

NEW!

510(k) Cleared CE

HIGH-SENSITIVITY CRP (hsCRP) ASSAY

Dual Vial Stable Liquid



Dynamic Test Range

- Accurate results from 0.2 mg/L to 20 mg/L
- Outstanding sensitivity, Limit of Detection(LOD) of 0.13 mg/L
- Ideal for accurate and reliable testing in the high sensitivity range

Accurate

- R² of 0.990
- The calibrator of Diazyme hsCRP assay is traceable to the International Federation of Clinical Chemistry International Reference Preparation for Plasma Proteins certified by the Bureau of Reference of the European Community
- Virtually interference free serum samples show less than 10% variance from 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

Precise

- Less than 4.0% CV's across the reportable range
- Less than 2% CV's at critical decision point (1.75 mg/L)

Convenient and Flexible

- Choice of serum or plasma testing
- Stable Liquid with a variety of instrument parameters
- Extended on-board and calibration stability

**INNOVATIONS IN
CLINICAL DIAGNOSTICS**



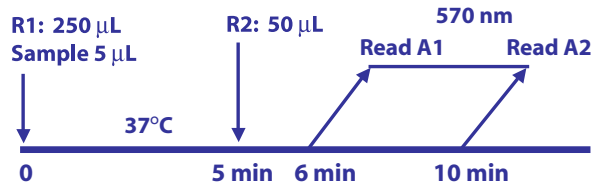
DIAZYME hsCRP ASSAY (DUAL VIAL STABLE LIQUID)

SUMMARY OF PERFORMANCE

Background

CRP (C-reactive protein) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infectious, histolytic disease and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now come to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious disease. 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.

Assay Method

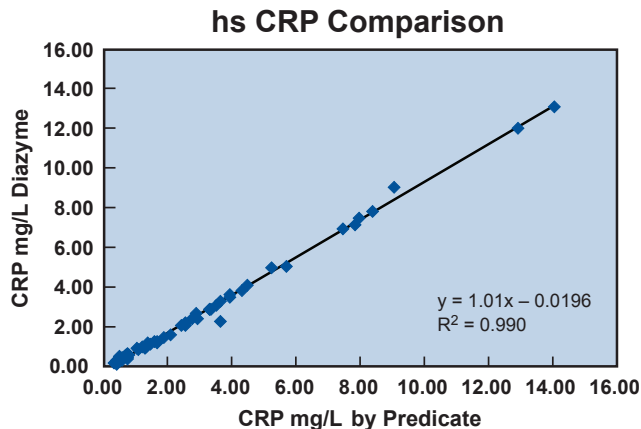


Diazyme's CRP assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.

Performance

Accuracy

Correlation studies were performed by testing 57 serum samples with CRP concentrations ranging from 0.2 to 18.9 mg/L in comparison with an existing commercial CRP assay method. The linear regression gives a correlation of r^2 value of 0.990, slope of 1.01, and y intercept of 0.0196.



Precision

The intra-precision of the Diazyme CRP Assay was evaluated as follows: in the study, three samples containing CRP were tested in duplicates on a Hitachi 917 over 20 days with 2 runs per day.

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

Linearity

CRP linearity set was prepared by diluting a specimens containing 40.0 mg/L CRP with saline according to CLSI EP6-A. Assay linearity was tested on the Hitachi 917. Data analysis using EP Evaluator 8 showed that the Diazyme hsCRP assay was linear through a measured range of 0.20 to 20.0 mg/L with an allowable systematic error of 4.5%.

Traceability

The calibrator of Diazyme hsCRP assay is traceable to the International Federation of Clinical Chemistry International Reference Preparation for Plasma Proteins lot ERM-DA 472/IFCC certified by the Bureau of Reference of the European Community.

Interference

Interference for the Diazyme hsCRP was evaluated on Hitachi 917. The following substances normally present in serum produced less than 10% deviation at the listed concentrations: Triglyceride at 1000 mg/dL, Ascorbic Acid at 176mg/dL, Bilirubin at 40 mg/dL, Bilirubin Conjugate at 40 mg/dL, Hemoglobin at 500 mg/dL, Rheumatoid factor 400 IU/mL.

DIAZYME LABORATORIES

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