Myoglobin FS*

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

Order Information

Cat. No.	Kit size
1 7098 99 10 935	R1 2 x 12 mL + R2 1 x 8 mL
1 7030 99 10 058	4 x 1 mL TruCal Myoglobin: Calibrator set with 4 different levels

Summary [1-6]

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.
Under thrombolytic therapy a rapid and steep increase of myoglobin (≥ 150 µg/L/h or a relative increase >4-fold in 90 min after begin of treatment) is suggestive of a successful reperfusion.
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.

Method

Particle enhanced immunoturbidimetric test

Principle

Fixed time determination of the concentration of myoglobin through photometric measurement of antigen-antibody-reaction among antibodies to human myoglobin coated 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	
	Latex particles coated with anti-myoglobin antibodies (rabbit)		< 1%
	Glycine		< 1.5%

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [10].
4. Please refer to the safety data sheets 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The latex reagent (R2) must be carefully mixed before use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum or plasma (EDTA, heparin, citrate)

Stability [7]:	2 days	at	15 – 25°C
	1 week	at	2 – 8°C
	3 months	at	–20°C

Discard contaminated specimens. Only freeze once!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	580 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	20 µL
Dist. water	20 µL	-
Reagent 1	600 µL	600 µL
Mix, incubate for 3 – 5 min. Then add:		
Reagent 2	200 µL	200 µL
Mix and read absorbance (A1) within 30 sec. Incubate for 5 min. and read absorbance again (A2).		

ΔA= (A2 – A1) sample or calibrator

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 four calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.
Stability of calibration: 4 weeks.

Conversion factor

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

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal Myoglobin calibrator set is recommended. The assigned values of the calibrators have been made traceable to a reference preparation based on pure antigen. For internal quality control, DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
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

* fluid stable

Performance Characteristics

Measuring Range

The measuring range is from 5 – 600 µg/L, at least up to the concentration of the highest calibrator. When values exceed this range the samples should be diluted 1+2 with NaCl solution (9 g/L) and the result multiplied by 3.

Prozone Limit

No prozone effect was observed up to a myoglobin value of 15000 µg/L.

Specificity/Interferences

Due to its antibodies, DiaSys Myoglobin FS is a specific immunoassay for human myoglobin. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 1000 mg/dL triglycerides, and RF up to 500 IU/mL. For further information on interfering substances refer to Young DS [8].

Sensitivity/Limit of Detection

The lower limit of detection is 5 µg/L.

Precision (n = 20)

Intra-assay precision	Mean [µg/L]	SD [µg/L]	CV [%]
Sample 1	34.2	0.61	1.77
Sample 2	69.0	0.45	0.66
Sample 3	202	1.09	0.54

Inter-assay precision	Mean [µg/L]	SD [µg/L]	CV [%]
Sample 1	51.5	0.70	1.36
Sample 2	243	2.92	1.20
Sample 3	219	1.91	0.87

Method Comparison

A comparison of DiaSys Myoglobin FS (y) with a commercially available assay (x) using 95 samples gave the following results:
y = 1.071 x + 3.095 µg/L; r = 0.996

Reference Range [3]

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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Manufacturer

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