

HIGH SENSITIVITY CRP (hsCRP) TEST KIT LIQUID STABLE ASSAY

510k Cleared 

hsCRP IS CONSIDERED TO BE ONE OF THE MOST SENSITIVE INDICATORS OF INFLAMMATION

All acute inflammatory processes (infectious and non-infectious), and certain malignant conditions, result in a rise in serum CRP as a non-specific phenomenon. CRP production by the liver is considered a key part of the body's innate defense mechanisms. hsCRP is much more sensitive than conventional CRP methods and is used for evaluation of conditions thought to be associated with inflammation, in otherwise healthy individuals. High sensitivity CRP (hsCRP) measurements may be used as an independent risk marker for the identification of individuals at risk for future cardiovascular disease. Measurement of hsCRP, 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.

EXCELLENT ANALYTICAL SENSITIVITY AND PRECISION

Diazyme's hsCRP Kit provides an ideal blend of analytical performance features for accurate and reliable testing in the high sensitivity range. The assay offers outstanding sensitivity with a limit of Detection (LOD) of 0.13 mg/L. Precision is less than 4.2% CV's across the high sensitivity range from 0.2 mg/L to 20 mg/L. The assay is extremely precise (Less than 3% CV's) at the critical decision point of 1.75 mg/L.

A FULL RANGE OF INSTRUMENT PARAMETERS

A wide range of instrument parameters and applications are available for most major families of instruments from leading manufacturers such as Roche, Beckman, Abbott, and many others.

AN ASSAY AND CALIBRATORS WITH UNCOMPROMISING QUALITY

The calibrator for Diazyme's hsCRP assay is traceable to the International Federation of Clinical Chemistry (IFCC) International Reference Preparation for Plasma Proteins certified by the Bureau of Reference of the European Community. A four level calibrator set is available for use with the assay.

UNCOMPROMISING QUALITY HAS A PRICE

Since Diazyme manufactures our reagents in our own US manufacturing facility in California our products are extremely cost effective.





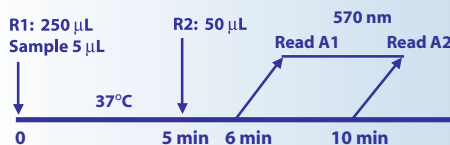
HIGH SENSITIVITY CRP (hsCRP) TEST KIT

LIQUID STABLE ASSAY

High Sensitivity C Reactive Protein (hsCRP)

Method	Latex enhanced immunoturbidimetric assay
Traceability	Traceable to IFCC International Reference Preparation for Plasma Proteins certified by the Bureau of Reference of the European Community
Method Correlation to Predicate	N = 62 r ² = 0.999 y = 0.095x + 0.0146
Reportable Range	0.2 mg/L to 20 mg/L
On Board Stability*	Two Weeks
Calibration Interval	Two Weeks
Calibration	Four Level Set
Sample Type	Serum Lithium Heparin and EDTA Plasma
Sample Volume	5 µL
Assay Range	0 to 200 U/L

Assay Method



DYNAMIC TEST RANGE

- ♦ Ideal for accurate and reliable testing in the high sensitivity range

CONVENIENT AND FLEXIBLE

- ♦ Choice of serum or plasma testing
- ♦ Stable Liquid with a variety of instrument parameters

VIRTUALLY INTERFERENCE FREE TESTING

SERUM SAMPLES SHOW LESS THAN 10% VARIANCE

- ♦ Rheumatoid Factor to 400 IU/mL
- ♦ Triglyceride to 1000 mg/dL,
- ♦ Ascorbic Acid to 176 mg/L,
- ♦ Bilirubin and Bilirubin Conjugate to 40 mg/dL

HIGHLY PRECISE RESULTS

Within-Run Precision

	Level 1:	Level 2:	Level 3:	Serum	Serum
N	80	80	80	80	20*
Mean	0.85	1.75	8.62	3.62	15.56
SD	0.03	0.03	0.06	0.05	0.19
CV%	4.0%	1.7%	0.7%	1.4%	1.2%

Total Precision

	Level 1:	Level 2:	Level 3:	Serum	Serum
N	80	80	80	80	20*
Mean	0.85	1.75	8.62	3.62	15.56
SD	0.04	0.05	0.12	0.09	0.24
CV%	4.2%	2.6%	1.4%	2.4%	1.6%

*Sample was tested on Hitachi 917 over 5 days with 2 runs per day

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