

# CRP-ultrasensitive (MICRO CRP / ULTRA CRP)

Latex turbidimetry

## IVD

Store 2 - 8°C.

### PRINCIPLE OF THE METHOD

The CRP-ultrasensitive is a quantitative turbidimetric test for the measurement of low levels 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. CRP may be also useful in detecting atherosclerotic process and providing important prognostic information about patients with asymptomatic heart disease, unstable angina, and myocardial infarction. Recent studies in apparently healthy people show that CRP concentration in serum rise long before traditional symptoms of heart and vascular diseases are noticed.

### 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: ACC16-035 CRP Ultra Control.  |

### 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:** Shake the latex vial gently before use. Prepare the necessary amount as follows:

- 1 mL Latex Reagent + 14 mL Diluent. (1:15)

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

- 50 µL sample or control + 450 µL NaCl 9 g/L (1:10)

### 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 contamination 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.

### ADDITIONAL EQUIPMENT

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

### 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 hemolized or lipemic samples.

### TEST PARAMETER

Filter: set the filter on POSITION A  
Reading time: 240 seconds

### PROCEDURE

1. Pipette into an appropriate number of cuvettes:

| kind of reagent | µL  |
|-----------------|-----|
| Working reagent | 500 |

2. Incubate the cuvettes in position 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 240 sec.

### QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics CRP ULTRA CONTROL is available (Ref.: ACC16-035). Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

### REFERENCE VALUES

Between 0.2 and 0.7 mg/L.

Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

1. Linearity limit: Up to 5 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/3 in NaCl 9 g/L and re-tested again. The linearity limit depends on the sample / reagent ratio. 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 0.05 mg/L give non-reproducible results.
3. Prozone effect: No prozone effect was detected upon 100 mg/L.
4. Sensitivity:  $\Delta$  44 mA.mg/L.
5. Precision:

|                    | Mean | SD   | CV% |
|--------------------|------|------|-----|
| Intra-assay (n=10) | 3.0  | 0.06 | 2.0 |
| Iner-assay (n=10)  | 3.0  | 0.11 | 3.7 |

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a quimioluminescent kit (Image,Beckman) reagent (x) with similar characteristics. 89 samples ranging from 1 to 10 mg/L of CRP were assayed. The correlation coefficient (r) was 0.92 and the regression equation  $y = 0.996x + 0.474$ .

### INTERFERENCES

Bilirubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (75 IU/mL), hemoglobin (20 g/L), do not interfere. Other substances may interfere<sup>8</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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8. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

### PACKAGING

Ref: ACC16-025

|       |
|-------|
| Cont. |
|-------|

: 1 x 30 mL R1  
: 1 x 2 mL R2  
: 1 x 50 mL Saline solution