

## Quantitative determination of C-Reactive Protein (CRP) IVD

Store 2 - 8°C.

### 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

<b>R1</b>	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
<b>R2</b>	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Sodium azide 0.95 g/L.
<b>Saline Solution</b>	NaCl 9% (for samples predilution)
<b>Optional</b>	Ref.: ACC16-026 Control serum ASO/CRP/RF Level L Ref.: ACC16-027 Control serum ASO/CRP/RF Level H

### PRECAUTIONS

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

The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM). It is not recommended the use of other commercially available CRP calibrators.

### PREPARATION

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

- 1 mL R2 + 9 mL R1 (1:10 dilution)

**Samples and Controls Pre-Dilution:** Before the use, samples and/or controls must be diluted in this way:

- 25 µL sample or control + 500 µL NaCl 9 g/L (1:21)

### ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers (ref. code ACC16-037)

### 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.

### SAMPLES

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

### TEST PARAMETER

Filter: set filter on position A

Reading time: 120 seconds

### PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	µL
Working reagent	500

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 50 µL of the diluted sample or control
4. Read the result which will appear automatically on the reader's display after 120 sec.

### QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics SERUM PROT CONTROL BILEVEL (Cod.: ACC16-038) is available.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

### REFERENCE VALUES

Up to 6 mg/L.

Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

1. **Linearity limit:** Up to 100 mg/L, under the described assay conditions. 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, 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:**  $\Delta$  4.2 mA.mg/L.
5. **Precision:**

	Mean	SD	CV%
Intra-assay (n=10)	10	0.599	6.5
Inter-assay (n=10)	9	0.717	7.8

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  $y=0.982x + 0.282$ .

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

### INTERFERENCES

Bilirubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Hemoglobin ( $\geq$  5 g/L), interferes. Other substances may interfere<sup>7</sup>.

### NOTES

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

### BIBLIOGRAPHY

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2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 - 144.
3. Yoshitsugu 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. Werner Müller 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.

### PACKAGING

Ref: ACC16-018	Cont.	: 1 x 45 mL R1
		: 1 x 5 mL R2
		: 1 x 50 mL Saline Solution