C-REACTIVE PROTEIN

Cat. No. | Pack name | Packaging (Content)
---|---|---
BLT20009 | CRP | 5 x 25 ml CRP Buffer 1 x 10 ml CRP Antiserum 1 x 1 ml CRP Calibrator
BLT20010 | CRP | 2 x 25 ml CRP Buffer 1 x 5 ml CRP Antiserum 1 x 1 ml CRP Calibrator

AUTOMATION
Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure
Sample/Control dilution: None
Reference curve: Generate a reference curve by successive 1:2 dilutions of Calibrator High in saline or use the ready for use calibrator set.
Use saline as zero point.
Test: Mix 60 µl of calibrators and samples with 1000 µl of buffer. Read optical density (OD1) of calibrators, controls and samples at 340 nm. Add 100 µl of CRP antiserum, mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of calibrators, controls and samples at 340 nm. Calculate ∆OD’s, plot a calibrator curve and read the concentration of controls and samples.

REFERENCE VALUES
0 – 10 mg/l (IFCC), resp. 0-1 mg/dl
This range is given for orientation only. Each laboratory should establish its own reference values.

PERFORMANCES
The performance characteristics for the CRP reagents were measured on a clinical chemistry analyzer (Cobas Mira).

Sensitivity: 0.0094 ABS units/concentration unit

Accuracy:

<table>
<thead>
<tr>
<th>Concentration [mg/dl]</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>19.2 (16.3-22.1)</td>
<td>20.9</td>
<td></td>
</tr>
<tr>
<td>Erba</td>
<td>25.9 (20.7-31.0)</td>
<td>27.8</td>
<td></td>
</tr>
</tbody>
</table>

LIMITATIONS:

- None

PRECAUTIONS AND WARNINGS

1. In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azides in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

3. Polyethylene glycol is not biohazardous
4. Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

REFERENCES


USED SYMBOLS

LOT | Lot Number
IN VITRO DIAGNOSTICS | See Instruction for Use
REF | Catalogue Number
| Manufacturer
CONT | Content
| Expiry Date
| Storage Temperature

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