CRP TURBILATEX SYSTEM PACK

(LATEX TURBIDIMETRY METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120, Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA216	CRP Turbilatex System Pack	1x20 + 1x5 ml
BA216C	CRP Turbilatex System Pack	2x20 + 2x5 ml

Quantitative determination of C-Reactive Protein (CRP)
IVD
Store 2-8°C

PRINCIPLE OF THE METHOD

CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C- reactive protein (CRP) in human serum or plasma.
Latex particles coated with specific anti- human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

CLINICAL SIGNIFICANCE

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

REAGENTS

Reagent 1 Diluent	Tris buffer 20 mmol/L Preservative.
Reagent 2 Latex Reagent	Latex particles coated with goat IgG anti-human CRP, Preservative.
Reagent 3 Calibrator	Calibrator. C-Reactive protein concentration is stated on the vial label.

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION

Use CRP Calibrator Provided with the kit.
Recalibrate when control results are out of specification tolerance, when using different lot of reagent and when the instrument is adjusted.

PREPARATION

CRP Calibrator : Ready to use

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2 - +8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.
On board stability: Min. 30 days if refrigerated (+8 - +14°) and not contaminated.

Reagent deterioration: Presence of particles and turbidity.

CRP Calibrator:
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

SAMPLES

Fresh serum. Stable7 days at +2 - +8°C or 3months at -20°C.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

QUALITY CONTROL

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Normal values up to 6 mg/L.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1 Linearity limit: Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again.
The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. Detection limit: Values less than 2 mg/L give non-reproducible results.
3. Prozone effect: No prozone effect was detected up to 400 mg/L.
4. Sensitivity: Δ 4.2 mA. mg/L
5. Precision:

	Intra-assay (n=10)			Inter-assay (n=10)		
mean (IU/mL)	8.6	16.8	50.5	8.6	16.8	50.5
SD	0.56	0.61	0.97	0.74	1.11	3.2
CV	6.5	3.6	1.9	7.7	6.6	6.3

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6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x)with similar characteristics. 65 samples ranging from 1 to 150 mg/L of CRP were assayed. The correlation coefficient (r)was 0.98 and the regression equation y = 0.892x +0.282.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL), do not interfere. Hemoglobin (≥ 5 g/L) interferes. Other substances may interfere.

WARNING AND PRECAUTIONS

MSDS will be provided on request.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem200, Beaconic chem 200,Beaconic B200,Beaconic analyzer 120,Bonavera chem 100
(Fully Auto Biochemistry Analyzer)

Test Name	CRP TURBILATEX
Full Name	CRP TURBILATEX
PRI Wave	546 nm
SEC Wave	-
Assay/Point	FIXED TIME
Start	18
End	25
Decimal	2
Unit	mg/l
Linearity Range Low	2
Linearity Range High	150
Sample Volume	2 µl
Reagent 1 (R1) Volume	240 µl
Reagent 1 (R2) Volume	60 µl
Substrate Depleted/Abs.limit	-
Linearity	150 mg/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTES

The program is made as per the in house testing, it can be modified as per requirements.
Clinical diagnosis should not be made on findings of a single test result, but both clinical and laboratory data.

BIBLIOGRAPHY

1. Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997; 10: 196-201.
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3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1:15-27.
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606 - 607.
5. Werner Muller et al. Journal of Immunological Methods 1985; 80: 77 - 90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121 - 2124.

Symbols Used On Labels

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

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