

CARDIAC TROPONIN I ASSAY

Cardiovascular
Marker

Published literature states that serum levels of cardiac enzymes and isoenzymes are essential to the diagnosis or exclusion of myocardial damage and that Cardiac Troponin I (cTnI) is specific for cardiac tissue and is detected in the serum only if myocardial injury has occurred.¹⁻⁶

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 CARDIAC TROPONIN I ASSAY ADVANTAGES

- Latex enhanced immunoturbidimetric methodology offers excellent analytical performance
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

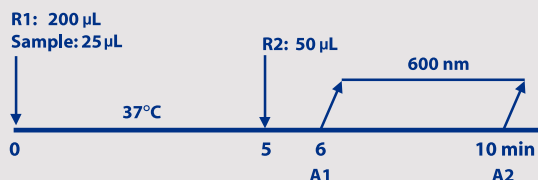
EU: **CE** **IVD**

SKU For Export Only. Not for Distribution in the USA.

ASSAY SPECIFICATIONS

| | |
|-----------------------------------|--|
| Method | Latex Enhanced Immunoturbidimetric |
| Sample Type & Volume | <ul style="list-style-type: none"> Serum Plasma - Li-heparin <p>Sample Volume 25 µL</p> |
| Method Correlation | <p>N = 38</p> <p>y-intercept = 0.0232</p> <p>Slope = 0.9971</p> <p>R² = 0.992</p> |
| Linearity | Up to 10 ng/mL |
| LOD | 0.28 ng/mL |
| Calibration Levels | 6-Point Calibration |
| Reagent On-Board Stability | <p>Opened:</p> <p>Four weeks when stored at 2-8°C</p> |

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 |
| SD (ng/mL) | 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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