SIEMENS Healthineers

Dimension Vista®
System

*hs*CRP Flex® reagent cartridge

CardioPhase® *high sensitivity* CRP

Revision bar indicates update to previous version.

Intended Use

The CardioPhase® *high sensitivity* CRP (*hs*CRP) method is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and heparinized plasma on the Dimension Vista® System.

High sensitivity CRP measurements may be used for evaluation of conditions thought to be associated with inflammation, in otherwise healthy individuals and as an independent risk marker for the identification and stratification of individuals at risk for future cardiovascular disease*. Measurements of *hs*CRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

Summary and Explanation

CRP is one of the 'acute-phase' proteins, the serum or plasma levels of which rise during general, nonspecific response to infectious and non-infectious inflammatory processes. CRP is synthesized in the liver and is normally present as a trace constituent of serum or plasma.

In various disease states resulting in tissue injury, infection or acute inflammation, CRP values may rise above normal to 20 to 500 mg/L[3]. As elevated CRP values are always associated with pathological changes, the CRP method provides useful information for the diagnosis, therapy and monitoring of inflammatory processes and associated diseases[4,5,6]. Increases in CRP values are non-specific and should not be interpreted without a complete clinical history. Studies have shown that measurement of CRP by high sensitivity methods is a strong independent predictor of risk for future cardiovascular and peripheral vascular disease[1]. High sensitivity CRP measurements have also been shown to add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular disease[7,8,2]. Elevated CRP values determined by high sensitivity CRP methods may be indicative of the prognosis of individuals with acute coronary syndromes, and may be useful in the management of such individuals[1].

Principles of the Procedure

Polystyrene particles coated with monoclonal antibodies specific to human CRP are aggregated when mixed with samples containing CRP. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Wells[a,b]	Form	Ingredient	Concentration[c]	Source
1–8	Liquid	*hs*CRP Supplement Reagent:		
		Phosphate buffer;		
		Polidocanol	1.9 g/L	
9–12	Liquid	*High sensitivity* CRP Reagent:		
		Polystyrene particles;	1 g/L	
		Monoclonal antibodies	13 mg/L	Mouse

[a] Wells are numbered consecutively from the wide end of the cartridge.
[b] Contains Sodium azide (<1 g/L) as a preservative.
[c] Nominal value per well in a cartridge.

Store at
2 to 8 °C.

Expiration
Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 90 days.

Open well stability
21 days for wells 1 to 12.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION!
Federal (USA) law restricts this device to sale by or on the order of licensed healthcare professionals.

CAUTION! POTENTIAL BIOHAZARD
Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests that are CE marked or FDA approved for this purpose. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Reagent Preparation

All reagents are liquid and ready to use.

Specimen Collection and Handling

Collecting the Specimen

Recommended specimen types: serum or heparinized plasma.

Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture[9].

Follow the instructions provided with your specimen collection device for use and processing[10].

For serum, complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection[11].

Storing the Specimen

Samples should be as fresh as possible (stored for no more than seven days at 2 to 8 °C) or stored frozen. Samples can be stored at below –20 °C for up to eight months, if they are frozen within 24 hours after collection and if repeated freeze-thaw cycles are avoided. Lipemic or frozen samples, which become turbid after thawing, must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing. Specimens should be free of particulate matter.

Procedure

Materials Provided

REF	Contents	Number of Tests
K7046	Dimension Vista® *hs*CRP Flex® reagent cartridge	2 × 200

Materials Required but not Provided

Item	Description
REF KC780	Dimension Vista® PROT2 CAL (Protein 2 Calibrator)
REF KS804	System Diluent
REF OUMT05	N DILUENT, N Diluent
	Quality Control Material, such as:
REF KC755	Dimension Vista® *hs*CRP CON L (*High sensitivity* CRP Control L (low))
REF KC757	Dimension Vista® *hs*CRP CON H (*High sensitivity* CRP Control H (high)
Instruments, such as:	• Dimension Vista® 500 System • Dimension Vista® 1000T System • Dimension Vista® 1500 System • Dimension Vista® 3000T System

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

	Test Conditions
Initial Sample Dilution	1:1 (neat)
	Cuvette
Sample Volume (delivered to the cuvette)	1.37 µL
Diluent Volume	118 µL
High Sensitivity CRP Reagent	27.3 µL
Temperature	37 °C
Reaction time	5 minutes 50 seconds
Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT2 CAL, REF KC780
Calibration Scheme	7 levels, n = 3
Units	mg/dL [mg/L][d] (mg/dL x 10) = [mg/L]

Typical Calibration Levels	0.012, 0.025, 0.056, 0.111, 0.222, 0.50, 1.0 mg/dL [0.12, 0.25, 0.56, 1.11, 2.22, 5.0, 10.0 mg/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT2 CAL is diluted automatically with System Diluent by the instrument to the following dilutions: Level 1: 1:162 dilution Level 2: 1:81 dilution Level 3: 1:36 dilution Level 4: 1:18 dilution Level 5: 1:9 dilution Level 6: 1:4 dilution Level 7: 1:2 dilution
Calibration Frequency	Every 45 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

[d] Système International d'Unités [SI Units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. If not otherwise specified, analyze a minimum of two levels of a Quality Control (QC) material with known C-reactive protein concentrations, e. g., *hs*CRP CON L or H at least once each day of use.

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Analytical Measurement Range (AMR)

0.016 to 0.95 mg/dL [0.16 to 9.50 mg/L]

This is the measuring range for undiluted samples that are automatically processed by the instrument. If the readings obtained are outside the initial measuring range, the method can be repeated using a higher dilution of the sample.

Refer to your Dimension Vista® Operator's Guide for information on repeat measurements using other dilutions.

- Samples with results in excess of 0.95 mg/dL [9.50 mg/L] can be repeated on a higher dilution.
- Samples with results less than 0.016 mg/dL [0.16 mg/L] will be reported as "less than 0.016 mg/dL" by the instrument.

Results

The instrument calculates the concentration of C-reactive protein in mg/dL [mg/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Limitations

Turbidity and particles in the sample may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples, which cannot be clarified by centrifugation (10 minutes at approximately 15 000 × g), must not be used.

Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in CardioPhase® *hs*CRP results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This method has been designed to minimize interference from heterophilic antibodies[12]. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

If a result exceeds the upper limit of the extended measuring range, it can be repeated by manual dilution.

Manual Dilution: Dilute with **N DILUENT** to obtain results within the analytical measurement range. Enter dilution factor on the instrument. Reassay. Results are multiplied by the dilution factor.

AHA/CDC Expert Panel Recommendations[1]

The AHA/CDC Expert Panel has the following recommendations for limitations on the use of *hs*CRP assays:

- *hs*CRP levels should not be substituted for assessment of traditional cardiovascular risk factors.
- Application of management guidelines for acute coronary syndromes should not be dependent on *hs*CRP levels.
- When using the assay for risk assessment, patients with persistently unexplained, marked elevation of *hs*CRP (> 10 mg/L) after repeated testing should be evaluated for non-cardiovascular etiologies.
- The expert panel recommends against screening of the entire adult population for *hs*CRP as a public health measure.
- Patients with evidence of active infection, systemic inflammatory processes or trauma should not be tested for cardiovascular disease risk assessment until these conditions have abated.
- Application of secondary prevention measures should not depend on *hs*CRP determination, but rather an array of risk factors (global risk assessment).
- Serial measurements of *hs*CRP should not be used to monitor effects of treatment.
- Two separate *hs*CRP measurements (optimally two weeks apart) should be obtained before performing risk assessment, due to within-subject *hs*CRP variability.

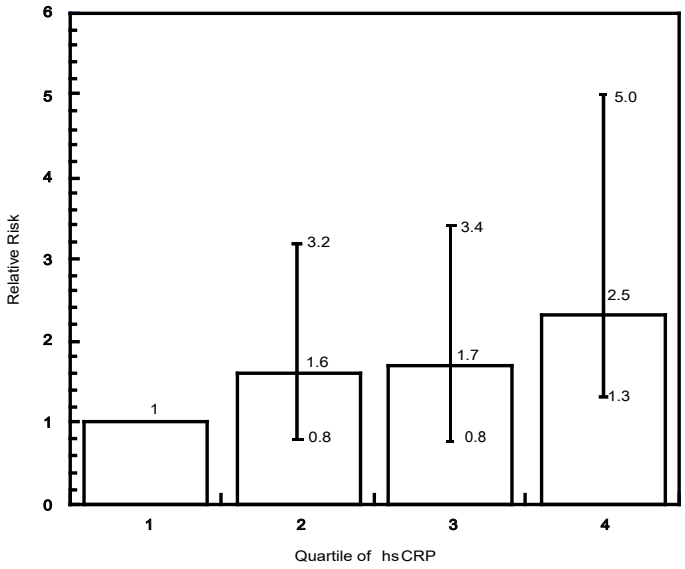
Interpretation of Results

Recent medical events resulting in tissue injury, infection or inflammation, which may cause elevated CRP levels should also be considered when interpreting results.

Cardiovascular and Peripheral Vascular Disease

Risk Assessment

Several studies have examined the utility of *hs*CRP measurements for cardiovascular disease risk prediction. In a subset consisting of 280 individuals participating in the Physician's Health Study, baseline samples were tested for a number of biomarkers, including *hs*CRP. The population was followed for nine years to assess the development of peripheral arterial disease (PAD). The following graph shows the relative risk (95 % confidence interval) of developing future PAD as a function of quartile of *hs*CRP[13].



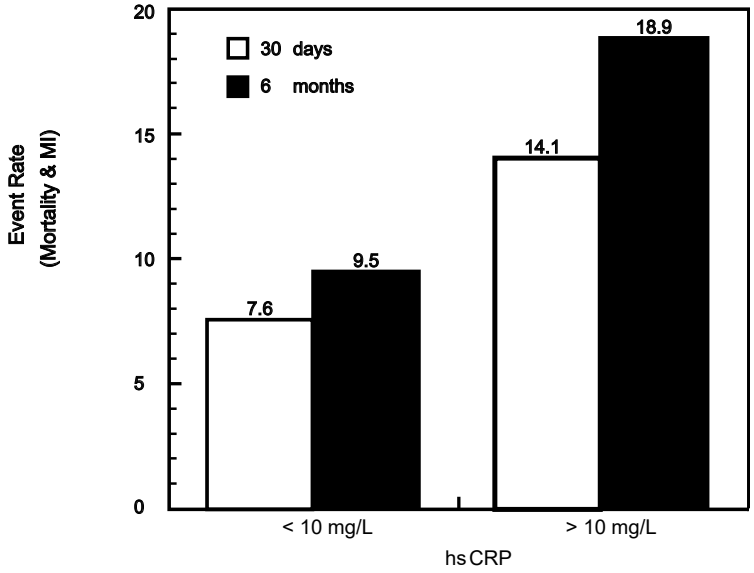
The AHA/CDC Scientific Statement[1] provides the following risk assessment guidelines:

Risk	hsCRP (mg/L)
Low	< 1.0
Average	1.0–3.0
High	>3.0

Risk Stratification

For patients with acute coronary syndromes, measurement of *hs*CRP may provide prognostic information. A value of CRP >10 mg/L in the early period (6 - 24 hours after onset of symptoms), has been shown to be indicative of an increased risk for short term (30 days - 1 year) recurrent cardiac events[1].

A sub-study of 447 patients in the CAPTURE trial examined the clinical implications of elevated levels of CRP for risk stratification in patients with unstable angina. As shown in the following graph, patients with a CRP >10 mg/L experienced a higher event rate (mortality or MI) than patients with a CRP < 10 mg/L[14].



Expected Values

< 0.50 mg/dL [< 5.0 mg/L]

This reference interval applies to serum samples from healthy adults[15].

The reference intervals are affected by many factors that may differ for each population studied. Each laboratory should establish its own expected values for CardioPhase® *hs*CRP as performed on the Dimension Vista® System.

Performance Characteristics

The following data represent typical performance for the Dimension Vista® System.

Specificity

HIL Interference

The CardioPhase® *hs*CRP method was evaluated for interference according to CLSI EP7-A2[18]. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10 % is considered interference.

Substance Tested	Substance concentration		CRP mg/dL [mg/L]	Bias[e] (%)
Hemoglobin (hemolysate)	1 000 mg/dL	[0.155 mmol/L]	0.093 [0.93]	+1
Bilirubin (unconjugated)	60 mg/dL	[1026 µmol/L]	0.097 [0.97]	–3
Bilirubin (conjugated)	60 mg/dL	[1026 µmol/L]	0.097 [0.97]	+1
Lipemia	Refer to "Specimen Collection and Handling", page 2 section			

[e] Analyte results should not be corrected based on this bias.

Maximum Observed Repeatability

The expected maximum observed standard deviations (SD) for repeatability (within-run precision) using n = 5 replicates at the following nominal CRP concentrations are:

CRP Concentration	Acceptable SD Maximum
0.10 mg/dL [1 mg/L]	0.023 mg/dL [0.23 mg/L]
0.30 mg/dL [3 mg/L]	0.057 mg/dL [0.57 mg/L]

A system malfunction may exist if the acceptable SD maximum is exceeded.

Precision[16,f]

	Mean		Repeatability			Within-Device/Lab Precision		
Material	(mg/dL)	(mg/L)	SD (mg/dL)	SD (mg/L)	CV (%)	SD (mg/dL)	SD (mg/L)	CV (%)
*hs*CRP CON L	0.115	1.15	0.006	0.06	4.8	0.006	0.06	5.4
*hs*CRP CON H	0.346	3.46	0.014	0.14	4.0	0.015	0.15	4.4
Serum pool	0.239	2.39	0.013	0.13	5.2	0.013	0.13	5.2
Serum pool	0.650	6.50	0.033	0.33	5.0	0.037	0.37	5.7
Serum pool	0.772	7.72	0.036	0.36	4.6	0.042	0.42	5.4

[f] CLSI EP5-A2 was used. During each day of testing, two separate runs, with two test samples, for each test material, were analyzed for 20 days.

Method Comparison[17]

Regression Statistics[g]

Comparative Method	Slope	Intercept mg/dL [g/L]	Correlation Coefficient	n
*hs*CRP Flex® reagent cartridge on the BN ProSpec® System	1.044	0.0003 [0.003]	0.995	133[h]

[g] CLSI EP9-A2 was used. The method used to fit the linear regression line was Passing Bablok.

[h] The range of CRP values in the correlation study was 0.0169 mg/dL to 0.8922 mg/dL [0.169 mg/L to 8.922 mg/L].

Non-Interfering Substances

The following substances do not interfere with the CardioPhase® *hs*CRP method when present in serum and plasma at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10 % at CRP concentrations of 0.023 mg/dL to 0.591 mg/dL [0.23 mg/L to 5.91 mg/L].

Substance	Test Concentration	SI Units
Acetaminophen	0.025 mg/dL	1.66 µmol/L
Amikacin	15 mg/dL	256 µmol/L
Ammonium heparin	3 U/mL	3 000 U/L
Ampicillin	5.3 mg/dL	152 µmol/L
Ascorbic acid	5 mg/dL	227 µmol/L
Caffeine	6 mg/dL	308 µmol/L
Carbamazepine	3 mg/dL	127 µmol/L
Chloramphenicol	5 mg/dL	155 µmol/L
Chlordiazepoxide	1 mg/dL	33.3 µmol/L
Chlorpromazine	0.2 mg/dL	6.27 µmol/L
Cholesterol	500 mg/dL	12.9 mmol/L
Cimetidine	2 mg/dL	79.2 µmol/L
Creatinine	30 mg/dL	2 652 µmol/L
Dextran 40	6 000 mg/dL	1 500 µmol/L
Diazepam	0.5 mg/dL	17.6 µmol/L
Digoxin	5 ng/mL	6.15 nmol/L
Erythromycin	6 mg/dL	81.6 µmol/L
Ethanol	400 mg/dL	86.8 mmol/L
Ethosuximide	25 mg/dL	1 770 µmol/L
Furosemide	6 mg/dL	181 µmol/L
Gentamicin	12 mg/dL	251 µmol/L
Ibuprofen	50 mg/dL	2 425 µmol/L
Immunoglobulin G (IgG)	5 g/dL	50 g/L
Lidocaine	1.2 mg/dL	51.2 µmol/L
Lithium chloride	2.3 mg/dL	3.2 mmol/L
Lithium heparin	3 U/mL	3 000 U/L
Nicotine	0.1 mg/dL	6.2 µmol/L
Penicillin G	25 U/mL	25 000 U/L
Pentobarbital	8 mg/dL	354 µmol/L
Phenobarbital	10 mg/dL	431 µmol/L
Phenytoin	5 mg/dL	198 µmol/L
Primidone	4 mg/dL	183 µmol/L
Propoxyphene	0.2 mg/dL	4.91 µmol/L
Protein, Albumin	6 g/dL	60 g/L
Rheumatoid Factors	500 IU/mL	500 IU/mL
Salicylic acid	60 mg/dL	4.34 mmol/L

Substance	Test Concentration	SI Units
Sodium heparin	3 U/mL	3 000 U/L
Theophylline	4 mg/dL	222 µmol/L
Urea	500 mg/dL	83.3 mmol/L
Uric acid	20 mg/dL	1 190 µmol/L
Valproic acid	50 mg/dL	3 467 µmol/L

Hook Effect

The CardioPhase® *hs*CRP method shows no hook effect up to 130.22 mg/dL [1 302.2 mg/L].

Recovery

Recovery of protein reference material ERM-DA470 (CRM 470) ranged from 96.6 - 104.1 % with a mean recovery of 99.2 %.

Limit of Quantitation

0.016 mg/dL [0.16 mg/L]

The limit of quantitation represents the lower limit of the reportable range for CRP.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Applicable Version of electronic Instructions for Use

As Siemens Healthineers continuously monitors the product performance and safety, the users are required to ensure that they work with the correct revision of the instructions for the product lots in use. Please periodically review the availability of new electronic labeling revisions to ensure safe use of the product.

The IFU version number is visible on each product box label. Siemens Healthineers ensures that all products lots bearing the same IFU version number are compatible with the electronic labeling provided via siemens-healthineers.com/eIFU.

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Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
	Non-sterile	CE	CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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