MYOGLOBIN ASSAY

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: CE IVD

DIAZYME
Innovations in Clinical Diagnostics

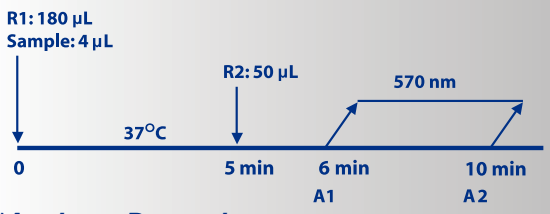
MYOGLOBIN ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - Li-heparin - K_3EDTA Sample Volume 4 µL
Method Correlation	Deming Regression: N = 66 y-intercept = -5.141 Slope = 0.959 R^2 = 0.9927 Sample Range: 16.9 – 615.9 ng/mL
Linearity	13.2 – 615.9 ng/mL
LOD LOB LOQ	4.4 ng/mL 7.2 ng/mL 13.2 ng/mL
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

1. George A. Ordway and Daniel J. Garry (2004). "Myoglobin: an essential hemoprotein in striated muscle". Journal of Experimental Biology 207 (Pt 20): 3441–6.

2. JC Kendrew et. al. (1958). Three-Dimensional Model of the Myog-lobin Molecule Obtained by X-Ray Analysis". Nature 181 (4610): 662–6

3. 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.

4. M. Weber, et. al. (2005). "Diagnostic utility of new immunoassays for the cardiac markers cTnI, myoglobin and CK-MB mass". Clini-cal Biochemistry 38 (11): 1027–30.

5. Montague C, Kircher T. "Myoglobin in the early evaluation of acute chest pain. Am J Clin Pathol. 1995 Oct;104(4):472-6.

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*		
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*		

DIAZYME LABORATORIES, INC.
12889 Gregg Court, Poway, CA 92064 USA
PO Box 85608, San Diego, CA 92186 USA
Tel: +1-858-455-4768 +1-888-DIAZYME
www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH
Zum Windkanal 21, 01109 Dresden, Germany
Tel: +49-351-886-3300 Fax: +49-351-886-3366
sales@diazyme.de

DIAZYME SHANGHAI CO., LTD.
Room 201,1011 Halei Road, Zhangjiang Hi-tech Park
Shanghai, 201203, People's Republic of China
Tel: +86-21-51320668 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com