



CRP Latex L

Quantitative turbidimetric latex assay for the measurement of C Reactive Protein (CRP) in human serum



ORDER INFORMATION

REF	Kit size
GD8427 00	1x40 + 1x10 ml
KL8427 00	1x40 + 1x10 ml
BK8427 00	2x(40+10 ml)

CLINICAL SIGNIFICANCE⁽¹⁻⁴⁾

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.

METHOD 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)

COMPOSITION

Reagent A-Diluent

Tris buffer 20 mmol/l, pH 8.2.

Reagent B-Latex

Latex particles coated with goat anti-human CRP, pH 7.3.

PREPARATION OF THE REAGENTS

Working reagent

Swirl the latex vial before use. Mix Latex and Diluent in a 1:5 ratio (i.e. 2 ml RB + 8 ml RA) 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: stable 20 days at 2-8 °C.

Shake gently the vial before use.

Reagent deterioration: presence of particles and turbidity.

ANCILLARY EQUIPMENT

- Automatic pipette to measure reagent and sample
- Thermostatic bath at 37 °C
- Spectrophotometer or photometer thermostatable at 37 °C capable to read 540 ± 20 nm
- Analysis cuvettes (optical path = 1 cm)
- NaCl (9 g/l) solution
- CRP Calibrator L (Ref. GD8429 00)
- Plasmaprotein Normal Control L (Ref. GD8461 00)
- Plasmaprotein Pathological Control L (Ref. GD8464 00)
- Plasmaprotein Normal and Pathological Control L (Ref. GD8466 00)

SAMPLES

Fresh serum.

Stable for 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.

PROCEDURE

1. Prewarm the reagent and the photometer (cuvette holder) to 37 °C.
2. Using distilled water zero the instrument at 540 nm.
3. Pipette into a cuvette:

Sample/Calibrator	5 µl
Working Reagent	1000 µl

4. Mix well and insert the cuvette into the photometer. Record the absorbance (A₁) immediately and after 2 minutes (A₂) of the sample or calibrator addition.

CALCULATION

$$\text{CRP, mg/l} = \frac{(A_2 - A_1) \text{ sample}}{(A_2 - A_1) \text{ calibrator}} \times \text{mg/l calibrator}$$

REFERENCE VALUES^(3,7,8)

Adults: up to 5 mg/l

It is recommended that each laboratory establishes its own reference range according to the examined population.

QUALITY CONTROL

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

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

ANALYTICAL PERFORMANCES

Linearity

The method is linear up to 150 mg/l, under the described assay conditions. Samples with higher concentrations should be diluted 1:5 with NaCl 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

Prozone effect is not observed 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 reagent 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 interfere⁽⁹⁾.

Note:

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet 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.

PRECAUTIONS IN USE

The reagents contain inactive components such as preservatives (Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/ECC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

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.

The use of the laboratory reagents according to good laboratory practice is recommended.⁽¹⁰⁾

Waste Management

Please refer to local legal requirement.

REFERENCES

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