DIAZYME

CARDIOVASCULAR MARKER

MYOGLOBIN ASSAY

Dual Vial Liquid Stable

Diazyme's Myoglobin Assay is an excellent cost effective cardiovascular test that is used to aid in the early detection of myocardial damage. The latex enhanced immunoturbidimetric methodology is highly precise with excellent correlations to existing commercial myoglobin tests and is designed to work on most modern high throughput clinical chemistry analyzers. The Myoglobin assay offers liquid stable reagent, calibrator, high and low end controls separately for added convenience.

DIAZYME MYOGLOBIN 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

510(k) Cleared

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi

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Dual Vial Liquid Stable

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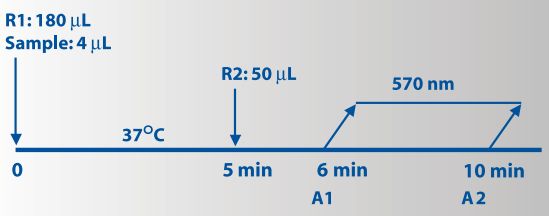
ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - Li-heparin - K_3EDTA Sample Volume 4 µL
Method Comparison	Deming Regression: N = 66 y-intercept = -5.141 Slope = 0.959 R^2 = 0.9927 Regression Analysis: N = 66 y-intercept = -4.228 Slope: 0.9526 R^2: 0.9855 Samples Ranged From: 16.9 – 615.9 ng/mL
Assay Range	13.2 – 615.9 ng/mL
LOB LOD LOQ	4.4 ng/mL 7.2 ng/mL 13.2 ng/mL
Calibration Levels	5-Point Calibration
Reagent On-Board Stability	Opened: Eight weeks on board analyzer

*Myoglobin Assay Procedure**



***Analyzer Dependent**

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

ASSAY PRECISION

The precision of the Diazyme Myoglobin Assay was evaluated according to CLSI EP5-A guideline. In the study, three levels of serum based controls containing approximately 66, 170, and 335 ng/mL of myoglobin, and three serum sample containing approximately 35, 150, and 414 ng/mL of myoglobin, respectively, were tested with 2 runs per day in duplicates over 20 working days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following tables:

	Control Level 1	Control Level 2	Control Level 3	Serum Level 1	Serum Level 2	Serum Level 3
N	80	80	80	80	80	80
Mean	65.97	175.8	337.0	37.78	148.6	414.3
SD	2.45	6.69	11.9	1.77	3.53	19.7
CV%	3.71%	3.87%	3.54%	4.69%	2.37%	4.80%

	Control Level 1	Control Level 2	Control Level 3	Serum Level 1	Serum Level 2	Serum Level 3
N	80	80	80	80	80	80
Mean	65.97	172.8	337.0	37.78	148.6	414.3
SD	3.37	7.37	14.9	1.97	5.32	21.8
CV%	5.10%	4.30%	4.40%	5.20%	3.58%	5.3%

ASSAY INTERFERENCE

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

Ampicillin:	up to 152 µM	Hemoglobin:	up to 1000 mg/dL
Carbamazepine:	up to 0.13 mM	Bilirubin:	up to 40 mg/dL
Na2+-Cefoxitin:	up to 1549 µM	Conjugated Bilirubin:	up to 40 mg/dL
Ibuprofen:	up to 2425 µM		
Cyclosporin:	up to 0.125 µM	Triglycerides:	up to 1000 mg/dL
Levodopa:	up to 30.4 mM	Intralipid:	up to 125 mg/dL
Methyldopa:	up to 71 µM	Ascorbic acid:	up to 176 mg/dL
Metronidazole:	up to 701 µM	Rheumatoid factor:	up to 100 IU/mL
Rifampicin:	up to 78.1 µM	Heparin:	up to 1.5 IU/mL
Theophylline:	up to 222 µM	N-acetylcysteine:	up to 11.04 mM
Phenylbutazone:	up to 650 µM	Acetylsalicylic acid:	up to 2.78 mM
Valproic Acid, Sodium Salt:	up to 3.5 mM		

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