respons®920

Myoglobin FS*

Diagnostic reagent for quantitative in vitro determination of myoglobin in serum or plasma on DiaSys respons®920

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 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [10].
5. 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.
6. 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

DiaSys TruCal Myoglobin calibrator set is recommended for calibration. The assigned values of the calibrators have been made traceable to an international 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 20 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**	12 µg/L Myoglobin
No prozone effect up to 15000 µg/L Myoglobin	
On-board stability	6 weeks
Calibration stability	4 weeks

Interfering substance	Interferences < 10 %	MYO [µg/L]
Hemoglobin	up to 1100 mg/dL	61.7
	up to 1100 mg/dL	126
Bilirubin, conjugated	up to 60 mg/dL	67.7
	up to 60 mg/dL	136
Bilirubin, unconjugated	up to 50 mg/dL	68.2
	up to 65 mg/dL	139
Lipemia (triglycerides)	up to 1900 mg/dL	77.7
	up to 1900 mg/dL	124
Rheumatoid factor	up to 640 IU/mL	70.7
	up to 640 IU/mL	130
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]	45.7	64.7	197
Coefficient of variation [%]	1.90	1.49	1.41
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	41.2	70.0	207
Coefficient of variation [%]	2.37	2.76	1.66

Method comparison (n=105)	
Test x	DiaSys Myoglobin FS Hitachi 917
Test y	DiaSys Myoglobin FS respons®920
Slope	1.021
Intercept	1.428 µg/L
Coefficient of correlation	0.999

** 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.
5. Bhayana V, Henderson AR. Biochemical markers of myocardial damage. Clin Biochem 1995; 28: 1-29.
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.
8. Laperche T, Steg PG, Dehoux M, Benessiano I, Grollier G, Aliot E et al. A study of biochemical markers of reperfusion early after thrombolysis for acute myocardial infarction. Circulation 1995; 92: p. 2079-86.
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

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* fluid stable

respons®920

Myoglobin FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	MYO				Auto Rerun		☐
Report Name	:	Myoglobin				Online Calibration		☐
Unit	:	µg/L	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	505	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline	Reagent R1	:	MYO R1
M1 Start	:	21	M1 End	:	21	Reagent R2	:	
M2 Start	:	30	M2 End	:	30	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank		0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1		**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 2		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 3		**
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 4		**
Technical Minimum	:	*	Technical Maximum	:	*			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

*Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Please enter calibrator value.

Test Details			Test Volumes		Reference Ranges
Test	:	MYO			
Sample Type	:	Serum			

Sample Volumes

Normal	:	5.00 µL	Dilution Ratio	:	1	X
Increase	:	10.00 µL	Dilution Ratio	:	1	X
Decrease	:	3.00 µL	Dilution Ratio	:	3	X
Standard Volume	:	5.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	150 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	50 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	MYO		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (µg/L)	Upper Limit (µg/L)
Normal	:	0.00	70.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other