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

EN CE IVD

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

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 tissular 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.
Routinely available immunochemical 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 immunoassay 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 (0.20%).
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 (9 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 ΔOD's, 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
Detection Limit: 0.13 mg/l
Hook Effect: No risk

Precision:
[%CV]

	Ultra Low	Low	Medium	High
Intra-Run	3.63	3.15	1.61	1.66
Inter-Run	4.23	3.84	2.41	2.08

Accuracy:
[mg/dl]

Control	Assigned	Measured
Aptec	6.2 (5.3 – 7.1)	6.6
Behring	12.3 (10.5 – 14.1)	12.5

Specificity: Monospecific

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

Limitations: None

Comparison with nephelometry: y = 1.114x + 0.6988
r = 0.9962

PRECAUTIONS AND WARNINGS
1.*In vitro* diagnostic use only.
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.Polyethyleneglycol 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.

Also available Calibrators and Controls

Cat. No.	Product name	Pack name	Content
BLT20014	CRP CONTROL	CRP CON L	1 x 1 ml
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1	1 x 1 ml
BLT20035	MULTICONTROL LEVEL 2	MULTICON L2	1 x 1 ml

REFERENCES

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4. Grau AJ, Buggle F, Becher H, Werle E, Hacke W. The association of leukocyte count, fibrinogen and C-reactive protein with vascular risk factors and ischemic vascular diseases. Thromb Res 1996; 82:245-255
5. Dixon JS, Bird HA, Sitton NG et al. C-Reactive protein in the serial assessment of disease activity in rheumatoid arthritis. Scand J Rheum 1984; 13: 39-44
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8. Macy EM, Hayes TE, Tracy RP. Variability in the measurement of C-reactive protein in healthy subjects: implications reference intervals and epidemiological applications. Clin Chem 1997; 43: 52-58

USED SYMBOLS

LOT Lot Number
IVD In vitro Diagnostics
See Instruction for Use
REF Catalogue Number
Manufacturer
CONT Content
Expiry Date
Storage Temperature

N/76/18/B/INT *Date of revision: 22. 1. 2018*