MYO2

cobas®

Tina-quant Myoglobin Gen.2

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
05950759190	05950759500	Tina-quant Myoglobin Gen.2 (150 tests)	System-ID 03 6923 1	**cobas c** 701/702

Materials required (but not provided):

04580044190	C.f.a.s. Myoglobin (3 x 1 mL)	Code 689	
11730835216	Myoglobin Control Set (2 x 3 mL)	Code 206 Level I Code 207 Level II	
05172152190	Diluent NaCl 9 % (119 mL)	System-ID 08 6869 3	

English

System information

MYO-2: ACN 8620

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 principle[18]

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 to 8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks
On-board on the Reagent Manager:	24 hours

Specimen collection and preparation

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 K_2-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.

Centrifuge samples containing precipitates before performing the assay.

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

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

Stability:[19]	2 days at 15-25 °C
	1 week at 2-8 °C
	3 months at (-15)-(-25) °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.

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cobas®

Application for serum and plasma

cobas c 701/702 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 21-38		
Wavelength (sub/main)	800/570 nm		
Reaction direction	Increase		
Units	µg/L (nmol/L, ng/mL)		
Reagent pipetting		Diluent (H_2O)	
R1	90 µL	–	
R3	30 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	3 µL	15 µL	135 µL
Increased	6 µL	–	–

Calibration

Calibrators	S1: H_2O
	S2-6: C.f.a.s. Myoglobin
	Multiply the lot-specific C.f.a.s. Myoglobin calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:
	S2: 0.0625 S5: 0.5
	S3: 0.125 S6: 1
	S4: 0.25
Calibration mode	RCM
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).

Results must be corrected by + 8 (µg/L or ng/mL) in order to keep traceability. Performance has only been validated using this correction (see also Calculation section).

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. 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.

To maintain traceability, enter the instrument factor y = ax + b, where a = 1.0 and b = + 8 (for µg/L or ng/mL).

Conversion factors: µg/L x 0.0571 = nmol/L

µg/L = ng/mL

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at a myoglobin concentration of 60 µg/L (3.4 nmol/L, 60 ng/mL).

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 (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 (857 nmol/L, 15000 ng/mL).

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, manual input is required in certain cases. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SmpCln1+2/SCCS Method Sheet and for further instructions refer to the operator's manual.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

15-500 µg/L (0.86-28.6 nmol/L, 15-500 ng/mL)

The technical limit of the high end of measuring range in the instrument setting is defined as 492 µg/L due to the instrument factor for MYO-2 (b = 8 µg/L; see above chapters Calibration and Calculation)

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

Lower detection limit of the test

15 µg/L (0.86 nmol/L, 15 ng/mL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Values below the lower detection limit (< 15 µg/L) will not be flagged by the instrument.

Expected values[24]

Men: 23-72 µg/L (1.31-4.11 nmol/L, 23-72 ng/mL)

Women: 19-51 µg/L (1.08-2.91 nmol/L, 19-51 ng/mL)

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. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained on the **cobas c** 701 analyzer:

Repeatability	*Mean*	*SD*	*CV*
	µg/L (nmol/L, ng/mL)	*µg/L (nmol/L, ng/mL)*	*%*
Myoglobin Control Set level 1	63.0 (3.60, 63.0)	1.3 (0.07, 1.3)	2.1
Myoglobin Control Set level 2	257 (14.7, 257)	2 (0.1, 2)	0.9
Human serum A	24.7 (1.41, 24.7)	0.7 (0.04, 0.7)	2.8
Human serum B	49.2 (2.81, 49.2)	0.8 (0.05, 0.8)	1.6
Human serum C	405 (23.1, 405)	3 (0.2, 3)	0.8
Human serum D	481 (27.5, 481)	6 (0.3, 6)	1.3
Intermediate precision	*Mean*	*SD*	*CV*
	µg/L (nmol/L, ng/mL)	*µg/L (nmol/L, ng/mL)*	*%*
Myoglobin Control Set level 1	55.8 (3.19, 55.8)	1.2 (0.07, 1.2)	2.1
Myoglobin Control Set level 2	248 (14.2, 248)	2.5 (0.1, 2.5)	1.0
Human serum 3	61.1 (3.49, 61.1)	1.0 (0.06, 1.0)	1.6
Human serum 4	257 (14.7, 257)	2.1 (0.1, 2.1)	0.8

Results for intermediate precision were obtained on the **cobas c** 501 analyzer. The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 701 analyzer(s).

Method comparison

Myoglobin values for human serum and plasma samples obtained on a **cobas c** 701 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Sample size (n) = 67

Passing/Bablok[25]	Linear regression
y = 1.042x + 5.28 µg/L	y = 1.036x + 6.44 µg/L
τ = 0.975	r = 1.000

The sample concentrations were between 17.8 and 471 µg/L (1.02 and 26.9 nmol/L, 17.8 and 471 ng/mL).

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:

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	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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CE 0123

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