HIGH SENSITIVITY C-REACTIVE PROTEIN (hsCRP)

Dual Vial Liquid Stable

Diazyme's High Sensitivity C-Reactive Protein (hsCRP) assay is a cost effective system utilizing both human serum and plasma on automated clinical chemistry analyzers. Diazyme's hsCRP assay is based on a latex enhanced immunoturbidimetric methodology which provides excellent analytical performance features for accurate and reliable testing in the high sensitivity range. The assay is traceable to the International Federation of Clinical Chemistry (IFCC) International Reference Preparation for Plasma Proteins and is compatible with most major families of instruments.

DIAZYME hsCRP ASSAY ADVANTAGES

- Fast test results (10 minutes) for a rapid turnaround time
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable reagent kit, calibrator and control sets offered separately
- Liquid stable format requires no reagent preparation saving time and reducing sample handling

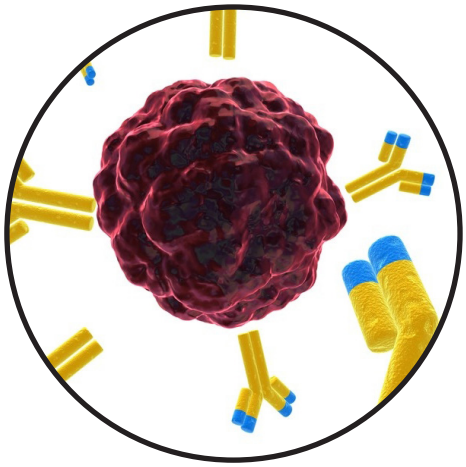
REGULATORY STATUS

510(k) Cleared

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi



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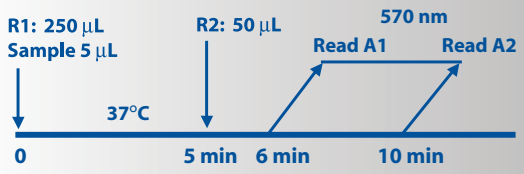
DIAZYME LABORATORIES

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - EDTA - Li-heparin Sample Volume 5 µL
Method Comparison	N = 57 y-intercept = 0.0196 Slope = 1.01 R2 = 0.990 Samples Ranged From: 0.2 mg/L – 18.9 mg/L
Linear Range	0.20 – 20.0 mg/L
LOB LOD LOQ	0.08 mg/L 0.13 mg/L 0.20 mg/L
Calibration Levels	4-Point Calibration
Traceability	Traceable to IFCC International Reference Preparation for Plasma Proteins certified by the Bureau of Reference of the European Community
Reagent On-Board Stability	Opened: Two weeks on board analyzer

hsCRP Assay Procedure*



****Analyzer Dependent***

Parameter questions for hsCRP assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

The intra-precision of the Diazyme hsCRP Assay was evaluated as follows: in the study, three serum controls 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%

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% basis):

Hemoglobin:	up to 500 mg/dL
Bilirubin:	up to 40 mg/dL
Bilirubin conjugated:	up to 40 mg/dL
Triglycerides:	up to 1000 mg/dL
Ascorbic acid:	up to 176 mg/dL
Rheumatoid factor:	up to 400 IU/mL

REFERENCE RANGE

The assay reference interval was determined using serum specimens from 103 apparently healthy adults with age of 18-62 according to CLSI C28-A3 guideline. The serum specimens were tested in duplicate by the Diazyme hsCRP method. EP Evaluator 8 Software was used to verify the reference interval. The results showed that < 5.0 mg/L CRP was obtained in 95% of the population tested. However, it is recommended that each laboratory establishes a range of normal values for the population it serves.

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