### C-REACTIVE PROTEIN

#### INTENDED USE
Quantitative determination of C-Reactive Protein (CRP) in human serum by turbidimetric immunnoassay.

#### 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 disease, the concentration of CRP increases and decreases more quickly than the red cell 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.

#### METHODOLOGY
Measurement of antigen-antibody reaction by the end-point method.

#### REAGENT COMPOSITION
R1 (Buffer)  
Phosphate buffered saline (pH 7.43)  
Polyethylene glycol 40 g/l  
Sodium azide (0.09 %)

R2 (Antiserum)  
Phosphate buffered saline (pH 7.43)  
Polyclonal goat anti-human CRP variable  
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.

#### SAMPLE COLLECTION
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.

#### 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.
- Controls.
- Saline (9 g/l NaCl)

#### ASSAY PROCEDURE
Refer to the assay parameters for details.

### CALIBRATION
Blank: Saline

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Product name</th>
<th>Pack name</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>XSYS0053</td>
<td>CRP CALIBRATOR</td>
<td>CRP CAL SH</td>
<td>1 x 1 ml</td>
</tr>
</tbody>
</table>

Calibration 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.

#### QUALITY CONTROL
For quality control use

<table>
<thead>
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<th>Content</th>
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<tbody>
<tr>
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<td>CRP CONTROL</td>
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<tr>
<td>BLT20034</td>
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<td>MULTICONTROL LEVEL 1</td>
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<tr>
<td>BLT20035</td>
<td>MULTICONTROL LEVEL 2</td>
<td>MULTICONTROL LEVEL 2</td>
<td>1 x 1 ml</td>
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</table>

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

#### EXPECTED VALUES
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.

#### PERFORMANCE DATA
Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

#### ACCURACY
Comparison between XL-Systems CRP (y) and a commercially available test (x) using 34 samples gave following results:

- y = 0.955 x – 0.002 mg/dl
- r = 0.998

Measuring Range: 0 – 22 mg/dl (resp. 0 – 220 mg/l)

Detection Limit: 0.1 mg/dl (resp. 1 mg/l)

Hook Effect: > 84 mg/dl (resp. 840 mg/l)

#### PRECISION

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV (%)</th>
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</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>3.65</td>
<td>0.03</td>
<td>0.82</td>
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<tr>
<td>Sample 2</td>
<td>7.37</td>
<td>0.07</td>
<td>0.89</td>
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<tr>
<td>Sample 1</td>
<td>3.73</td>
<td>0.09</td>
<td>2.46</td>
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<tr>
<td>Sample 2</td>
<td>4.71</td>
<td>0.16</td>
<td>3.51</td>
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#### SPECIFICITY
Monospecific

#### INTERFERENCES
No interference for: Hemoglobin (1000 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (40 mg/dl), Triglyceride (125 mg/dl)

#### LIMITATIONS
None

#### STABILITY
Stability at 4°C: At least 3 years after production

#### 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 but contain less than 0.1% sodium azide.

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

3. Polyethylene glycol is non biohazardous.

4. Each donor unit used 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.

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

#### REFERENCES

### QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

[Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, CZ  
e-mail: diagnostics@erbalachema.com, www.erbamannheim.com  
N70/14/C/JNT Date of revision: 28. 4. 2015]
### ASSAY PARAMETERS (conventional units)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>XL-100</th>
<th>XL-200</th>
<th>XL-300/600</th>
<th>XL-640</th>
<th>XL-1000</th>
<th>XL-180</th>
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<tbody>
<tr>
<td>EM-100</td>
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### Test Details

**Test Code**: CRP

**Report Name**: C-Reactive Protein

**Unit**: mg/dl

**Decimal Places**: 1

**Wavelength-Primary**: 340

**Wavelength-Secondary**: 700

**Assay type**: 2-Point

**Curve type**: Cubic Spline

**M1 Stir**: 16 16

**M2 Stir**: 34 36

**Sample replicates**: 1

**Auto Rerun**: No

**Reagent Abs Min**: 1

**Sample Type**: SERUM

**Sample Volumes**: Normal

**Dilution Ratio**: 1

**Dilution Ratio**: Increase

**Dilution Ratio**: Decrease

**Dilution Ratio**: Standard volume

**Reagent Volumes and Stirrer speed**: RGT-1 Volume 180

**RGT-2 Volume**: 45

**RGT-3 Volume**: 0

**R2 Stirrer Speed**: High

**Reference Ranges**: Test

**Revision Number**: Revision

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### SYMBOLS USED ON LABELS

- **REF**: Catalogue Number
- **LOT**: Lot Number
- **EXPIRY DATE**: Expiry Date
- **CE Mark**: Device comply with the Directive 98/79/EC
- **IVD**: In Vitro Diagnostics
- **CONT**: Storage Temperature
- **CONT**: Content
- **SEE**: See Instruction for Use