

CRP - Turbidimetric

REF 3120025 1 x 50 mL CONTENTS R1.Reagent 1x 40 mL R2. Reagent 1 x 10 mL CAL. 1 x 1 mL	REF 3120030 2 x 50 mL CONTENTS R1.Reagent 2 x 40 mL R2. Reagent 2 x 10 mL CAL. 1 x 1 mL	REF 3120035 2 x 200 mL CONTENTS R1.Reagent 2 x 160 mL R2. Reagent 4 x 20 mL CAL. 1 x 1 mL
For <i>in vitro</i> diagnostic use only		

CRP - Turbidimetric Latex Turbidimetry

PRINCIPLE

The latex particles coated with anti-CRP are agglutinated when they react with samples that contain C-reactive protein (CRP). The latex particles agglutination is proportional to the concentration of the CRP in the sample and can be measured by turbidimetry.^{6,8}

REAGENTS COMPOSITION

- R1** **Diluent.** Tris buffer, 20 mmol/L, pH 8.2.
- R2** **Latex.** Latex particles coated with goat anti-human CRP, pH 7.3
- CAL** **Calibrator.** (Ref. 3931205). Human serum. CRP concentration is stated on the label vial and it is traceable to the Certified Reference material ERM-DA470 (IRMM).

Precautions: The reagents contain sodium azide 0.95 g/L. Avoid any contact with skin or mucous. The reagents from human donors have given negative results to anti-HIV 1/2, HBsAg and anti-HCV. It is recommended to handle with caution.

REAGENT PREPARATION

- R1** Ready to use.
- R2** Ready to use. Mix gently the vial by inversion before use (Note 4).
- CAL** Ready to use.

Working reagent. Swirl the latex vial before use. Mix Latex and Diluent in a 1:5 ratio (i.e. 2 mL R2 + 8 mL R1) prior to use.

STORAGE AND STABILITY

- The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use the reagents after the expiration date.
- Working reagent is stable during 20 days at 2-8 °C. Shake gently the vial before use.
- Reagent deterioration: Presence of particles and turbidity.

SAMPLES

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

MATERIAL REQUIRED

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 ± 20 nm filter.

PROCEDURE

Preliminary Procedure

Prewarm the working reagent and the photometer (cuvette holder) to 37 °C.

Analytic Procedure

- Using distilled water zero the instrument at 540 nm.
- Pipette into a cuvette:

Sample / Calibrator	5 µL
Working Reagent	1.0 mL

- Mix well and record the absorbances immediately (A_1) and after 2 minutes (A_2) after the sample addition.

Calculation

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

QUALITY CONTROLS

Control sera are recommended to monitor the performance of manual and automated assay procedures. It is recommended to use Plasma Protein Control N-I (ref: 3915010) and N-II (ref: 3915015).

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

REFERENCE VALUES^{3, 7,8}

Adults: Up to 5 mg/L.
Each laboratory should establish its own reference range.



CLINICAL SIGNIFICANCE¹⁻⁴

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.

4. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

ANALYTICAL PERFORMANCE

- **Linearity limit:** Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 en C/Na 9 g/L and retested again.
- **Detection limit:** Values less than 1 mg/L give non-reproducible results.
- **Analytical sensitivity:** 2.9 mA /mg CRP/L.
- **Prozone effect:** Up to 250 mg/L.
- **Precision:**

	Mean (mg/L)	CV (%)
Intra-assay N = 10	8.0	6.7
	19.7	3.7
	71.8	2.6
Inter-assay N = 10	8.0	5.3
	19.7	5.6
	71.8	4.3

- **Accuracy:** Results obtained with this reagents did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.
- **Interferences:** Bilirubin (40 mg/dL), hemoglobin (12 g/L), lipemia (10 g/L) and rheumatoid factors (800 IU/mL), do not interfere. Other substances may interfere⁹.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. 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.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Hansson LO, Lindquist L. *Current Opinion in Infectious Diseases*. 10:196 (1997).
2. Hokama Y, Nakamura RM. *Journal of Clinical Laboratory Analysis*. 1:15 (1987).
3. Kindmark C-O. *Sacnd. J. Clin. Lab. Invest*. 29 : 407(1972).
4. Le Carrer D, Giraud F, Siramy M, Bataille R. *Feuillets de Biologie*. 34 :39 (1995).
5. Vaishnavi C. *Immunology & Infectios Diseases*. 6 :139 (1996).
6. Winkles J, Lunec J, Deverill I. *Clin Chem*. 33:685 (1987).
7. Tietz Textbook of Clinical Chemistry, 3rd Ed. Burtis CA, Ashwood ER. WB Saunders Co., (1999).
8. Adam A, Ers P, Herman G, Stas JL. *J. Clin. Chem. Clin. Biochem*. 23 : 787 (1985).
9. Young DS. *Effects of drugs on clinical laboratory tests*. 3th ed. AACCC Press (1997).

T3120-5/1504
R1.ing

