Myoglobin FS*

Diagnostic reagent for quantitative in vitro determination of myoglobin in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7098 99 10 966
R1: 2 x 100 tests
R2: 2 x 100 tests

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the myoglobin concentration by photometric measurement of antigen-antibody-reaction among antibodies against 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	
	Glycine		< 1.5%
	Latex particles coated with anti-myoglobin antibodies (rabbit)		< 1%

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 accord ing 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 bottles are placed directly into the reagent trays. The latex reagent (R2) must be carefully mixed before use.

Specimen

Serum or plasma (EDTA, heparin, citrate)

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

Discard contaminated specimens. Freeze only once!

Calibrators and Controls

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

	Cat. No.	Kit size
TruCal Myoglobin (4 Levels)	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

Measuring range from 7 up to 600 µg/L myoglobin, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	2 µg/L myoglobin
No prozone effect up to 15000 µg/L myoglobin	
On-board stability	10 weeks
Calibration stability	6 weeks

Interferences < 10% by
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Lipemia (triglycerides) up to 1000 mg/dL
For further information on interfering substances refer to Young DS [2]

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	30.6	63.6	200
Coefficient of variation [%]	2.40	1.15	0.62
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	34.0	66.0	203
Coefficient of variation [%]	2.70	1.79	0.97

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	0.9999

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

Conversion factor

Myoglobin [µg/L] x 0.0585 = Myoglobin [nmol/L]

Reference Range [3]

Men and women < 70 µg/L (< 4.1 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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2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
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4. Stone MJ, Willerson JT, Gomez-Sanchez CE, Waterman MR. Radioimmunoassay of myoglobin in human serum. Results in patients with acute myocardial infarction. J Clin Invest 1975; 56: 1334-9.
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7. De Winter RJ, Koster RW, Sturk A, Sanders GT. Value of myoglobin, troponin T and CK-MB mass in ruling out myocardial infarction in the emergency room. Circulation 1995; 92: 3401-7.
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Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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BioMajesty

Myoglobin FS

Chemistry code 10 709

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	60
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2.0
Sample vol (U)	2.0
Reagent 1 mix	strong
Reagent 2e mix	weak
Reagent 2 mix	strong
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	36
M-DET.P.n	37
S-DET.P.p	22
S-DET.P.r	23
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc.

Sub-analy. Conditions	
Name	MYO
Digits	2
M-wave L.	571
S-wave.L	884
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2.0
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	2.0	2.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting

Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	5

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	2.0	No dil	0	0	0	9.999	-9.999
1	#	2.0	No dil	0	0	0	9.999	-9.999
2	#	2.0	No dil	0	0	0	9.999	-9.999
3	#	2.0	No dil	0	0	0	9.999	-9.999
4	#	2.0	No dil	0	0	0	9.999	-9.999

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