C REACTIVE PROTEIN (CRP)
Immuo-Turbidimetry

Intended Use
In vitro diagnostic reagents for the quantitative determination of C Reactive Protein (CRP) in human serum by turbidimetric immunoassay.

Background
C-reactive protein (CRP) is one of the acute phase proteins being synthesised by hepatocytes. The serum concentration of CRP increases during acute stages of diverse diseases associated with inflammation and tissue injury. Elevated CRP has been demonstrated in nearly all bacterial and viral infections. In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery. The diagnosis usefulness of CRP is based on the velocity and on the magnitude of its increase. Serum concentrations are raised within hours of disease onset and the increase can be as much 2000-fold. A rapid fall of CRP levels indicates recovery.

Test Principle
This CRP test is based upon the C reactive protein (CRP) antigen-antibody reaction.

Reagents
R1 Buffer Reagent
Phosphate buffered saline(pH 7.43).
Polyethylene glycol (40 g/L).
Sodium azide (0.95 g/L).

R2 Antiserum
Phosphate buffered saline(pH 7.43).
Polyclonal goat anti-human CRP (variable).
Sodium azide (0.95 g/L).

Materials required but not provided with the kit
1- Standard
CRP concentration is stated on the vial label.

2- Controls

Precautions and Warnings
For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Reagent Preparation, Storage and Stability
All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 °C).

CRP Standard:
The Standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 °C). Once opened the Standard is stable for 6 weeks if stored tightly closed at 2 - 8 °C after use.

For further storage at - 30 °C divide Standard into aliquots. Stability 3 months. once thawed never freeze again.

Specimen Collection and Preparation
Fresh or deep frozen serum. CRP remain stable for 2 days at (2 - 8 °C). If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolyzed or contaminated samples. Heavily lipaemic sera and turbid frozen serum samples must be cleared with a delipidating agent. The cleared patient serum sample must be used on the same day, as turbidity may reoccur.

Procedure
1 - Bring the reagents and the photometer to room temperature
2 - Assay conditions:
Wavelength: 340 nm
Temperature: room temperature
Cuvette: 1cm light path
3 - Adjust the instrument to zero with distilled water.
4 - Pipette into a cuvette:

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<tr>
<th>Standard</th>
<th>Sample</th>
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<tbody>
<tr>
<td>Reagent (R1)</td>
<td>400 µl</td>
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<tr>
<td>Standard</td>
<td>25 µl</td>
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<tr>
<td>Sample</td>
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Mix and record 1st reading (A1).

Reagent (R2) | 40 µl | 40 µl |

After addition of R2, incubate at room temperature and after 5 minutes record 2nd reading (A2)

Calculation
Generate a reference curve by successive 1 : 2 dilutions of calibrator in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each calibrator as following: Δ absorbance of sample = (A2 - A1) sample Δ absorbance of each calibrator = (A2 - A1) each standard Plot the calibration curve and obtain the result.

Sensitivity
1 mg/L

Linearity
Up to 220 mg/L.
Specimens showing higher concentration should be diluted 1:4 using physiological saline and repeat the assay (result×5).

Quality Controls
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.
Expected Values

0 - 10 mg/L.

Each laboratory should establish an expected range for the geographical area in which it is located.

References


ORDERING INFORMATION

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<thead>
<tr>
<th>CATALOG NO.</th>
<th>QUANTITY</th>
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<td>100 test</td>
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