respons®910

Myoglobin FS*

Diagnostic reagent for quantitative in vitro determination of myoglobin in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 7098 99 10 921
4 twin containers for 100 tests each
Cat. No. 1 7098 99 10 926
2 twin containers for 100 tests each

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the myoglobin concentration by 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 (0.95 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 bottles are placed directly into the reagent rotor. 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 DiaSys TruCal Myoglobin calibrator set is recommended. The assigned values of TruCal Myoglobin calibrator have been made traceable to a reference preparation based on pure antigen. DiaSys TruLab Protein controls 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 13 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 rerun function).	
Limit of detection**	6 µg/dL Myoglobin
No prozone effect up to 15000 µg/L Myoglobin	
On-board stability	4 weeks
Calibration stability	7 days

Interfering substance	Interferences < 10 %	MYO [µg/L]
Hemoglobin	up to 1200 mg/dL	68.8
	up to 1200 mg/dL	131
Bilirubin, conjugated	up to 60 mg/dL	72.9
	up to 60 mg/dL	159
Bilirubin, unconjugated	up to 60 mg/dL	58.0
	up to 60 mg/dL	141
Lipemia (triglycerides)	up to 700 mg/dL	65.4
	up to 1100 mg/dL	153
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]	40.0	63.7	197
Coefficient of variation [%]	4.58	2.24	0.91
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	65.1	104	198
Coefficient of variation [%]	3.98	2.88	2.77

Method comparison (n=120)	
Test x	DiaSys Myoglobin FS Hitachi 917
Test y	DiaSys Myoglobin FS respons®910
Slope	1.028
Intercept	2.46 µg/L
Coefficient of correlation	0.9997

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [3]

Men and women < 70 µg/L

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

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 38-9.
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.
3. Mair J, Artner-Dworzak E, Lechleitner P, Morass B, Smidt J, Wagner I et al. Early diagnosis of acute myocardial infarction by a newly developed rapid immunoturbidimetric assay for myoglobin. Br Heart J 1992; 68: 462-8.
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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6. Zaninotto M, Altinier S, Lachin M, Celegon L, Plebani M. Strategies for the early diagnosis of acute myocardial infarction using biochemical markers. Am J Pathol 1999; 111: 399-405.
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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9. Baum H, Booksteegers P, Steinbeck G, Neumeier D. A rapid assay for the quantification of myoglobin: evaluation and diagnostic relevance in the diagnosis of acute myocardial infarction. Eur J Clin Chem Biochem 1994; 32: 853-8.
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Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	MYO
Shortcut:	
Reagent barcode reference:	711
Host reference:	711

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	150
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	50
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	570
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	05:00
Last reading time [min:sec]	08:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	6.0000
Concentration technical limits-Upper	600.0000
SERUM	
Normal volume [µL]	5.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	5.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	5.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	5.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	5.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	µg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>= <=70
URINE	
PLASMA	>= <=70
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	
	Max delta abs.
Cal. 1	0.0050
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	
Drift limit [%]	2.00

Calculations	
Model	Akima Spline
Degree	

* Enter calibrator value