AGD
TurbiPak
CRP ULTRA

Turbilatex(Highly sensitive Wide range)

Code : AGD-CRP50
Pack Size : R1-2X12.5mL
R2-2X12.5mL
100 Test

Intended use :

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

Clinical Significance :

C-reactive protein (CRP) is a protein that is produced as part of the inflammatory response or due to tissue necrosis.It is therefore useful in detection and evalu-ation of infection, inflammation, tissue injury etc.

Measurement of CRP levels are also useful in identif-ying individuals at risk of future cardiovascular diseases. CRP is normally present in low concentrations in blood of healthy individuals (<5 mg/L) Its levels rapidly incre-ase in infections, inflammations and postoperative conditions.The immunoturbidimetric test has 2 applications.

Normal application : In infection and inflammation the value may reach as high as 500mg/L.

High sensitive application : It is recommended for samples with concentrations lower than 20mg/L and where high precision and extremely good sensitivity is required.

Useful to determine future cardiovascular risk in asymp-tomatic individuals.

Principle :

In samples, an antigen-antibody reaction occurs between CRP and anti-human C-reactive protein mouse monoclonal antibody-coated latex, resulting in agglutination of the latex. The CRP content is determined by measuring the agglutina-tion as the change of absorbance.

CRP in samples + Anti-human C-reactive protein mouse monoclonal antibody-coated latex → Agglutination by antigen-antibody reaction

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, store in a refrigerator for up to 7 days and subsequently freeze at below -20°C. Bring samples to room temperature (15–30°C) before use.

Interfering substances:

Assay results are not affected by free bilirubin (up to 50mg/dL), conjugated bilirubin (up to 50mg/dL), conjugated bilirubin (up to hemoglobin (up to1000mg/dL), or ascorbic acid (100mg/dL).

Reagents composition :

R1: CRP Buffer	2-Amino-2-hydroxymethyl-1,3-propanediol buffer
R2: CRP Latex	Anti-human C-reactive protein mouse monoclonal antibody-coated latex

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: 2 years from the date of manufacture (The expiration-date is printed on the kit label.)

Procedure :

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

	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6	Sample
Saline	5µL	-	-	-	-	-	-
Calibrator 1	-	5µL	-	-	-	-	-
Calibrator 2	-	-	5µL	-	-	-	-
Calibrator 3	-	-	-	5µL	-	-	-
Calibrator 4	-	-	-	-	5µL	-	-
Calibrator 5	-	-	-	-	-	5µL	-
Sample	-	-	-	-	-	-	5µL
Reagent 1	250µL	250µL	250µL	250µL	250µL	250µL	250µL
Reagent 2	250µL	250µL	250µL	250µL	250µL	250µL	250µL
Mix and aspirate immediately							

Programme the analyzer as per assay parameters.

Parameters	
Reaction Type	Fixed Time/Two Time
Wavelength	578nm
Optical Path Length	1cm
Reaction Temperature	37ºC
Blank/ Zero Setting	Water
Reagent Volume 1	250µL
Reagent Volume 2	250µL
Sample volume	5µL
Delay Time	35 secs
Read Time	265 secs
Calibrator Concentrations	As stated on vials
Low Normal	0 mg/L
High Normal	6 mg/L
Linearity	420 mg/L
Units	mg/L
Calibration	Spline(6 point)

Calculations:

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

Performance Characteristic :

1. Reagent blank: The change of absorbance is ≤ 0.015. **Sensitivity :** The change of absorbance is 0.02-0.20 per 1 mg/L of CRP

2. Accuracy : 90–110% of the expected assay value

3. Within-run Reproducibility : Coefficient of variation ≤ 5% **Measurement Range :** 0.1-420 mg/L

4. Correlation

1) Serum N=50 r=0.999 y=1.02x - 0.07

Control method: Approved in vitro diagnostic (Latex turbidimetric assay)

2) Plasma N=50 r=0.999 y=0.99x + 0.03

Control method: Approved in vitro diagnostic (Latex turbidimetric assay)

5. Linearity : Reagent is linear up to 420 mg/L.Dilute the sample appropriately and re-assay if CRP concentration exceeds 420mg/L. Multiply result with dilution factor.

Parameters for AGD2260 Fully automated analyzers	
Short name	CRP
Name	C- Reactive Protein
Method	Two point
Main wave	578nm
Sub wave	0
Decimal	2
Unit	mg/L
R1 Volume	120µL
Incubation	120 secs
R2 volume	120µL
Sample volume	3.0µL
Incubation	0
Mixing speed	0
Reaction time	35 secs
Check time	265 secs
Linear range	0 - 420
Absorbance range	0.0-2.5
Linearity limit	50%
Discrepancy	-
Detection slope	-
Dilution ratio	6
Sample volume(µl)	50
Calibration	Spline (6 point)

Normal Reference Range :

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

For high sensitive application to assess the risk of cardiovas-cular diseases

Low < 1 mg/L

Average 1.0 to 3.0 mg/L High > 3.0 mg/L

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.

Caution :

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.

2. Precautions for use

This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have previously been frozen.

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2 To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a con-centration of greater than 0.1%.

Reference :

1) Medical Practice Editorial Board: Laboratory test guide 2013–2014, 202, Bunkodo, 2013.
2) Comprehensive blood and urine chemical tests and immu-nological tests (1): Jpn J Clin Med, 57, 197 (1999 extra-edition).
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 467, Kanehara Shuppan, 2015.

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