Myoglobin Assay Kit (MYO/Mb)

Method: Latex Enhanced IT

Cat . No.	Size	Instrument
GB240X	R1:1×60 ml R2:1×20 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GS241X	R1:1×60ml R2:1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000

INTENDED USE

Diagnostic reagent for quantitative in vitro determination of myoglobin in serum or plasma on photometric systems.

CLINICAL SIGNIFICANCE

Myoglobin is an oxygen-binding heme protein present in cardiac and skeletal muscle. In case of a damage of these muscles, as in the case of an acute myocardial infarction (AMI) or muscle trauma, myoglobin is released in the blood circulation.

After an AMI it can already be measured in the blood 2-3 hours from chest pain onset reaching pathological levels before other cardiac markers like creatin kinase (CK) or its MB isoenzyme (CK-MB). Myoglobin achieves peak levels after 7-10 hours returning to values within the reference range after approx. 24 hours.

The determination of myoglobin represents a rapid and sensitive laboratory test which complements the ECG during the early phase of AMI. If myoglobin is still within the reference range 8 hours after onset of chest pain, an AMI can be excluded with great probability. Increased concentrations of myoglobin in blood can also be measured in conditions not associated with AMI such as muscle trauma, myopathies, strong physical exercise, kidney insufficiency or rhabdomyolysis.

ASSAY PRINCIPLE

When an antigen-antibody reaction occurs between Mb in a sample and anti-Mb antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of Mb in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris/HCl buffer	50 mmol/L
Polyethylene Glycol	7%
Reagent 2 (R2)	
Tris/HCl buffer	20 mmol/L
Anti (human) Myoglobin	0.12%
NaCl	150 mmol/L

SAMPLE COLLECTION AND PREPARATION

Fresh serum or plasma.

Stability 2-8 ℃ preservation can be stable 1 week. - 20 ℃ can be stable at least six months, not repeated freezing and thawing.

STABILITY AND PREPARATION OF REAGENTS

Reagents in 2-8 ℃ avoid light preservation, can be stable for 12 months.

Already open reagent don't contaminated, reagent in the stability of instrument storehouse in 28 days.

ASSAY PROCEDURE

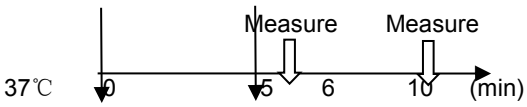
Test Procedure for Analyzers (Hitachi 7180)

Assay Mode: 2 Point End 19-34

Wave length (sub/main): 800/570nm

Sample 6 µl

R1: 180µl R2: 60 µl



CALIBRATION

Recommend using Gcell calibrator (Cat .No. GC-Mb).

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of Mb in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use Gcell GQ-Mb as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Serum/Plasma：≤70ng/ml

It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 10 ~ 850 ng/ml, the linear correlation

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coefficient $r^2 \geq 0.990$.

PRECISION

The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(ng/ml)	82.4	264
SD	1.52	2.88
CV(%)	1.84	1.09

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	86.9	86.2	85.3
$\bar{x}$	86.1		
(Xmax-Xmin)/$\bar{x}$	(86.9-85.3)/86.1*100=1.08%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid	up to 50 mg/dl
Bilirubin	up to 50 mg/dl
Hemoglobin	up to 500mg/dl
Intralipid	up to 1000mg/dl
Heparin	uo to 500mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Galvin, J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983)
2. Singer, J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med.,21, 888 (1956)

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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