

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



AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- Roche
- Hitachi



CARDIAC TROPONIN I ASSAY

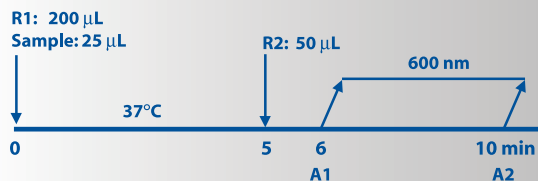
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ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - Li-heparin Sample Volume 25 μ L
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 \pm 0.39)	Control 2 (5.77 \pm 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

DIAZYME LABORATORIES

12889 Gregg Court, Poway, CA 92064
PO Box 85608, San Diego, CA 92186
Tel: 858-455-4768 888-DIAZYME

www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH

Zum Windkanal 21, 01109 Dresden, Deutschland
Tel. +49 (0) 351 886 3300 Fax +49 (0) 351 886 3366

sales@diazyme.de

SHANGHAI DIAZYME CO., LTD.

Room 201,1011 Halei Road, Zhangjiang Hi-tech Park
Shanghai, 201203, People's Republic of China
Tel: 086-21-51320668 Fax: 086-21-51320663

www.lanyuanbio.com service@lanyuanbio.com

