AGD
TurbiPak
CRP
(Turbilatex)

Code : AGD-CRPT50
Pack Size : R1-1X40mL
R2-1X10mL
CRP Calibrator -1X1mL

Intended use :

Latex enhanced immuno-turbidimetric test for the quantitative measurement of C-reactive protein in human serum or plasma.

Clinical Significance :

C- Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cells sedimentation rate. CRP lacks diagnostic value when the patients illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases.

Principle :

The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-CRP, capable of aggregation in the presence of CRP. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the absorbance of the system

Sample :

Serum and plasma may be used. The isolated serum (plasma) should be tested on the same day. If samples cannot be measured on the same day,freeze it at below -20^{0}C. Bring samples to room temperature (15 - 30^{0}C) before use.

Interfering substances:

No interference was observed by Bilirubin (171 µmol/L), Hemoglobin (5g/L), Triglycerides (2.28 mmol/L), RF(210 IU/mL) other drugs and substances may interfere in the test

Reagents composition

R1- CRP Buffer	Phosphate buffer 100 mM, pH 6.5 sodium azide 0.9 g/l
R2 - CRP Latex	Suspension of Latex particles sensitized with anti-human CRP, sodium azide 0.9 g/l
CRP Calibrator	Printed on the label of vial

Before using this product, gently invert the CRP Latex Solution R2 bottle to mix it thoroughly, and check that there are no bubbles.

Storage and Shelf Life :

Storage temperature: 2-8ºC
Shelf life: (The expiration date is printed on the kit label.)

Procedure : For Semi Automated Analyzer

- **Procedure with 1- point calibration**

The samples and reagents should be brought to room temperature prior to use.

Reagent	Calibrator(C)	Test (T)
R1	400µL	400µL
R2	100µL	100µL
Calibrator	5µL	-
Sample	-	5µL

Mix and read immediately.

- **Procedure with multi point calibration**

The Turbi-chem CRP is based on Non-Linear Reactions, hence it is strongly recommended to run Multi standard mode to plot the Multi-point curve to have better accuracy and precision result.

Dilution Table	Tube 1 Normal Saline	Tube 2 2nd Dilution	Tube 3 3rd Dilution	Tube 4 4th Dilution	Tube 5 5th Dilution	Tube 6 Neat (No Dilution)
Normal Saline	100µL	100µL	100µL	100µL	100µL	0
Calibrator Volume	-	100µL	100µL	100µL	100µL	Neat Calibrator
Ratio ofdilution	-	1/16	1/8	1/4	1/2	-
Concentration	0	7.5	15	30	60	120

***Note : This tubes are example of Serial dilution considering 100ul is total Dilution Volume out of which 5ul of each dilution is used for generating the calibration curve.**

	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6	Sample
Concentration	0	7.5	15	30	60	120	-
Saline	5µL	-	-	-	-	-	-
2nd Dilution	-	5µL	-	-	-	-	-
3rd Dilution	-	-	5µL	-	-	-	-
4th Dilution	-	-	-	5µL	-	-	-
5Th Dilution	-	-	-	-	5µL	-	-
Neat Calibrator	-	-	-	-	-	5µL	-
Sample	-	-	-	-	-	-	5µL
Reagent 1	400µL	400µL	400µL	400µL	400µL	400µL	400µL
Reagent 2	100µL	100µL	100µL	100µL	100µL	100µL	100µL
Mix and aspirate immediately							

***Note: If the sample concentration is more than 120; kindly dilute the sample with Normal Saline and multiply with dilution factor.**

Programme the analyzer as per assay for Semi Automated Analyzer.

Parameters	
Reaction Type	Fixed Time/ Two point
Wavelength	546nm
Optical Path Length	1cm
Reaction Temperature	37°C
Blank/ Zero Setting	Water
Reagent Volume 1	400µL
Reagent Volume 2	100µL
Sample volume	5µL
Delay Time	10 sec
Read Time	120 sec
Calibrator Concentrations	As stated on the vial
Low Normal	0.00 mg/L
High Normal	6.00mg/L
Linearity	150mg/L
Units	mg/L
Calibration	1 point/Spline (6 point)

Calculations :

Calculate ΔA (A2-A1). Plot a spline calibration curve using 0 Concentration (saline) and 5 dilutions of CRP Calibrator. Measure concentration of controls, samples.

Calibration :

- 1- point calibration :

CRP Concentration (mg/L) =

Absorbance of sample x Concentration of Calibrator

Absorbance of Calibrator

- Multi point calibration

Calculate ΔA (A2-A1). Plot a spline calibration curve using 0 Concentration (saline) and 5 dilutions of CRP Calibrator. Measure concentration of controls, samples.
Calibration :

Quality Control :

To ensure adequate quality control, it is recommended that the laboratory should use a normal and abnormal commercial reference control serum. Please note that the quality control material is used to check the function of reagents and the machine together.

Parameters for AGD2260 Fully automated analyzers	
Short name	CRP
Name	C- Reactive Protein
Method	Two point
Main wave	546nm
Sub wave	0
Decimal	2
Unit	mg/L
R1 Volume	240µL
Incubation	120s
R2 volume	60µL
Sample volume	3.0µL
Incubation	0
Mixing speed	1
Reaction time (Delay Time)	10s
Check time(Read Time)	120s
Linear range	150mg/L
Absorbance range	0.0-2.5
Linearity limit	50%
Discrepancy	-
Detection slope	-
Dilution ratio	6
Sample volume(µl)	50
Calibration	Spline (6 point)

Linearity:

Reagent is linear up to 150mg/L.

Dilute the sample appropriately and re-assay if CRP Concentration exceeds 150mg/L.Multiply the result with dilution factor.

Normal Reference Range :

0 - 6 mg/L in healthy individuals with no signs of infection or inflammation.

The kit is for in vitro diagnostic use only. Not for use in humans or animals.

The instruction must be followed to obtain accurate results.

Do not use the reagents beyond the expiration date.

Treat all specimens as infectious. Proper handling and disposal procedure of specimens and the test, materials should be strictly followed

Reference :

1. Manack, J.R. and Richards, CB., J. Immunol. 20,1019(1971)
2. Ritchie, RF., J.Lab.Clin.Med.70,512(1967)
3. Pepys MB.et al., Ann. NY Acad. Sci,389, 459(1982)

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