

C-Reactive Protein (CRP)

Intended use

The measurement of CRP is intended as an aid in the detection and evaluation of infection, tissue injury, and inflammatory disorders and associated diseases.

Summary

C-Reactive Protein (CRP) is an acute-phase protein consisting of five identical polypeptide chains that form a five-membered ring with a molecular weight of 120,000 Daltons. CRP belongs to the pentraxin family of proteins and it is synthesized in the liver by hepatocytes. CRP has been shown to interact with the humoral and cellular effector system and to have an important role, for example, in the elimination of foreign pathogens and potentially toxic substances produced as a result of tissue damage [1,2].

In healthy people, plasma concentrations of CRP are normally below 5 mg/L and elevated levels are attributed to various tissue-damaging processes. Although the increase of CRP is non-specific, CRP measurements have proven to be useful in the detection and monitoring of, for example, inflammatory conditions, infections and malignant diseases. CRP levels rise within 6-8 hours after an acute stimulus and may double approximately every 8 hours. The peak level, which in severe cases can be 100-1000 times the normal value, is usually reached within 50 hours [3,4,5].

Additionally, monitoring of CRP concentrations using high-sensitivity methods (hsCRP) has been reported to be useful in the assessment of cardiovascular risk.



A test kit contains

- Ten CRP Test Cartridges for performing 80 tests
- One CRP CAL Cartridge for performing one calibration adjustment
- One “CRP Factory-defined Calibration Data” sheet with barcode

The kits are stored unopened at 2-8 °C.

The onboard stability of a test cartridge is 6 days.

Product calibrator traceability

The calibration of the CRP assay is traceable to the WHO International Standard – Human C-Reactive Protein 1st International Standard NIBSC 85/506.

Samples

Blood samples are collected by venipuncture. Whole-blood or plasma samples with either EDTA or lithium heparin as anticoagulant can be used.

Procedures

The procedures consist of the following steps:

1. Place the capped sample tube in the sample inlet.
2. Select the required test panel(s) and/or parameter(s) to be tested.
3. Start the analysis.

Performance characteristics

Analytical sensitivity and measuring range

The limit of detection has been determined to be 1.1 mg/L.

The reportable range of the assay is 5-500 mg/L.

Reference values

EDTA whole blood and plasma were obtained from 273 apparently healthy individuals (144 women and 129 men) and analyzed using the AQT90 FLEX CRP assay. The 95th percentile for both whole-blood and plasma samples was determined to be <5 mg/L.

Imprecision

For plasma, within-run and total imprecision were determined by analyzing plasma pools over 20 days, two runs a day, four replicates per run.

For whole blood, within-run and total imprecision were determined by analyzing spiked whole blood with three reagent lots, 5-6 analyzers and a total of 150-180 measurements.

Sample	CRP mean mg/L	Within-run	Total*
		% CV	% CV
Spiked plasma 1	12.2	9.0	9.9
Spiked plasma 2	171.2	5.7	6.0
Spiked whole blood 1	9.6	8.7	11.0
Spiked whole blood 2	129.9	9.0	9.6
Spiked whole blood 3	358.2	7.6	7.9

*Includes within-run, between-run and between-day contributions for plasma and within-run, between-run, between-batch and between-day (found in plasma precision study) contributions for whole blood.

Hook effect

No hook effect was found when CRP concentrations up to 2,000 mg/L were measured.

Carry-over

Carry-over from a sample with high CRP value (>2,000 mg/L) to an adjacent very low sample (<1 mg/L) was determined to be <100 ppm.

Interfering substances

Hemolytic, lipemic and icteric samples do not interfere with the assay. Neither do elevated levels of albumin, glucose, alkaline phosphatase or fibrinogen.

The following interfering substances were tested (using plasma samples with 85 mg/L CRP) at concentrations about five times the upper therapeutic range and found to have no notable effect on the AQT90 FLEX CRP assay (interference <20 %):

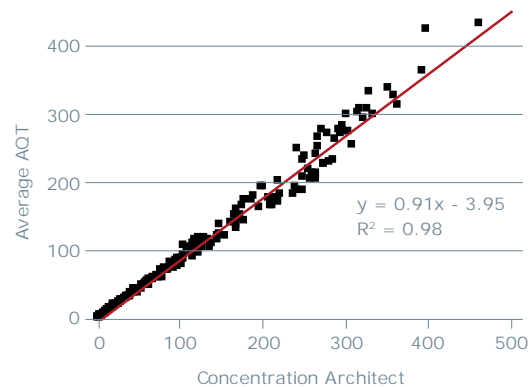
abciximab, acetaminophen, acetylcysteine, acetylsalicylic acid, allopurinol, ambroxol, ampicillin, ascorbic acid, atenolol, caffeine, captopril, cefoxitin, cinnarizine, cocaine, cyclosporine, diclofenac, digoxin, dopamine, erythromycin, ethanol, furosemide, low molecular weight heparin, sodium heparin, ibuprofen, levodopa, methyldopa, metronidazole, nicotine (\pm), nifedipine, nitrofurantoin, nitroglycerin, nystatin, oxytetracycline, phenylbutazone, phenytoin, propranolol, quinidine, rifampicin, tetracycline, theophylline, trimethoprim, verapamil, warfarin.

Method comparison

The AQT90 FLEX CRP assay (y) was compared to a commercially available CRP assay for the Abbott Architect immunoassay system (x) using lithium-heparin plasma samples in the range of 5-500 mg/L (with the AQT90 FLEX CRP assay).

The linear regression line and correlation coefficient were found to be:

$$y = 0.91x - 3.91; R^2 = 0.98 \text{ (n = 207)}$$



References

1. Kilpatrick JM, Volanakis JE. Molecular genetics, structure, and function of C-reactive protein. *Immunol Res* 1991; 10: 43-53.
2. Kolb-Bachofen V. A review on the biological properties of C-reactive protein. *Immunobiol* 1991; 183: 133-45.
3. Dati F, Schumann G, Thomas L et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP Reference Material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34(6): 517-20.
4. Pepys MB, Baltz ML. Acute phase proteins with special reference to C-reactive protein and related proteins (pentaxins) and serum amyloid A protein. *Adv Immunol* 1983; 34: 141-212.
5. Clyne B, Olshaker JS. The C-reactive protein. *J Emerg Med* 1999; 17(6): 1019-25.



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