Myoglobin FS*

Order Information

Cat. No.	Kit size		
1 7098 99 10 935	R1 2 x 12 mL	+	R2 1 x 8 mL

Kit for use in conjunction with DiaSys CE applications.

Intended Use

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

Summary

Myoglobin is an intracellular heme protein with a molecular weight of about 17,800 daltons, which is mainly found in heart and skeletal muscles and serves as an oxygen-binding molecule. Myoglobin is released rapidly after muscle damage and can therefore be a useful biomarker in the early stages of injury [1]. Elevated myoglobin levels are indicative for muscle damage and can be observed in acute and chronic skeletal muscle diseases, kidney failure, myocarditis, open heart surgery and intense physical exercise [1-3]. Increasing public awareness of myocardial infarction leads to early presentation of patients to emergency departments when symptoms occur. Initiation of thrombolytic therapy within the first 6 hours after onset of chest pain is crucial for patient prognosis and early reperfusion, ensuring a positive clinical outcome. Release of myoglobin into the bloodstream starts as early as 2 to 4 hours after cell damage, peaks between 9 and 12 hours, and returns to baseline within 24–36 hours. Myoglobin serves as an early indicator of myocardial infarction and as a rule-out criterion [1,4,5]. Myoglobin demonstrates a negative predictive value of 99%, improving the rule-out capabilities of emergency departments and minimizing inappropriate admissions to Coronary Care Units for patients with symptoms atypical of acute myocardial infarction. When used in conjunction with other cardiac markers such as CK-MB or troponin I, myoglobin becomes a valuable diagnostic tool for early assessment of potential acute myocardial infarction in patients [1].

Method

Particle enhanced immunoturbidimetric test

Determination of myoglobin concentration by photometric measurement of antigen antibody reaction between antibodies against myoglobin bound to latex particles and myoglobin present in the sample.

Reagents

Components and Concentrations

R1:	Buffer	pH 8.3	
	Glycine		< 1.5%
R2:	Buffer	pH 7.3	
	Glycine		< 1.5%
	Latex particles coated with anti-myoglobin antibody (rabbit)		< 1%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 15 months until expiry date.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

Reagent 1 is ready to use.

The latex enhanced reagent 2 has to be mixed up by successive inversions before first use. Avoid formation of foam.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [7]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
3 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	571/884 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	2.0 µL
Reagent 1	60 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 22/23 (326 s/340 s)
Absorbance 2	Cycle 36/37 (518 s/532 s)
Calibration	Spline

Calculation

The myoglobin concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 4 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Conversion Factor

Myoglobin [µg/L] x 0.059 = Myoglobin [nmol/L]

Calibrators and Controls

DiaSys TruCal Myoglobin is recommended for calibration. Calibrator values have been made traceable to a reference preparation based on pure antigen. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Myoglobin	1 7030 99 10 058	4 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range from 7 µg/L up to 600 µg/L, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.	
Limit of detection**	2 µg/L
No prozone effect up to 15000 µg/L.	

Interference by	Interferences ≤ 10% up to	Analyte concentration [µg/L]
Bilirubin (conjugated)	60 mg/dL	67.0
Bilirubin (unconjugated)	60 mg/dL	67.9
Hemolysis	1000 mg/dL	74.6
Lipemia (triglycerides)	1000 mg/dL	72.1

For further information on interfering substances, refer to the literature [8-10].

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	30.6	63.6	200
CV [%]	2.40	1.15	0.615
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	34.0	66.0	203
CV [%]	2.70	1.79	0.973

Method comparison (n=126)	
Test x	DiaSys Myoglobin FS (Hitachi 912)
Test y	DiaSys Myoglobin FS (BioMajesty® JCA-BM6010/C)
Slope	0.989
Intercept	1.70 µg/L
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [11]

Men and women < 70 µg/L 4.13 nmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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IVD CE

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