GENESIS

Instructions For Use

CRP Turbilatex (4+1) (Turbidimetric Method)

Cat no.	size
6102 101	50 Test
6102 102	100 Test
6102 103	200 Test

INTENDED USE
CRP Turbi Latex Reagent is intended for the in vitro Quantitative diagnostic determination of C-reactive protein (CRP) in human serum or plasma

PRINCIPLE OF THE METHOD
CRP Turbilatex is a quantitative turbidimetric test for the measurement of C-reactive protein (CRP) in human serum or plasma.Latex particles coated with specific anti- human 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.

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 up to 300 mg/L in 12-24 hours.

REAGENTS:-

Reagent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Reagent (R2)	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Sodium azide 0.95 g/L.
Calibrator	Calibrator. C-Reactive protein concentration is stated on the vial label.

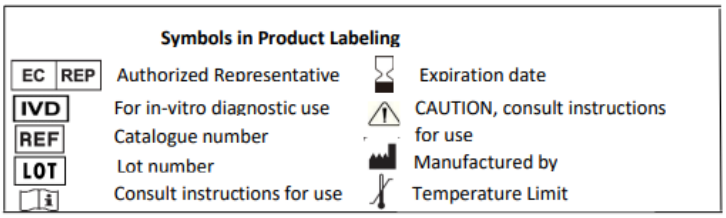
PRECAUTIONS AND WARNINGS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV 1/2. However handle cautiously as potentially infectious.

CALIBRATION
Use CRP Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material ERM-DA 472/IFCC. Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PREPARATION
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows:

4 part of Diluent + 1 part of Latex Reagent
Ex: 400 µL Diluent + 100 µL Latex Reagent

CRP Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.
Reconstituted Calibrator:
Stable for 1 month at 2-8°C or 3 months at –20°C.
STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.



Reagent deterioration: Presence of particles and turbidity.
Working reagent: Stable for 30 days at 2-8°C.
Do not freeze: frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT
-Thermostatic bath at 37°C.
-Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

SAMPLES
1.Fresh serum. Stable 7 days at 2-8°C or 3 months at –20°C.
2.The samples with presence of fibrin should be centrifuged before testing.
3.Do not use highly hemolized or lipemic samples.

PROCEDURE
1. Bring the working reagent and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   Mode: fixed time
   Wavelength: 540 nm (530-550)
   Temperature: 37°C
   Cuvette ligth path: 1 cm
   Delay time: 5 sec
   Measuring time: 120 sec
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

R1	**400 µL**
R2	**100 µL**
Calibrator or sample	**5 µL**

5. Mix and read the absorbance (A1) after 5 sec and after 2 minutes read the absorbance (A2).

CALCULATIONS

$$\frac{\textbf{(A2-A1) sample}}{\textbf{(A2-A1) calibrator}} \textbf{ x Calibrator concentration = mg/L CRP}$$

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used Controls ASO/CRP/RF Level (Low) and Level (High).
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES
Normal values up to 6 mg/L.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

***1.* Linearity limit:** Up to 150 mg/L, for higher values dilute sample **1/3** with physiological saline and repeat. The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

***2.* Detection limit:** Values less than 2 mg/L give non-reproducible results.

***3.* Prozone effect:** No prozone effect was detected upon 800 mg/L.

***4.* Sensitivity:** 4.2 mA.mg/L.

***5.* Precision:**

	Intra-assay (n=20)			Inter-assay (n=20)		
Mean (mg/L)	**8.5**	**17.0**	**60.0**	**8.5**	**17.0**	**60.0**
SD	**0.46**	**0.56**	**0.8**	**0.55**	**0.8**	**2.1**
CV	**5.4**	**3.3**	**1.33**	**6.4**	**4.7**	**3.5**

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 65 samples ranging from 1 to 150 mg/L of CRP were assayed. The correlation coefficient (r) was 0.98 and the regression equation y=0.892x + 0.282.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirrubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Hemoglobin (≥ 5 g/L), interferes. Other substances may interfere.

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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.

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IFU-CRP-08
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

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