

MYOGLOBIN ASSAY

Cardiovascular
Marker

Measurement of myoglobin is used as an aid in the diagnosis of acute myocardial infarction. The rapid increase in the concentration of myoglobin after muscular trauma makes it an important diagnostic indicator of cardiac stress and muscle damage, and provides early detection of necrosis in cardiac and skeletal muscle. Myoglobin determination can be useful in exclusion diagnosis for myocardial infarction if the myoglobin level has not increased after serial determination.¹⁻⁶

Diazyme's Myoglobin Assay is an excellent cost effective cardiovascular test used for the quantitative determination of myoglobin in human serum and plasma. Diazyme's Myoglobin Assay is highly precise with excellent correlations to existing commercial myoglobin tests.

DIAZYME MYOGLOBIN ASSAY ADVANTAGES

- The Myoglobin Assay is designed to work on most clinical chemistry analyzers
- Latex enhanced immunoturbidimetric method
- 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

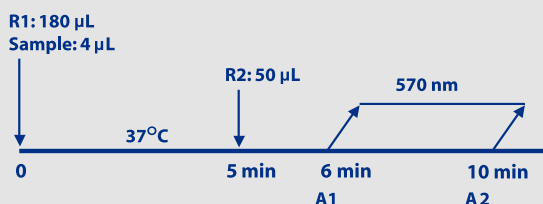
REGULATORY STATUS

510(k) Cleared; EU:  

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	<ul style="list-style-type: none"> Serum Plasma <ul style="list-style-type: none"> - Li-heparin - K₃EDTA <p>Sample Volume 4 µL</p>
Method Correlation	<p>Deming Regression: N = 66 y-intercept = -5.141 Slope = 0.959 R² = 0.9927</p> <p>Sample Range: 16.9 – 615.9 ng/mL</p>
Linearity	13.2 – 615.9 ng/mL
LOD LOB LOQ	<p>4.4 ng/mL</p> <p>7.2 ng/mL</p> <p>13.2 ng/mL</p>
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Opened: Eight weeks when stored at 2-8°C

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

- George A. Ordway and Daniel J. Garry (2004). "Myoglobin: an essential hemoprotein in striated muscle". *Journal of Experimental Biology* 207 (Pt 20): 3441–6.
- JC Kendrew et. al. (1958). "Three-Dimensional Model of the Myog-Iobin Molecule Obtained by X-Ray Analysis". *Nature* 181 (4610): 662–6
- Toshio Naka et. al. (2005). "Myoglobin clearance by super high-flux hemofiltration in a case of severe rhabdomyolysis: a case re-port". *Critical Care* 9 (2): R90–5.
- M. Weber, et. al. (2005). "Diagnostic utility of new immunoassays for the cardiac markers cTnI, myoglobin and CK-MB mass". *Clinical Biochemistry* 38 (11): 1027–30.
- Montague C, Kircher T. "Myoglobin in the early evaluation of acute chest pain. *Am J Clin Pathol.* 1995 Oct;104(4):472-6.
- Stacy Foran Melanson et al "Reevaluation of Myoglobin for Acute Chest Pain Evaluation" *Am J Clin Pathol* 2004;121:804-808

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 (ng/mL)	65.97	175.8	337.0	37.78	148.6	414.3
SD (ng/mL)	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 (ng/mL)	65.97	172.8	337.0	37.78	148.6	414.3
SD (ng/mL)	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	Bilirubin:	up to 1000 mg/dL
Cyclosporin:	up to 0.125 µM	Triglycerides:	up to 125 mg/dL
Levodopa:	up to 30.4 mM	Intralipid:	up to 176 mg/dL
Methyldopa:	up to 71 µM	Ascorbic acid:	up to 100 IU/mL
Metronidazole:	up to 701 µM	Rheumatoid factor:	up to 1.5 IU/mL
Rifampicin:	up to 78.1 µM	Heparin:	up to 11.04 mM
Theophylline:	up to 222 µM	N-acetylcysteine:	up to 2.78 mM
Phenylbutazone:	up to 650 µM	Acetylsalicylic acid:	up to 3.5 mM
Valproic Acid, Sodium Salt:	up to 3.5 mM		

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