C-REACTIVE PROTEIN HIGH SENSITIVE

**Cat. No.** | **Pack name** | **Packaging (Content)**
---|---|---
BLT20011 | CRP-HS | 2 x 25 ml CRP-HS Buffer
| | | 1 x 10 ml CRP-HS Latex
| | | 1 x 1 ml CRP-HS Calibrator

**INTENDED USE**
Diagnostic reagent for in vitro high sensitive determination of C-Reactive Protein (CRP) by turbidimetric immunossay.

**DIAGNOSTIC IMPLICATIONS**
C-Reactive Protein (CRP) is an acute marker of inflammatory processes. In case of an acute inflammation the concentration of CRP increases and decreases more quickly than the red cell sedimentation rate. The increase of CRP occurs in a non-specific way in different kinds of tissue aggression, as for example in infectious states, rheumatoid arthritis, myocard infarct, malignant tumour, etc. Although not diagnostic it is very useful for following-up and monitoring such illnesses, as well as for differential diagnosis in certain cases.

Routine available immunohemassay assay methods for CRP have limited sensitivity, and until recently, CRP concentrations below 10 mg/l could not be measured precisely, leading to the wide spread adoption of this value as the upper limit of the health-associated reference range. This is satisfactory for most purposes in general medicine. However, in neonatal pediatric practice, a high sensitive CRP immunossay shows that health-associated reference values are below 1 – 2 mg/l and that any rise above such values is associated with serious disease, usually bacterial infection.

More recently, application of sensitive CRP assays to studies of adult cardiovascular disease has revealed important prognostic relationships between modest increase of CRP and the occurrence, progression, and thrombo-occlusive complications of atherosclerosis. We therefore developed a high sensitive CRP assay with a detection limit around 0.13 mg/l and a high measuring range (0 – 140 mg/l HS CRP).

**METHOD**
Measurement of antigen-antibody reaction by the end-point method.

**REAGENTS PROVIDED**
- **Buffer**
- Sodium chloride (9 g/l).
- Detergent (0.1%).
- Sodium azide (0.09 %).
- **Latex**
- Glycine buffer (pH 8.42).
- Rabbit anti-human CRP sensitized latex (0.2%).
- Sodium azide (0.09 %).
- **Calibrator**
- Dilution of purified CRP with phosphate buffered saline.
- Contains 0.09 % sodium azide.
- Concentration: see bottle label

**PREPARATION AND STABILITY OF REAGENTS**
- **Reagent Preparation**
- Liquid reagents, ready for 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.

**REAGENTS REQUIRED BUT NOT SUPPLIED**
- **Saline** (8 g/l NaCl)
- **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.

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

**REFERENCE VALUES**
Less than 1.0 mg/l = Low Risk for CVD
1.0 – 2.9 mg/l = Intermediate Risk for CVD
Greater than 3.0 mg/l = High Risk for CVD

**Manual Procedure**
- **Sample/Control dilution: none**
- **Reference curve: Generate a reference curve by successive 1:2 dilutions of HS CRP Calibrator in saline 9 g/l. Use saline 9 g/l as zero point.**
- **Test:** Mix 8 µl of calibrators, controls and samples with 1000 µl of buffer. Read optical density (OD1) of calibrators , controls and samples at 600 nm. Add 240 µl of HS CRP latex, mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of calibrators, controls and samples at 600 nm. Calculate ∆OD, plot a calibration curve and read the concentration of controls and samples.

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

**Measuring Range:**
0 - 140 mg/l

**Precision:**
- **Intra-Run:**
  - 3.63 µg/ml
  - 3.15 µg/ml
  - 1.61 µg/ml
  - 1.66 µg/ml
- **Inter-Run:**
  - 4.23 µg/ml
  - 3.84 µg/ml
  - 2.41 µg/ml
  - 2.08 µg/ml

**Accuracy:**

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**SPECIFICITY**
- **Interferences:**
  - No interference for: Haemoglobin (500 mg/dl), bilirubin (30 mg/dl), intrafat (5%), rheumatoid factor (560 IU/ml), triglyceride (2500 mg/dl) and Heparin (50 mg/dl)

**REFERENCES**
1. Claus DR, Osmund AP, Gewurz H. Radiimmunooassay of human C-reactive protein and levels in normal sera. J Lab Clin Med 1976; 87: 120-128
7. Hanson LÅ, Wadsworth Ch. Das C-reacktive Protein und sein diagnosticher Wert, insbesondere bei infektionen. Laboratoriumblätter 1979; 29: 58-68

**USED SYMBOLS**
- **LOT:** Lot Number
- **IVD:** In vitro Diagnostics
- **See Instruction for Use**
- **REF:** Catalogue Number
- **CONT:** Content
- **Expiry Date**
- **Storage Temperature**