

# CRP TURBILATEX SYSTEM PACK

(LATEX TURBIDIMETRY METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)



## BEACON

Code	Product Name	Pack Size
UNI16	CRP Turbilatex System Pack	2 X 40 + 2 X 10 ml
UNI16A	CRP Turbilatex System Pack	4 X 40 + 4 X 10 ml

### Quantitative determination of C-Reactive Protein (CRP)

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

<b>Reagent 1 Diluent</b>	Tris buffer 20 mmol/L ,Preservative.
<b>Reagent 2 Latex Reagent</b>	Latex particles coated with goat IgG anti-human CRP, Preservative.
<b>Reagent 3 Calibrator</b>	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°C ) 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. Stable 7 days at +2-+8 °C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed 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.

#### PPRFORMANCE 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:**  $\Delta 4.2$  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

**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 ( $\geq 5$  g/L), interferes. Other substances may interfere<sup>7</sup>.

#### NOTES

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.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
3. Yoshitsugu 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 Müller et al. Journal of Immunological Methods 1985; 80: 77 – 90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121 – 2124.

TEST NAME	CRP TURBILATEX
FULL NAME	CRP TURBILATEX
PRI WAVE	546 nm
SEC WAVE	-
ASSAY/POINT	KINETIC
START	10
END	23
DECIMAL	2
UNIT	mg/l
LINEARITY RANGE LOW	2
LINEARITY RANGE HIGH	150
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	240 µl
REAGENT 1 (R2) VOLUME	60 µl
SUBSTRATE DEPLETED	-
LINEARITY	150mg/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.
SAMPLE VOLUME	2 µ l



**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