QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN

ORDER INFORMATION

REF: CRP TURBILATEX

Cont.
R1: Diluent 1 x 45 ml
R2: Latex 1 x 5 ml
Calibrator 1 x 1 ml

CLINICAL SIGNIFICATION

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue, 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.

PRINCIPLE OF THE METHOD

The 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 cause an absorbance change, dependent upon the CRP content of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

REAGENT

| Diluent (R1)  | Tris buffer 20 mmol/L, Ph 8.2. sodium azide 0.95 g/L |
| Latex (R2)   | Latex particles coated with goat IgG anti-human CRP, Ph 7.3. sodium azide 0.95 g/L |
| Calibrator   | Human serum. C-Reactive Protein concentration is stated on the vial label. |

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 prevented during their use. Do not use reagent over the expiration date.

PREPARATION

Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows.
- 1 ml Latex Reagent +9 ml Diluent

CRP Calibrator: Reconstitute with 1.0 ml of distilled water, Mix gently and incubate 10 minutes at room temperature before use.

Reagent deterioration: Presence of particles and turbidity.

Working Reagent: Stable for 30 days at 2-8°C.

CRP Calibrator: Stable for 1 month at 2-8°C. or 3 months at-20°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 thermostable at 37°C. with a 540 nm filter (530-550nm).

PROCEDURE

1. Bring the working reagents and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   - Wavelength: 540 nm (530-550nm)
   - Temperature: 37°C
   - Cuvette light path: 1cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:
5. Mix and read the absorbance after 10 Seconds (A1) and after 2 minutes (A2) of the sample addition.

PRECUATION

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. It is not recommended to use other commercially available CRP Calibrators.

CALCULATIONS

\[(A2-A1)_{sample} \times \text{Calibrator concentration} = \text{mg/L CRP} \]

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCES VALUES

Up to 6 mg/L
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity limit: Up to 150 mg/L under the described assay conditions. The linearity limits 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 2mg/L give non-reproducible results.
3. Prozone effect: No prozone effect was detected upto 800 mg/L.
4. Sensitivity: 4.2 ma, mg/L.
5. **Precision:**

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay (n=10)</th>
<th>Inter-assay (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (IU/mL)</td>
<td>135 236 372</td>
<td>135 236 372</td>
</tr>
<tr>
<td>SD</td>
<td>3.4 16.2 5.9</td>
<td>7.9 13.2 17.8</td>
</tr>
<tr>
<td>CV</td>
<td>2.5 2.3 1.6</td>
<td>5.9 5.5 4.8</td>
</tr>
</tbody>
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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 correction coefficient (r) was 0.98 and the regression equation \( y = 0.982 \times + 0.282 \).

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

**INTERFERENCES**

Bilirubin (20 mg/dL) and lipaemia (10g/dL) and rheumatoid factors (300 IU/ml), do not interfere. Hemoglobin (≥ 5g/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.
5. Werner Muller et al., Journal of Immunological Methods 1985; 80; 99-90.