INTENDED USE

The TRUEchemie CRP Test kit is a quantitative turbidimetric test for the measurement of C-Reactive Protein (CRP) in human serum or plasma.

INTRODUCTION

C-Reactive Protein (CRP) is an acute phase protein produced by the liver in response to inflammation, infection and tissue injury. Increased CRP concentrations occur much earlier than other acute phase reactants and this rapid response to trauma or infection is the distinguishing feature of CRP. In addition, CRP levels return to normal quickly at the end of an acute episode making CRP useful for both the detection of acute episodes as well as in treatment monitoring.

PRINCIPLE

Latex particles coated with specific rabbit 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 calibrators of known CRP concentrations.

PACK SIZE

<table>
<thead>
<tr>
<th>Kit Size</th>
<th>25 mL</th>
<th>50 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat No.</td>
<td>ADX 911</td>
<td>ADX912</td>
</tr>
<tr>
<td>Kit contents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRP Reagent (R1)</td>
<td>1 x 20 mL</td>
<td>1 x 40 mL</td>
</tr>
<tr>
<td>CRP Buffer Reagent (R2)</td>
<td>1 x 5 mL</td>
<td>1 x 10 mL</td>
</tr>
<tr>
<td>CRP Calibrator</td>
<td>1 x 0.5 mL</td>
<td>1 x 0.5 mL</td>
</tr>
</tbody>
</table>

REAGENTS COMPOSITION

1. CRP Reagent (R1) : Tris buffer
2. CRP Buffer Reagent (R2) : Latex particles coated with specific rabbit anti-human CRP
3. CRP Calibrator : Human serum CRP concentration is stated on the vial label

STORAGE AND STABILITY

The components of the kit, stored at 2 - 8 °C, will remain stable until the expiry date stated on the label.

Working reagent: Stable for 30 days at 2-8 °C. Shake the vial gently before use.

Reagent deterioration: Reagent should be clear and colorless. Any turbidity may be a sign of deterioration and reagent should be discarded. Do not freeze the reagents, frozen Latex or Diluent could change the functionality of the test.

Calibrator: Stable till expiry when stored at 2-8 °C. Samples with presence of fibrin should be centrifuged before testing.

REAGENT PREPARATION

Ready-to-use reagents.

SAMPLE / SPECIMEN AND STORAGE

Fresh Serum (Do not use lipemic or hemolyzed sample). Stable for 7 days at 2-8 °C. Samples with presence of fibrin should be centrifuged before testing.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostics use only.
2. 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.
3. Avoid ingestion. DO NOT PIPEET BY MOUTH.
4. The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37 °C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 540 nm

TEST PROCEDURE

1. Bring the working reagent and the photometer (cuvette holder) to 37 °C.
2. Assay conditions:

<table>
<thead>
<tr>
<th></th>
<th>Blank (mL)</th>
<th>Calibrator (mL)</th>
<th>Sample (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distilled water</td>
<td>1.000</td>
<td>0.800</td>
<td>0.800</td>
</tr>
<tr>
<td>CRP Reagent (R1)</td>
<td>-</td>
<td>0.200</td>
<td>-</td>
</tr>
<tr>
<td>CRP Buffer Reagent (R2)</td>
<td>-</td>
<td>0.005</td>
<td>-</td>
</tr>
<tr>
<td>Calibrator</td>
<td>-</td>
<td>0.000</td>
<td>-</td>
</tr>
<tr>
<td>Sample</td>
<td>-</td>
<td>0.005</td>
<td>-</td>
</tr>
</tbody>
</table>

Blank the Photometer with Distilled water.
Mix well and read absorbance of calibrator and sample against distilled water at 540 nm as follows:
Initial absorbance A0 – Exactly after 10 sec.
Final absorbance A1 – Exactly after 120 sec. after A0
Determine ∆A for Calibrator (C) and Sample (S)

\[
\Delta AC = \Delta AC - \Delta AS
\]

Calculations:

\[
\text{Serum/plasma C-reactive protein (mg/L)} = \frac{\Delta AS}{\text{Calibrator concentration (mg/L)}} \times \frac{\text{Sample volume (mL)}}{\text{Reagent volume (mL)}}
\]

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.

NORMAL VALUES

Normal values up to 6 mg/L. Each laboratory should establish its own reference range.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

CALIBRATION

Use TRUEchemie CRP Calibrators, which are ready to use. Re-calibrate when control result are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

LIMITATIONS

1. Linearity limit: Up to 150 mg/L, under the described assay conditions. If the concentration is greater than linearity (150 mg/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Detection limit: Values less than 2 mg/L give non-reproducible results.
3. Prozone effect: No prozone effect was detected up to 1000 mg/L.

INTERFERENCES

Bilirubin (20 mg/dL), Lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Hemoglobin (¿5 g/L), interferes. Other substances may interfere.

SYSTEMS PARAMETERS

<table>
<thead>
<tr>
<th>Mode</th>
<th>Fixed kinetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave length</td>
<td>540 nm (530-540nm)</td>
</tr>
<tr>
<td>Units</td>
<td>mg/L</td>
</tr>
<tr>
<td>Flow cell Temp</td>
<td>37 °C</td>
</tr>
<tr>
<td>Blank</td>
<td>Distilled water</td>
</tr>
<tr>
<td>Reagent volume</td>
<td>1.000 mL</td>
</tr>
<tr>
<td>Sample volume</td>
<td>0.005 mL</td>
</tr>
<tr>
<td>Delay time</td>
<td>10 sec.</td>
</tr>
<tr>
<td>Read time</td>
<td>120 sec. (2min.)</td>
</tr>
<tr>
<td>Low Normal</td>
<td>0</td>
</tr>
<tr>
<td>High Normal</td>
<td>6</td>
</tr>
</tbody>
</table>

REFERENCES


Index of Symbols

- Use-by date
- Do not use if package is damaged
- Keep-dry
- European Conformity Authorized Representative
- Effective date: 03.06.2019 Rev. B

English version

EC REP
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