DIAZYME

CARDIOVASCULAR MARKER

CARDIAC TROPONIN I ASSAY

Dual Vial Liquid Stable

Cardiac Troponin I is specific for cardiac tissue and is detected in the serum only if myocardial injury has occurred. Diazyme's Cardiac Troponin I Assay is a cost effective dual vial liquid stable reagent system intended for the in vitro quantitative determination of Cardiac Troponin I in serum and plasma. Diazyme's Cardiac Troponin I has been designed to work on most all modern high throughput clinical chemistry analyzers and the assays liquid stable format requires no reagent preparation saving time and reducing sample handling. The latex enhanced immunoturbidimetric methodology offers excellent analytical performance, improving laboratory efficiency and work-flow.

DIAZYME CARDIAC TROPONIN I ASSAY ADVANTAGES

- Fast test results for a rapid turnaround time
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation saving time and reducing sample handling

REGULATORY STATUS

USA: For Research Use Only

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi

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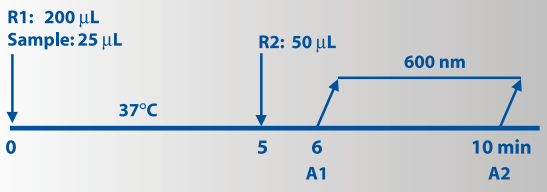
ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - Li-heparin Sample Volume 25 µL
Method Correlation	N = 38 y-intercept = 0.0232 Slope = 0.9971 R^2 = 0.992
Linear Range	Up to 10 ng/mL
LOD	0.28 ng/mL
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Opened: Four weeks on board analyzer

*Cardiac Troponin I Assay Procedure**



***Analyzer Dependent**

Parameter questions for Cardiac Troponin I Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

1. *Antman EM, Tanasijevic MJ, Thompson B, et al. Cardiac-specific troponin I levels to predict the risk of mortality in patients with acute coronary syndromes. N Engl J Med 1996;335:1342-1349*
2. *Apple FS, Voss E, Lund L, Preese L, Berger CR: Early detection of acute myocardial infarction and monitoring Chim Acta 1995;237:59-66*
3. *Mair J, Wagner I, Jakob G, Lechleitner P, Dienstl F, Puschendorf B, Michel G: Different time courses of cardiac contractile proteins after acute myocardial infarction. Clin Chim Acta 1994;231:47-60*
4. *Mair J, Morandell D, Genser N, Lechleitner P, Dienstl F, Puschendorf B: Equivalent early sensitivities of myoglobin, creatine kinase MB mass, creatine kinase isoform ratios, and cardiac troponins I and T for acute myocardial infarction. Clin Chem 1995;41:1266-1272*
5. *Katus HA, Remppis A, Neumann FJ, Scheffold T, Diederich KW, Vinar G, Noe A, Matern G, Kuebler W: Diagnostic efficiency of troponin T measurements in acute myocardial infarction. Circulation 1991;83:902-912*
6. *Wang K, Asinger RW, Marriott HJ. ST-segment elevation in conditions other than acute myocardial infarction. N Engl J Med 2003;349:2128-2135*

ASSAY PRECISION

In the study, two levels of controls containing 2.59 and 5.77 ng/mL troponin I and one serum sample were tested with Diazyme Troponin I Assay in replicates of 20 on an Olympus AU 400 analyzer. Precision is listed in the table below:

Expected Value (ng/mL)	**Control 1 (2.59±0.39)**	**Control 2 (5.77±0.87)**	**Serum Sample(0.80)**
Average (ng/mL)	2.38	5.62	0.83
Standard Deviation	0.092	0.175	0.074
CV%	3.9%	3.1%	8.9%

ASSAY INTERFERENCE

The common serum interfering substances triglyceride, ascorbic acid, bilirubin, hemoglobin, and rheumatoid factor showed less than 10% interference up to the concentrations summarized below:

Triglyceride:	500 mg/dL
Ascorbic Acid:	10 mM
Bilirubin:	10 mg/dL
Bilirubin Conjugated:	20 mg/dL
Hemoglobin:	200 mg/dL
Rheumatoid Factor:	150 IU/mL

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