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Technical Information

IMMAGE® Immunochemistry System

High Sensitivity C-Reactive Protein (CRPH)

Clinical Significance

Measurement of C-reactive protein aids in the evaluation of stress, trauma, infection, inflammation, surgery and associated diseases.

Summary and Explanation

Blood levels of C-Reactive Protein (CRP) are known to rise rapidly^{1,2} from normal baseline levels of <0.3mg/dL³ to as high as 50 mg/dL⁴ as part of the body's non-specific inflammatory response to infection or injury.^{5,6} In more recent years, the utility of measuring CRP has expanded from its historical use as a sensitive marker of acute inflammation to include assessment of cardiac events and risk.

A prognostic value for CRP has been suggested from studies with cardiac patients where elevated levels of CRP were associated with a higher risk of a future cardiac event^{7,8,9,10} and poor prognosis in cases of stable angina, unstable angina and myocardial infarction.^{9,10}

Cardiac disease is believed to be the end result of an interplay between minor changes in the cardiovascular endothelium and the corresponding inflammatory response to these changes.¹¹ The ability to measure CRP at extremely low concentrations has raised the possibility of using CRP to detect early inflammatory responses and potentially detect cardiac disease in the preclinical stages. Recent evidence supporting this potential application has shown that high baseline values of CRP in individuals without a history of cardiac disease were associated with an increased incidence of subsequent cardiac events.^{12,13} It is important to note that baseline CRP values are influenced by various non-pathological factors (age,¹⁴ gender,¹⁴ obesity,^{15,16} hormone replacement therapy,¹⁷ smoking¹⁸) and a single measurement may lead to an erroneous assessment of early cardiac inflammation.

Increases in CRP levels are non-specific and should not be interpreted without a complete clinical history. It is recommended that any estimations of inflammation be based on changes in CRP values from multiple measurements and be used in conjunction with other cardiac risk indicators (i.e. HDL, cholesterol).



Methodology

The IMMAGE CRPH reagent is based on the highly sensitive Near Infrared Particle Immunoassay rate methodology. An anti-CRP antibody-coated particle binds to CRP in the patient sample resulting in the formation of insoluble aggregates causing turbidity. The rate of aggregate formation is directly proportional to the concentration of CRP in the sample.

Type of Specimen

Serum samples are recommended. Plasma samples (EDTA, Lithium Heparin, and Sodium Heparin) can be used.

Serum or plasma samples should be collected in the manner routinely used for any clinical laboratory test.⁶ Freshly drawn serum or plasma from a fasting individual is preferred.

Anticoagulant Test Results

The following anticoagulants were assessed by Deming regression analysis with a minimum of 50 paired human serum and plasma samples. Values of serum (X) ranging from 0.034 mg/dL to 5.85 mg/dL were compared with the values for plasma (Y) yielding the following results.

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis (mg/dL)
Lithium Heparin	14 Units/mL	$Y = 1.05X - 0.02, r = 0.993$
Sodium Heparin	14 Units/mL	$Y = 1.026X - 0.018, r = 0.997$
EDTA	1.5 mg/mL	$Y = 1.042X - 0.018, r = 0.993$

Product Information

Beckman Coulter High Sensitivity C-Reactive Protein (CRPH) is intended for the quantitative determination of C-reactive protein in serum or plasma samples on the fully automated IMMAGE® Immunochemistry System. The IMMAGE Immunochemistry System utilizes proven rate nephelometry methodology to provide specific, reproducible, quantitative protein results. The IMMAGE system offers:

- Single-point calibration verification reduces labor and collateral costs
- 30-day calibration stability further reduces labor and collateral costs
- Liquid, ready-to-use reagents save time and reduce labor costs
- Up to 24-month open-bottle stability reduces waste

In addition to fast and accurate protein results, the IMMAGE system offers additional distinguishing features and benefits including:

- Patented dynamic blanking minimizes interference from non-specific reactions
- Antigen excess checking for greater confidence in results
- Low scheduled maintenance further reducing labor and costs

Product Specifications

Beckman Coulter High Sensitivity C-Reactive Protein (CRPH) is licensed per U.S. Patent number 6,040,147 (Ridker et al.).

PRINCIPLE

Rate Near Infrared Particle Immunoassay (NIPIA)

SENSITIVITY

0.006 mg/dL (0.06 mg/L)

MEASURING

0.02-144 mg/dL (0.2-1440 mg/L)

SAMPLE TYPE

Serum samples recommended. EDTA, Lithium Heparin and Sodium Heparin Plasma can be used

PRECISION

< 5.0% within-run
< 7.5% total

STABILITY

Until expiration date if stored at +2°C to +8°C with screw caps in place or 30 days with the evaporation caps in place.

CALIBRATION STABILITY

30 days

SAMPLE VOLUME

62 µL in a 0.5 mL Cup

Ordering Information

- 474630 CRPH Reagent Kit (300 tests)
- 447420 Buffer 4
- 447640 Diluent 1
- 465440 Vigil Serology Control – Level C (Low level control)
- 450162 Vigil Serology Control – Level 1
- 450163 Vigil Serology Control – Level 2

SAMPLE PREPARATION

None

INTERFERENCE

No interference was detected from the following:

- Bilirubin < 40 mg/dL
- Hemoglobin < 650 mg/dL
- Lipid* < 1000 mg/dL

*Lipemic specimens can be ultra centrifuged

REFERENCE INTERVAL

The reference interval value for IMMAGE CRPH was established using a population of 615 apparently healthy, non-smoking, >18 years of age, male and female adults from a Southern California blood bank.

<0.744 mg/dL (<7.44 mg/L)
(in 95% of the population tested)

METHOD COMPARISON

	NIA Method
N	162
Slope	0.982
Intercept	-0.0101
Mean (IMMAGE)	1.4094
Mean (NIA)	1.4461
Correlation Coefficient (r)	0.995

The equivalency values were determined using patient sample ranging from 0.02 to 5.8 mg/dL.