

Tina-quant Myoglobin Gen.2

Order information

REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
08252629190	08252629500	Tina-quant Myoglobin Gen.2 (200 tests)	System-ID 2092 001	cobas c 303, cobas c 503, cobas c 703

Materials required (but not provided):

04580044190	C.f.a.s. Myoglobin (3 x 1 mL)	Code 20689	
11730835216	Myoglobin Control Set (2 x 3 mL)	Code 20206 Level I Code 20207 Level II	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

English

System information

MYO2: ACN 20920

Intended use

In vitro test for the quantitative determination of myoglobin in human serum and plasma on **cobas c** systems.

Summary

Measurements of myoglobin, performed with this assay in human serum or plasma, are used as an aid-in-diagnosis of acute myocardial infarction.

Myoglobin is a small cytoplasmic protein in striated cardiac and skeletal musculature. It is involved in the transport of oxygen within the myocytes and also serves as an oxygen reservoir. Myoglobin has a low molecular weight (17.8 kDa) and is rapidly released into the bloodstream following myocardial injury.^{1,2,3}

The determination of myoglobin in serum may be used in the diagnosis of acute myocardial infarction (AMI),^{4,5} early reinfarction^{6,7} and successful reperfusion following lysis therapy.^{1,8,9,10}

Because of its small size and non-binding to the insoluble sarcomere, its concentration rises already after approximately 2 hours following the occurrence of symptoms, and is therefore regarded as an early marker of myocardial infarction.¹¹ It is rapidly excreted from the kidneys within 24 hours.¹⁰

During reperfusion myoglobin concentration peaks in less than 3 hours using thrombolytic measures,^{12,13,14} even within 15 minutes after primary percutaneous coronary intervention.¹⁵ Elevated myoglobin values can also occur after skeletal muscle damage and in cases of greatly restricted renal function.^{1,2} According to the 4th Universal Definition of Myocardial Infarction, cardiac troponins are the preferred biomarkers for the evaluation of myocardial injury, since other biomarkers are less specific and less sensitive. High-sensitivity cardiac troponin assays are recommended for routine clinical use.¹⁶ In the case that high-sensitivity cardiac troponin assays are not available, a combination of other cardiac biomarkers, including myoglobin, may increase sensitivity for the diagnosis of AMI compared to single biomarkers.¹⁷

Various nephelometric and turbidimetric methods are available for the determination of myoglobin. This Roche myoglobin assay is based on the principle of immunological agglutination with latex reaction enhancement.

Test principle¹⁸

Particle-enhanced immunoturbidimetric assay

Latex-bound anti-myoglobin antibodies react with antigen in the sample to form an antigen/antibody complex which after agglutination can be determined turbidimetrically.

Reagents - working solutions

R1 Glycine buffer: 170 mmol/L, pH 8.3; NaCl: 100 mmol/L; EDTA: 50 mmol/L; preservative

R3 Latex particles coated with anti-human myoglobin antibodies (rabbit): 0.1 %; glycine buffer: 170 mmol/L, pH 7.3; NaCl: 100 mmol/L; preservative

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

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

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Carefully invert reagent container several times prior to use to ensure that the reagent components are mixed.

Storage and stability

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 12 weeks

Specimen collection and preparation¹⁸

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and K₂-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Blood collected in capillary blood collection tubes is unsuitable for use in this assay.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

Stability:¹⁹ 2 days at 15-25 °C
1 week at 2-8 °C
3 months at -20 °C (± 5 °C)

Freeze only once.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma**Test definition**

Reporting time	10 min		
Wavelength (sub/main)	800/570 nm		
Reagent pipetting		Diluent (H ₂ O)	
R1	63 µL	–	
R3	21 µL	–	
Sample volumes	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	2.1 µL	–	–
Decreased	2.1 µL	10 µL	90 µL
Increased	2.1 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Calibrators	S1: H ₂ O S2-6: C.f.a.s. Myoglobin
Calibration mode	Non-linear
Calibration frequency	Full calibration - after reagent lot change - as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against a selected manufacturer's measurement procedure (immunological method).

Quality control

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 12 weeks.

Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

cobas c systems automatically calculate the analyte concentration of each sample in the unit µg/L (nmol/L, ng/mL).

Conversion factors:	µg/L × 0.0571 = nmol/L
	µg/L × 1.00 = ng/mL

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at a myoglobin concentration of 60 µg/L.

Icterus:²⁰ No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:²⁰ No significant interference up to an H index of 400 (approximate hemoglobin concentration: 249 µmol/L or 400 mg/dL).

Lipemia (Intralipid):²⁰ No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 100 IU/mL.

High-dose hook effect: No false result occurs up to a myoglobin concentration of 15000 µg/L.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{21,22}

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.²³

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Limits and ranges**Measuring range**

15-500 µg/L (0.86-28.6 nmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement*Limit of Blank, Limit of Detection and Limit of Quantitation*

Limit of Blank	= 15 µg/L (0.86 nmol/L)
Limit of Detection	= 15 µg/L (0.86 nmol/L)
Limit of Quantitation	= 15 µg/L (0.86 nmol/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 20 %. It has been determined using low concentration myoglobin samples.

Expected values²⁴**µg/L**

Men:	23-72 µg/L
Women:	19-51 µg/L

nmol/L*

Men:	1.31-4.11 nmol/L
Women:	1.08-2.91 nmol/L

*calculated by unit conversion factor

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c 503** analyzer.

Repeatability	Mean µg/L	SD µg/L	CV %
MYO CS Level I ^{a)}	61.0	1.75	2.9
MYO CS Level II ^{b)}	253	2.80	1.1
Human serum 1	22.9	1.53	6.7
Human serum 2	77.3	1.74	2.3
Human serum 3	161	2.47	1.5
Human serum 4	270	3.48	1.3
Human serum 5	421	3.77	0.9

Intermediate precision	Mean µg/L	SD µg/L	CV %
MYO CS Level I ^{a)}	61.0	2.03	3.3
MYO CS Level II ^{b)}	252	4.45	1.8
Human serum 1	22.9	1.61	7.0
Human serum 2	77.3	2.32	3.0
Human serum 3	157	3.38	2.2
Human serum 4	270	5.13	1.9
Human serum 5	423	6.89	1.6

a) Myoglobin Control Set Level I

b) Myoglobin Control Set Level II

The data obtained on **cobas c 503** analyzer(s) are representative for **cobas c 303** analyzer(s) and **cobas c 703** analyzer(s).

Method comparison

Myoglobin values for human serum and plasma samples obtained on a **cobas c 503** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 81

Passing/Bablok ²⁵	Linear regression
y = 1.065x - 2.95 µg/L	y = 1.040x + 0.366 µg/L
τ = 0.971	r = 0.999

The sample concentrations were between 16.6 and 489 µg/L.

Myoglobin values for human serum and plasma samples obtained on a **cobas c 303** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 501** analyzer (x).

Sample size (n) = 73

Passing/Bablok ²⁵	Linear regression
y = 1.012x + 3.35 µg/L	y = 0.983x + 7.04 µg/L
τ = 0.978	r = 0.998

The sample concentrations were between 15.3 and 490 µg/L.

Myoglobin values for human serum and plasma samples obtained on a **cobas c 703** analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c 503** analyzer (x).

Sample size (n) = 75

Passing/Bablok ²⁵	Linear regression
y = 1.027x + 0.602 µg/L	y = 1.015x + 1.60 µg/L

τ = 0.945

r = 1.000

The sample concentrations were between 15.1 and 466 µg/L.

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The Summary of Safety & Performance Report can be found here:
<https://ec.europa.eu/tools/eudamed>

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

	Contents of kit
	Volume for reconstitution
	Global Trade Item Number

Rx only For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.


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