CRP Turbidimetric Immunoassay

Reagent for quantitative determination of C-Reactive Protein (CRP) in human serum.

<table>
<thead>
<tr>
<th>REF CRP050E</th>
<th>R1 1 x 50 mL</th>
<th>R2 1 x 5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF CRP620E</td>
<td>R1 6 x 20 mL</td>
<td>R2 1 x 10 mL</td>
</tr>
</tbody>
</table>

**TECHNICAL SUPPORT AND ORDERS**
Tel: (33) 03 23 25 15 50
Fax: (33) 03 23 256 256

**CLINICAL SIGNIFICANCE**

C-Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cells sedimentation rate.

CRP lacks diagnostic value when the patient's illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases.

**PRINCIPLE**

Photometric measurement of turbidity, corresponding to antigen-antibody reaction, by the end-point method at 340 nm.

**REAGENTS**

**Vial R1 BUFFER**

- Phosphate buffered saline pH 7.43
- Polyethylene glycol 40 g/L
- Sodium azide 0.95 g/L

**Vial R2 ANTI-CRP**

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

**REAGENTS PREPARATION**

Liquid reagents, ready for use.

**SAFETY CAUTIONS**

Biolabo reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

**STABILITY AND STORAGE**

Store at 2-8°C, away from light (Do not freeze).

- Unopened reagents are stable until expiry date stated on the label.
- Once opened, when free from contamination, reagents R1 and R2 are stable at least for 3 months at 2-8°C, 24 h at room temperature and 30 days on the board of analyser.

**SPECIMEN COLLECTION AND HANDLING**

Use fresh serum.

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 48 hours.

If stored for a longer period, the sample should be frozen.

**INTERFERENCES**

No interference for: Haemoglobin (250 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Bilirubin (20 mg/dL), Triglyceride (2500 mg/dL)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

**MATERIAL REQUIRED BUT NOT PROVIDED**

1. Sodium chloride (9 g/L)
2. Calibrators and Controls.

**CALIBRATION**

Use Standards REF CRP CALSH1 or use the ready for use Standard Set REF CRP CALSET51 as indicated in the insert (§ MANUAL PROCEDURE) to generate a reference curve.

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

It is recommended to calibrate in the following cases:

1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of serum.
QUALITY CONTROL

- BIOLABO CRP Control Low: REF CRP CONTL1 or REF CRP CONTL5.
- BIOLABO CRP Control High: REF CRP CONTH1 or REF CRP CONTH5.
- Assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:
- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:
1. Repeat the test with the same control.
2. If control is still out of range, use a new vial of control serum and repeat the test.
3. If control is still out of range, use a new vial of calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (1)

IFCC Value: < 0.5 mg/dL

These values are applicable only to adults between 20 and 60 years of age

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES CHARACTERISTICS

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

**Precision:**

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-Run</td>
<td>4.06</td>
<td>2.57</td>
<td>3.44</td>
</tr>
<tr>
<td>Inter-Run</td>
<td>4.29</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

**Accuracy:**

<table>
<thead>
<tr>
<th></th>
<th>Assigned</th>
<th>Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOLABO</td>
<td>1.92 (1.63-2.21)</td>
<td>2.09</td>
</tr>
<tr>
<td>Biorad 2</td>
<td>2.59 (2.07-3.10)</td>
<td>2.78</td>
</tr>
</tbody>
</table>

Detection limit: approximately 0.5 mg/dL

Sensitivity: 0.0094 Abs/concentration unit

Specificity: Monospecific

Hook effect: > 84 mg/dL

Comparison study with Nephelometry: $y = 0.9981x - 0.0142$

$r = 0.9917$

LINEARITY

The assay is linear between 0.5 to 22 mg/dL.

Above 20 mg/dL, dilute the specimen with saline and re-assay taking into account the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagent and specimens at room temperature.

**Standard curve:**

Generate a Standard curve by successive 1:2 dilutions of Standard High: REF CRP CALSH1 in saline (5 different levels are recommended) or use the ready for use Standard Set: REF CRP CALSET51.

Use saline as sample to determinate zero point.

**Test:**

<table>
<thead>
<tr>
<th>Pipette into well identified test tubes:</th>
<th>Blank</th>
<th>Standards</th>
<th>Assays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer (Vial R1)</td>
<td>1 mL</td>
<td>1 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>Saline</td>
<td>60 µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standards</td>
<td>60 µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen</td>
<td>60 µL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mix well. Read absorbance (Abs A1) of standards, controls and assays at 340 nm against Blank.

**Anti-CRP (Vial R2)**

100 µL 100 µL 100 µL

Mix well. Incubate for exactly 5 minutes at room temperature.

Read absorbance (Abs A2) of standards, controls and assays at 340 nm against Blank.

Note:

Application procedures on clinical chemistry analyzers are available upon request.

**CALCULATION**

Calculate the result as follows:

Calculate $\Delta$Abs (Abs A2 – Abs A1) for standards, controls and assays.

Plot a Standard Curve “Concentration = f($\Delta$Abs)”.

Read the concentration of controls and samples on the graph.

REFERENCES