limit: Up to 150 mg/L (Calibration curve) under the described assay conditions and Up to 90 mg/L (one point calibration)
2. Prozone effect: No prozone effect was detected upon 800 mg/L.
3. Detection limit: Values less than 2 mg/L give non-reproducible results.
4. Sensitivity: Ä 4.2 mA.mg/L
5. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 25 samples ranging from 1 to 90 mg/L CRP were assayed. The correlation coefficient (r) was 0.991 and the regression equation was y=1.08x-3.4

Prepare the following CRP calibrator dilutions in NaCI 9 g/L as diluent. Multiply the concentration of the CRP calibrator by the corresponding factor to obtain the CRP concentration of each dilution.The standard dilutions must be issued for measurement within 24 hours.

QUALITY CONTROL

Serum controls are recommended for internal quality control. Each laboratory shouldestablish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerance.

INTERFERENCE

Do not interference in Bilirubin (20 mg/dL),Lipemia (10 g/L),Rheumatoid factors (300 IU/mL), Hemoglobin (5 g/L),Other substances may interfere
Notes: Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit 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.

References

1. Lars-Olof Hanson et al. Current Opinion in infect Diseases 1997; 10: 196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6:139-144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987;1: 15-27.
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606-607.
5. Wemer Muller et al. Journal of immunological Methods 1985; 80: 77-90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121-2124.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press,1995.

ASHSKY
A future for healthcare

ASHSKY CHEM INDIA PVT LTD