C-REACTIVE PROTEIN HIGH SENSITIVE

**Cat. No.**
- XSYS0084

**Pack Name**
- CRP-HS

**Packaging (Content)**
- R1: 2 x 40 ml (Buffer), R2: 2 x 8 ml (Latex)

**CLINICAL SIGNIFICANCE**
Diagnostic Reagent for quantitative in vitro determination of C-Reactive Protein in serum and plasma.

**REAGENT COMPOSITION**
- Sodium chloride 9 g/l
- Detergent 0.1%
- Sodium azide 0.09%
- R2 (Latex) Glycine buffer pH 8.42
- Rabbit anti-human C-RP sensitized latex 0.20%
- Sodium azide 0.09%

**REAGENT PREPARATION**
Liquid reagents, ready to use.

**STABILITY AND STORAGE**
The reagents are stable until expiry date when kept at 2–8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

**WARNING AND PRECAUTIONS**
1. For in vitro diagnostic use. To be handled by entitled and professionally educated person. Reagents of the kit are not classified as dangerous.
2. Each donor unit in the preparation of the standards 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.

**SAMPLE COLLECTION**
Use fresh serum. If the test can not 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.

**MATERIALS REQUIRED BUT NOT PROVIDED**
- Any instrument with temperature control of 37 ± 0.5°C that is capable of reading absorbance accurately at 340 nm may be used.
- Analyzer specific consumables such as sample cups.
- Controls.
- Saline (9 g/l NaCl)

**CALIBRATION**
Refer to the assay parameters for details.

**ASSAY PROCEDURE**
- Calibrator curve: generate a 6 point calibration curve by diluting the calibrator 1:32, 1:16, 1:8, 1:4, 1:2 and undiluted in saline.

**CALIBRATION VERIFICATION**
Not necessary.

**PERFORMANCE DATA**
Data obtained in your laboratory may differ from these values.

**Accuracy**
A comparison between XL-Systems CRP (y) and a commercially available test (x) using 40 samples gave following results:

\[
y = 1.069 x - 0.29 mg/l \quad r = 0.999
\]

**Measuring range:**
- 0.73 – 160 mg/l

**Detection Limit:**
- 0.24 mg/l

**Hook Effect:**
- No risk

**PRECISION**

<table>
<thead>
<tr>
<th>Sample</th>
<th>intra-assay precision</th>
<th>Mean (mg/l)</th>
<th>SD (mg/l)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>75.26</td>
<td>0.86</td>
<td>1.14</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>35.50</td>
<td>0.79</td>
<td>2.21</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>inter-assay precision</th>
<th>Mean (mg/l)</th>
<th>SD (mg/l)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>4.20</td>
<td>0.19</td>
<td>4.63</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>29.85</td>
<td>0.78</td>
<td>2.62</td>
<td></td>
</tr>
<tr>
<td>Sample 3</td>
<td>46.13</td>
<td>0.94</td>
<td>2.04</td>
<td></td>
</tr>
</tbody>
</table>

**SPECIFICITY**
- Monospecific

**INTERFERENCES**
- No interference for: Hemoglobin (10 g/l), rheumatic factor (560 IU/ml), Heparin (50 mg/dl), Bilirubin (40 mg/dl), Tri-glyceride (500 mg/dl)

**LIMITATIONS**
- None
- Stability at 4°C: At least 3 years after production

**WASTE MANAGEMENT**
Please refer to local legal requirements.

**QUALITY CONTROL**
For quality control use

**CALCULATION**
Results are calculated automatically by the instrument.

**EXPECTED VALUES**

<table>
<thead>
<tr>
<th>Reference Values</th>
<th>CVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1.0 mg/l = Low Risk for CVD</td>
<td></td>
</tr>
<tr>
<td>1.0 – 2.9 mg/l = Intermediate Risk for CVD</td>
<td></td>
</tr>
<tr>
<td>Greater than 3.0 mg/l = High Risk for CVD</td>
<td></td>
</tr>
</tbody>
</table>

**Method approved by the FDA.**

**QUALITY SYSTEM CERTIFIED**
ISO 9001 ISO 13485

**QUALITY MANAGEMENT**

**WASTE MANAGEMENT**

**Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ**
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com
<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Type</th>
<th>Sample Type</th>
<th>Sample Volumes</th>
<th>Normal Range</th>
<th>Prozone Check</th>
<th>Assay Type</th>
<th>Curve Type</th>
<th>Wavelength-Primary</th>
<th>Wavelength-Secondary</th>
<th>M1 Start</th>
<th>M1 End</th>
<th>M2 Start</th>
<th>M2 End</th>
<th>Reaction Abs Limit</th>
<th>Technical Maximum</th>
<th>Linearity Limit %</th>
<th>Prozone Limit %</th>
<th>React. Abs. Limit</th>
<th>Standard replicates</th>
<th>Sample replicates</th>
<th>Panin-Lower Limit</th>
<th>Normal-Lower Limit</th>
<th>Protein HS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPHS-2</td>
<td>C-Reactive</td>
<td>Serum</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Logit-Log</td>
<td>Increase</td>
<td>520</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
<td>2.5</td>
<td>16.6</td>
<td>16.6</td>
<td>16.6</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
</tr>
<tr>
<td>CRPHS-2</td>
<td>C-Reactive</td>
<td>Serum</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Logit-Log</td>
<td>Increase</td>
<td>520</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
<td>2.5</td>
<td>16.6</td>
<td>16.6</td>
<td>16.6</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
</tr>
<tr>
<td>CRPHS-2</td>
<td>C-Reactive</td>
<td>Serum</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Logit-Log</td>
<td>Increase</td>
<td>520</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
<td>2.5</td>
<td>16.6</td>
<td>16.6</td>
<td>16.6</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
</tr>
<tr>
<td>CRPHS-2</td>
<td>C-Reactive</td>
<td>Serum</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Logit-Log</td>
<td>Increase</td>
<td>520</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
<td>2.5</td>
<td>16.6</td>
<td>16.6</td>
<td>16.6</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
</tr>
<tr>
<td>CRPHS-2</td>
<td>C-Reactive</td>
<td>Serum</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Logit-Log</td>
<td>Increase</td>
<td>520</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0</td>
<td>520</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
<td>2.5</td>
<td>16.6</td>
<td>16.6</td>
<td>16.6</td>
<td>0.4</td>
<td>100</td>
<td>16.6</td>
</tr>
</tbody>
</table>

**Revision Details**

- **Revision**: CRPHS-2
- **Date**: 26.06.2015

**Technical Details**

- **Instrument**: XL-200, XL-300, XL-400, XL-640

**Test Details**

- **Test Code**: CRPHS-2
- **Test Type**: C-Reactive
- **Sample Type**: Serum
- **Sample Volumes**: 2
- **Normal Range**: 0-100
- **Prozone Check**: Logit-Log
- **Assay Type**: Increase
- **Curve Type**: Logit-Log
- **Wavelength-Primary**: 520 nm
- **Wavelength-Secondary**: 520 nm
- **M1 Start**: 0
- **M1 End**: 520
- **M2 Start**: 0
- **M2 End**: 520
- **Reaction Abs Limit**: 0.4
- **Technical Maximum**: 100
- **Linearity Limit %**: 16.6
- **Prozone Limit %**: 2.5
- **React. Abs. Limit**: 16.6
- **Standard replicates**: 16.6
- **Sample replicates**: 16.6
- **Panin-Lower Limit**: 0.4
- **Normal-Lower Limit**: 100
- **Protein HS**: C-Reactive
REFERENCES
1. Claus DR, Osmand AP, Gewurz H. Radioimmunoassay of human C-reactive protein and levels in normal sera. J Lab Clin Med 1976; 87: 120-128
7. Hanson LA, Wadsorth Ch. Das C-reactive Protein und sein diagnostischer Wert, insbesondere bei infektionen. Laboratoriumblätter 1979; 29: 58-68