

CRP

Clinical Significance:

CRP is one of the important acute phase proteins. CRP exist in low values in healthy people sera and rises in acute inflammation including: bacterial infections, tissue injuries. It's assay is useful in autoimmune diseases, infections, septicemia and newborn meningitidis. Since CRP is normally in low levels in blood it's level rise can indicate an inflammatory condition therefore, it's a reliable test for diagnosis and management of bacterial acute inflammations. This test is designed for quantitative measurement of human serum CRP.

Principle

In this method, serum CRP bonds with anti CRP agent presents in reagent and develops a turbidity. Levels of turbidity corresponds with CRP level existing in sample which is assayable photometrically.

Reagents Composition:

R1:

Buffer < 5gr/L Stabilizer < 1gr/L

Sodium Azide <0.99g/L pH 8.6+ 10% R2:
Anti-CRP Antibody
Sodium Azide <0.99 g/L

Reagents preparation:

R1 and R2 are ready for use

Storage:

Stable until expiration date in 2-8°C.

Notice: Onboard stability depends on storage and

contamination conditions.

Samples:

CRP stability in serum: 8 days in

2-8°C.

3 month at -20°C. Measurements:

Method: Turbidimetric Reading:

Two point end Curve: Increasing

Wavelength: 340 nm

Wavelength 2nd: 700-800 nm

Temperature: 37°C.

Sample	Cal/Stn	Blank			
R1	1000μΙ	1000μΙ	1000μΙ		
Cal/Stn		80µl			
Sample			80µl		
Mix R1 an sample, Incubate at 37°C 5 mins;					
read first OD, then add R2.					
R2	250μΙ	250μΙ	250μΙ		
After mixing reagents in 37°C 5 mins; read					
second OD.					

Notices:

Calculations:

$$CRP = \frac{STN.}{A2 - A1} \times C Standard = C Sample$$

$$STN.$$

Normal values:

Adults: < 6 mg/L

*Every lab should establish internal range. Calibration and Quality control

Use Novin Bio Kit Calibration and Control set. Calibration Stability

Totally depends on analyzer's characteristics. 30 days in desirable status.

Linearity Lower limits: 1 mg/L Upper limits: 200 mg/L

If values are upper than above range, it is recommended to dilute sample 9+1 with normal saline then repeat test. Multiply results to 10.

Interferences

No interferences observed under following conditions:

Haemoglobin < 12 g/Dl

Bilirubin < 15 mg/dL Triglycerides < 1000 mg/dL

Precision study: n:20

Precision Within Run (Repeatability)

Mean	6.77	14.58	77.65	219.9	
SD	0.33	0.55	3.63	10.64	
CV	5.005	3.81	4.67	4.84	

Precition Run to Run (Reproducibility)

Mean	6.55	16.14	84.8	194.17
SD	0.29	0.67	4.11	7.97
CV	4.54	4.19	4.84	4.10

Comparison Study:

in a comparison study done, NOVIN BIO KIT as "Y" with an established domestic brands "X" following results produced:

Y= 0.3100 + 0.9865 X

r:0.997

- 1. Use a pipettor while working with pipettes, avoid touch with skin.
- 2. Provide usual cares related to general labwares
- 3. Reacap reagent bottles after use and store in 2-8 °C.
- 4. Avoid working with random lots. Linearity depends on sample/reagent ratio.