CHRONOLAB

CE
IVD

CRP-turbilatex

Latex turbidimetry

Quantitative determination of C-Reactive Protein (CRP)

PACKAGING

Ref.: 101-0468	Cont.: 1 x 45 / 1 x 5 mL + 1 x 1 mL Cal.
Ref.: 101-0564	Cont.: 3 x 100 / 3 x 10 mL + 1 x 1 mL Cal.

Store 2 - 8º C.

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.

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.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex (R2)	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Preservative.
CRP-CAL	Calibrator. C-Reactive protein concentration is stated on the vial label.

Optional (not included in the kit)

Control serum ASO/CRP/RF Level L	Ref.: 101-0466	4 x 1 mL
Control serum ASO/CRP/RF Level H	Ref.: 101-0467	4 x 1 mL

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.

The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material ERM-DA 474/IFCC.

The calibration in the SPINLAB 180 is stable for 1 month.

Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

PREPARATION

CRP Calibrator: Reconstitute (→) with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

CRP Calibrator: Stable for 1 month at 2-8º C or 3 months at –20º C.

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

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 540 nm filter.

SAMPLES

Fresh serum. Stable 7 days at 2-8º C or 3 months at –20º C.

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

Do not use highly hemolized or lipemic samples.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

1.Bring the reagents and the photometer (cuvette holder) to 37º C.

2. Assay conditions:

Wavelength: 540 nm (530-550)
Temperature: 37º C
Cuvette ligth path: 1 cm

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:

Diluent R1	900 µL
Latex R2	100 µL
Calibrator or sample (µL)	5.0 µL

5. Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition.

CALCULATIONS

$$\frac{(A_2\text{-}A_1)_{sample}}{(A_2\text{-}A_1)_{calibrator}} \times \text{Calibrator concentration} = \text{mg/L CRP}$$

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

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

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.

Detection limit: Values less than 2 mg/L give non-reproducible results.

Prozone effect: No prozone effect was detected upon 400 mg/L.

Sensitivity: Δ 4.2 mA.mg/L.

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Precision:

	Intra-assay (n=10)			Inter-assay (n=10)		
Mean (mg/L)	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

Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 50 samples of different concentrations of CRP were assayed. The correlation coefficient (r) was 0.99 and the regression equation $y = 1.101x + 2.518$.

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

INTERFERENCES

Bilirrubin (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[7].

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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