Qualitative and semiquantitative determination of C-reactive protein by agglutination to latex

TEST SUMMARY
C-reactive protein, contained in the serum, produces agglutination of latex particles coated with anti-CRP antibody.

SAMPLES
Fresh serum. Stability 7 days at 2-8°C. For longer periods of time it is recommended to freeze samples at -20°C. Frozen samples must be totally unfrozen and brought to room temperature before using. Samples in which turbidity is observed must be cleared by centrifugation before being analysed.

REAGENTS
Latex
Latex particles coated with anti-CRP antibody; conservat and stabilizer.

Positive control
Human base stabilized solution having a CRP concentration 30-50 mg/L.

Negative control
Protein solution not reactive with latex. All reagents contain 0.095% of sodium azide.

REAGENTS PREPARATION AND STORAGE
Reagents are ready for the use. The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by centrifugation and to empty the dosage pipette many times. Stability: the components of this kit will remain stable until the expiration date stated on the label. Store at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED
Physiologic solution.
COD. AK00110 Slide and disposable stirrers.

PRECAUTION
Reagent may contain do not reactive and conservative components. It is important to avoid contacts with the skin and do not swallow. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

QUALITATIVE PROCEDURE

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Area</th>
<th>Area</th>
<th>Area</th>
<th>Area</th>
<th>Area</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiologic</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Sample</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
</tr>
<tr>
<td>Physiologic</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Latex from last area</td>
<td>Reject 50 µl from last area</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

EXPECTED VALUES
Generally CRP in healthy adults is below 5 mg/L, in a number of disease states these values often exceeded within 4 to 8 hours after an acute event and reach levels up to 500 mg/L. The average value of CRP on 143 healthy adults is resulted 0.64 mg/L with an interval from 0.08 mg/L to 3.11 mg/L. (Clinical chemistry 43:1; 52-58: 1997).

Every laboratory should establish own reference intervals in relation to own population.

CLINICAL SIGNIFICANCE
C-reactive protein is a protein present in normal serum, which increases significantly after most forms of tissue injury, bacterial and virus infections, inflammation, and malignant neoplasies. CRP contributes to non-specific defense by complement activation and accelerating phagocytosis. CRP testing has a high diagnostic value on a tentative diagnosis made on the basis of case history and clinical findings.

NOTE
- If reaction’s times are bigger than 2 minutes, they may cause a over-estimation of samples concentrations.
- Human sera used in controls have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION
Positive and Negative control sera should be always used to distinguish an eventual background’s agglutination of reactive.

TEST PERFORMANCE
Sensitivity
Test gives positive results as from concentrations of 6 mg/L (5-10 mg/L). Not happened phenomenon of prozone in CRP concentrations studied until 1634 mg/dl.

Specificity
A comparison with an available commercial method gave following results on 125 samples compared, giving a specificity = 96.2%:

<table>
<thead>
<tr>
<th>LTA srl</th>
<th>+</th>
<th>-</th>
<th>TOT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>44</td>
<td>2</td>
<td>46</td>
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</tr>
<tr>
<td>95.6%</td>
<td>4.35%</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>76</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td>3.8%</td>
<td>96.2%</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>TOT.</td>
<td>47</td>
<td>78</td>
<td>125</td>
</tr>
</tbody>
</table>

Interferences
Not happened interferences with:
- Haemoglobin ≤ 1000 mg/dl
- Bilirubin ≤ 20 mg/dl
- Lipids ≤ 1000 mg/dl
- Rheumatoid factor interfere to concentration ≥ 100 U/Iml.
- Lipemic or turbid samples may give false positivity.

WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK00110</td>
<td>Latex</td>
<td>1 x 5 ml</td>
</tr>
<tr>
<td>AK00111</td>
<td>Positive control</td>
<td>1 x 0.5 ml</td>
</tr>
<tr>
<td>AK00105</td>
<td>Negative control</td>
<td>1 x 0.5 ml</td>
</tr>
</tbody>
</table>

REFERENCES
Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 130-144.

MANUFACTURER
LTA srl
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

SBE
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SYMBOLS
- IVD: Only for IVD use
- LOT: Lot of manufacturing
- REF: Code number
- TEMP: Storage temperature interval
- EXPI: Expiration date
- WARN: Warning, read enclosed documents
- DIRE: Read the directions
- BIO: Biological risk

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