CPR Turbilatex Ref.: KCRP-T53 / KCRP-T434
Quantitative determinationof C-Reactive Protein
Only for in vitro use in clinical laboratory R1: 3x135 mL / 1x40 mL
Store at 2-8°C R2 1x100 mL / 1x10 mL
CAL: 1x1 mL / 1x1 mL

CRP TURBILATEX

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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

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. PreservativeL.
CRP-CAL	Calibrator. C-Reactive protein concentration is stated on the vial label.
Optional	Control serum ASO/CRP/RF Level L Control serum ASO/CRP/RF Level H

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

PREPARATION
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows:
1 mL Latex Reagent + 4 mL Diluent
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 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

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

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

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 hemolized or lipemic samples.

PROCEDURE
1. Bring the reagents and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
Wavelength: 540 nm (530-550)
Temperature: 37°C
Cuvette ligth path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Working Reagent	1.0 mL
Calibrator or sample	5.0 µL

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

We have instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

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

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures. It should be used Sorachim Controls ASO/CRP/RF Level L and Level H.
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 1 mg/L give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 800 mg/L.
4. **Sensitivity:** Δ 4.2 mA.mg/L.
5. **Precision:** The reagent has been tested for 20 days, using three different CRP concentrations in a EP5-based study.

EP5	CV (%)		
	9.2 mg/L	16.8 mg/L	57.97 mg/L
Total	7.3%	6.9%	5.9%
Within Run	2.8%	3.1%	2.9%
Between Run	6.1%	4.7%	3.9%
Between Day	3.0%	4.0%	3.4%

6. **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) and lipemia (10 g/L) 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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