MYO2

cobas®

Tina-quant Myoglobin Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04580010 190	Tina-quant Myoglobin Gen.2 100 tests	System-ID 07 6923 1	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
04580044 190	C.f.a.s. Myoglobin (3 x 1 mL)	Code 689	
11730835 216	Myoglobin Control Set (2 x 3 mL)	Code 206 Level I	
		Code 207 Level II	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

MYO2: ACN 620

For **cobas c** 502 analyzer:

MYO2: ACN 8620

Intended use

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

Summary[1,2,3,4,5,6,7]

Myoglobin is a hemoprotein having a molecular weight of approximately 17800 daltons. It transports and reversibly binds oxygen in muscle cells. It is found predominantly in striated muscle tissue (skeletal and cardiac muscle). Myoglobin is liberated from damaged heart muscle cells such as occurs during acute myocardial infarction. An increase in myoglobin concentrations in blood can generally be detected 2 to 4 hours after the onset of pain, which is earlier than other cardiac markers such as CK, CK-MB or troponin. Depending on the therapeutic reperfusion measures taken, the myoglobin concentration reaches its maximum value after 4 to 12 hours and then decreases relatively rapidly to normal levels due to renal elimination (biological half-life: approx. 15 minutes). A very rapid increase in the concentration of myoglobin occurs when therapeutic intervention is successful. The gradient of the concentration increase can be taken as an indication of the success of thrombolysis.

The myoglobin determination is of particular value in exclusion diagnosis for myocardial infarction: if there is no increase in the myoglobin concentration 6 hours after the onset of pain and after a repeat determination within 4 hours, then acute myocardial damage can essentially be excluded.

Increases in concentration of myoglobin not due to infarction may be a result of muscle trauma, crush syndrome, myopathy, muscle strain/stress, shock, rhabdomyolysis or decreased elimination due to renal failure.

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[7]

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

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.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

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

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.

Storage and stability

MYO2

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

Diluent NaCl 9 %

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 preparation[7]

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.

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

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

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

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 7-29
Wavelength (sub/main)	800/570 nm

MYO2

Tina-quant Myoglobin Gen.2

Reaction direction	Increase		
Units	µg/L (nmol/L, ng/mL)		
Reagent pipetting		Diluent (H_2O)	
R1	90 µL	–	
R2	30 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
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_2O)	
R1	90 µL	–	
R2	30 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
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_2O)	
R1	90 µL	–	
R2	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 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

- 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

Roche/Hitachi **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:[9] 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:[9] No significant interference up to an H index of 400 (approximate hemoglobin concentration: 249 µmol/L or 400 mg/dL).

Lipemia (Intralipid):[9] 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.[10,11]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[12]

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 Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD-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 not required.

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 Myo2 (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).

Expected values[13]

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:

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

Method comparison

Myoglobin values for human serum and plasma samples obtained on a Roche/Hitachi **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[14]	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).

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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MYO2

Tina-quant Myoglobin Gen.2

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