

Tina-quant Myoglobin Gen.2

Order information

REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
04580010190	04580010500	Tina-quant Myoglobin Gen.2 (100 tests)	System-ID 07 6923 1	cobas c 311 , cobas c 501/502 , COBAS INTEGRA 400 plus

Materials required (but not provided):

		cobas c 311 , cobas c 501/502	COBAS INTEGRA 400 plus
04580044190	C.f.a.s. Myoglobin (3 x 1 mL)	Code 689	System-ID 07 6875 8
11730835216	Myoglobin Control Set (2 x 3 mL)	Code 206 Level I Code 207 Level II	System-ID 07 6876 6 System-ID 07 6877 4
04489357190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	n.a.
20756350322	NaCl Diluent 9 % (6 x 22 mL)	n.a.	System-ID 07 5635 0

English

Intended use

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

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

Mix **cobas c** pack well before placing on the analyzer.

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

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.

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.

Calculation

The systems automatically calculate the analyte concentration of each sample.

Conversion factors:

$\mu\text{g/L} \times 0.0571 = \text{nmol/L}$

$\mu\text{g/L} \times 1.00 = \text{ng/mL}$

For **cobas c** systems:

To maintain traceability, enter the instrument factor $y = ax + b$, where $a = 1.0$ and $b = + 8$ (for $\mu\text{g/L}$ or ng/mL).

Expected values²⁰

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.

cobas c systems**System information**For **cobas c** 311/501 analyzers:**MYO-2:** ACN 620For **cobas c** 502 analyzer:**MYO-2:** ACN 8620**Reagents - working solutions**

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

R2 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 R2 is in position C.

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 |

Application for serum and plasma**cobas c 311 test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 7-29		
Wavelength (sub/main)	800/570 nm		
Reaction direction	Increase		
Units	µg/L (nmol/L, ng/mL)		
Reagent pipetting	Diluent (H ₂ O)		
R1	90 µL	–	
R2	30 µL	–	
<i>Sample volumes</i>	<i>Sample</i>	<i>Sample dilution</i>	
		<i>Sample</i>	<i>Diluent (NaCl)</i>
Normal	3 µL	–	–
Decreased	3 µL	15 µL	135 µL
Increased	3 µL	–	–

cobas c 501 test definition

Assay type	2-Point End		
Reaction time / Assay points	10 / 13-45		
Wavelength (sub/main)	800/570 nm		
Reaction direction	Increase		
Units	µg/L (nmol/L, ng/mL)		
Reagent pipetting	Diluent (H ₂ O)		
R1	90 µL	–	
R2	30 µL	–	
<i>Sample volumes</i>	<i>Sample</i>	<i>Sample dilution</i>	
		<i>Sample</i>	<i>Diluent (NaCl)</i>
Normal	3 µL	–	–

Decreased	3 µL	15 µL	135 µL
Increased	3 µL	–	–

cobas c 502 test definition

Assay type	2-Point End		
Reaction time / Assay points	10 / 13-45		
Wavelength (sub/main)	800/570 nm		
Reaction direction	Increase		
Units	µg/L (nmol/L, ng/mL)		
Reagent pipetting	Diluent (H ₂ O)		
R1	90 µL	–	
R2	30 µL	–	
<i>Sample volumes</i>	<i>Sample</i>	<i>Sample dilution</i>	
		<i>Sample</i>	<i>Diluent (NaCl)</i>
Normal	3 µL	–	–
Decreased	3 µL	15 µL	135 µL
Increased	6 µL	–	–

Calibration

Calibrators	S1: H ₂ O	
	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 six-point calibration curve:	
	S2: 0.0625	S5: 0.5
	S3: 0.125	S6: 1
	S4: 0.25	
Calibration mode	RCM	
Calibration frequency	Full calibration	
	<ul style="list-style-type: none"> • 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.

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:²¹ 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:²¹ No significant interference up to an H index of 400 (approximate hemoglobin concentration: 249 µmol/L or 400 mg/dL).

Lipemia (Intralipid):²¹ 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 < 100 IU/mL do not interfere.

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.^{22,23}

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.²⁴

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. The latest version of the carry-over evasion list can be found with the NaOH-SMS-SmpCln1+2-SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases.

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 in the instrument setting is defined as 7-492 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).

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** 501 analyzer:

Repeatability	Mean	SD	CV
	µg/L (nmol/L, ng/mL)	µg/L (nmol/L, ng/mL)	%
Myoglobin Control Set level 1	64.1 (3.66, 64.1)	1.1 (0.06, 1.1)	1.8
Myoglobin Control Set level 2	266 (15.2, 266)	3 (0.2, 3)	1.0
Human serum 1	73.1 (4.17, 73.1)	1.0 (0.06, 1.0)	1.4
Human serum 2	262 (15.2, 262)	2 (0.1, 2)	0.9
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

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

Method comparison

Myoglobin values for human serum and plasma samples obtained on a **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 59

Passing/Bablok ²⁵	Linear regression
y = 0.971x + 2.51 µg/L	y = 1.006x - 0.146 µg/L
τ = 0.976	r = 0.999

The sample concentrations were between 16.6 and 447 µg/L (0.948 and 25.5 nmol/L, 16.6 and 447 ng/mL).

The data obtained on **cobas c** 501 analyzer(s) are representative for **cobas c** 311 analyzer(s).

COBAS INTEGRA systems

System information

MYO-2: Test ID 0-023.

Reagents - working solutions

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

SR 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 SR is in position C.

Storage and stability

Shelf life at 2-8 °C	See expiration date on cobas c pack label
On-board in use at 10-15 °C	12 weeks

Application for serum and plasma

Test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A	583 nm
Calc. first/last	35/58
Typical prozone effect	> 1400 µg/L (> 79.9 nmol/L or > 1400 ng/mL)
Antigen excess check	Yes
Predilution factor	No
Postconcentration factor	No
Unit	µg/L

Pipetting parameters

		Diluent (H ₂ O)
R1	80 µL	
Sample	5.5 µL	10 µL
SR	40 µL	20 µL
Total volume	155.5 µL	

Calibration

Calibrator C.f.a.s. Myoglobin

Calibration dilution ratio	1:1, 1:2, 1:4, 1:8, 1:16, and 0 µg/L performed automatically by the instrument.
Calibration mode	Logit/log 4
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Enter the assigned lot-specific myoglobin value of the undiluted calibrator (µg/L) indicated in the package insert of C.f.a.s. Myoglobin.

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

Results must be corrected by + 10 µg/L. An additive factor has been introduced in the application (lab correlation - offset) in order to keep traceability. The performance has only been validated using this factor.

Quality control

Reference range	Myoglobin Control Set
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

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.

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Icterus:²¹ 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:²¹ No significant interference up to an H index of 500 (approximate hemoglobin concentration: 311 µmol/L or 500 mg/dL).

Lipemia (Intralipid):²¹ No significant interference up to an L index of 500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

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

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{22,23}

High-dose hook effect: Does not occur at myoglobin concentrations below 1400 µg/L (79.9 nmol/L) on COBAS INTEGRA 400 plus analyzers. Samples with concentrations > 1400 µg/L (79.9 nmol/L) up to > 10000 µg/L (571 nmol/L) are flagged either ">TEST RNG" or "HIGH ACT".

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.²⁴

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 INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

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

Limits and ranges

Measuring range

18-580 µg/L (1.03-33.1 nmol/L or 18-580 ng/mL)

The technical limit of the high end of measuring range in the instrument setting is defined as 570 µg/L due to the instrument factor for MYO2 (b = 10 µg/L; see above chapter calibration).

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

≤ 18 µg/L (≤ 1.03 nmol/L or ≤ 18 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 a zero sample (zero sample + 3 SD, repeatability, n = 21).

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 (1 aliquot per run, 1 run per day, 21 days). The following results were obtained on the COBAS INTEGRA 400 plus analyzer:

	Mean	CV repeatability
Level 1	61.9 µg/L (3.53 nmol/L or 61.9 ng/mL)	2.3 %
Level 2	267.6 µg/L (15.3 nmol/L or 267.6 ng/mL)	1.4 %
	Mean	CV intermediate precision
Level 1	60.9 µg/L (3.48 nmol/L or 60.9 ng/mL)	1.8 %
Level 2	270.2 µg/L (15.4 nmol/L or 270.2 ng/mL)	1.8 %

Method comparison

Myoglobin values for human serum samples obtained on a COBAS INTEGRA 400 analyzer with the COBAS INTEGRA Myoglobin Gen.2 (y) test were compared to those determined with the Myoglobin Gen.2 test on a Roche/Hitachi 917 analyzer (x). Samples were measured in duplicate. Sample size (n) represents all replicates.

Roche/Hitachi 917 analyzer

Sample size (n) = 60

Passing/Bablok ²⁵	Linear regression
y = 0.99x - 4.3 µg/L	y = 0.99x - 4.2 µg/L
τ = 0.973	r = 0.999
SD (md 95) = 26.7	Sy.x = 9.85

Values ranged from 31 to 613 µg/L (1.77-35.0 nmol/L or 31-613 ng/mL).

A comparison of the myoglobin determination using the COBAS INTEGRA Myoglobin Gen.2 test (y) with an immunological method (x) [selected manufacturer's procedure] gave the following correlation with human sera.

Immunological method

Tina-quant Myoglobin Gen.2

Sample size (n) = 58

Passing/Bablok²⁵ $y = 1.00x + 1.7 \mu\text{g/L}$ $\tau = 0.911$

SD (md 95) = 10.6

Values ranged from 26 to 381 $\mu\text{g/L}$ (1.48-21.8 nmol/L or 26-381 ng/mL).

Linear regression

 $y = 0.97x + 5.6 \mu\text{g/L}$ $r = 0.989$ $\text{Sy.x} = 5.02$ **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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Additions, deletions or changes are indicated by a change bar in the margin.

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