

Elecsys Myoglobin

REF			SYSTEM
12178214122	12178214500	100	cobas e 411 cobas e 601 cobas e 602

English

System information

For **cobas e 411** analyzer: test number 240
 For **cobas e 601** and **cobas e 602** analyzers: Application Code Number 056

Intended use

Immunoassay for the in vitro quantitative determination of myoglobin in human serum and plasma.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Summary

Measurements of myoglobin, performed with this device, 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}

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

The Elecsys Myoglobin assay is based on the sandwich principle using 2 different monoclonal antibodies directed against human myoglobin.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: Antigen in the sample (15 µL), a biotinylated monoclonal myoglobin-specific antibody, and a monoclonal myoglobin-specific antibody labeled with a ruthenium complex^{a)} react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode or e-barcode.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

The reagent rackpack is labeled as MYO.

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:
 Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-myoglobin-Ab~biotin (gray cap), 1 bottle, 10 mL:
 Biotinylated monoclonal anti-myoglobin antibody (mouse) 1.75 mg/L;
 phosphate buffer 85 mmol/L, pH 6.5; sodium azide < 0.1 %;
 preservative.

R2 Anti-myoglobin-Ab~Ru(bpy)₃²⁺ (black cap), 1 bottle, 10 mL:
 Monoclonal anti-myoglobin antibody (mouse) labeled with ruthenium complex 1.75 mg/L; phosphate buffer 85 mmol/L, pH 6.5; sodium azide < 0.1 %; preservative.

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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The reagents in the kit have been assembled into a ready-for-use unit that cannot be separated.

All information required for correct operation is read in from the respective reagent barcodes.

Elecsys Myoglobin

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on the analyzers	8 weeks

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, K₂-EDTA and K₃-EDTA plasma.

Li-heparin and K₂-EDTA plasma tubes containing separating gel can be used.

Criterion: Slope 0.9-1.1 + intercept within ± 10 ng/mL + coefficient of correlation ≥ 0.95 .

Stable for 8 days at 20-25 °C, 14 days at 2-8 °C, 12 months at -20 °C (± 5 °C). Freeze only once.

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.

Do not use samples and controls stabilized with azide.

Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- [REF] 12178222122, Myoglobin CalSet, 4 x 1.0 mL
- [REF] 04917049190, PreciControl Cardiac II, for 4 x 2.0 mL
- [REF] 11732277122, Diluent Universal, 2 x 16 mL sample diluent or [REF] 03183971122, Diluent Universal, 2 x 36 mL sample diluent
- General laboratory equipment
- **cobas e** analyzer

Additional materials for the **cobas e 411** analyzer:

- [REF] 11662988122, ProCell, 6 x 380 mL system buffer
- [REF] 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- [REF] 11930346122, Elecsys SysWash, 1 x 500 mL washwater additive
- [REF] 11933159001, Adapter for SysClean
- [REF] 11706802001, AssayCup, 60 x 60 reaction cups
- [REF] 11706799001, AssayTip, 30 x 120 pipette tips
- [REF] 11800507001, Clean-Liner

Additional materials for **cobas e 601** and **cobas e 602** analyzers:

- [REF] 04880340190, ProCell M, 2 x 2 L system buffer
- [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- [REF] 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- [REF] 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change

- [REF] 12102137001, AssayTip/AssayCup, 48 magazines x 84 reaction cups or pipette tips, waste bags
- [REF] 03023150001, WasteLiner, waste bags
- [REF] 03027651001, SysClean Adapter M

Additional materials for all analyzers:

- [REF] 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

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.

Resuspension of the microparticles takes place automatically prior to use. Read in the test-specific parameters via the reagent barcode. In exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Calibration

Traceability: The Elecsys Myoglobin assay has been standardized against the Elecsys Myoglobin STAT assay.

Every Elecsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

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

Renewed calibration is recommended as follows:

- after 8 weeks when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings outside the defined limits

Quality control

Use Elecsys PreciControl Cardiac II or other suitable controls for routine quality control procedures.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

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.

If necessary, repeat the measurement of the samples concerned.

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

Calculation

The analyzer automatically calculates the analyte concentration of each sample (either in ng/mL or µg/L).

Limitations - interference

The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), hemolysis (Hb < 0.869 mmol/L or < 1.4 g/dL), lipemia (Intralipid < 2200 mg/dL) and biotin (< 205 nmol/L or < 50 ng/mL).

Criterion: Recovery within ± 10 % of initial value.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL.

There is no high-dose hook effect at myoglobin concentrations up to 30000 ng/mL.

Elecsys Myoglobin

- 12 Jurlander B, Clemmensen P, Magnus Ohmann E, et al. Serum myoglobin for early non-invasive detection of coronary reperfusion in patients with acute myocardial infarction *European Heart Journal* 1996;17:399-406
- 13 Tanasijevic MJ, Cannon CP, Wybenga DR, et al. Myoglobin, creatine kinase MB, and cardiac troponin-I to assess reperfusion after thrombolysis for acute myocardial infarction: results from TIMI 10A Am Heart J 1997;134:622-630
- 14 Lee HS, Cross SJ, Jennings K. Rapid Myoglobin Analysis to Assess Coronary Artery Reperfusion after Acute Myocardial Infarction *Clin Cardiol* 1997;20:759-762
- 15 Özdemir M, Durakoglugil E, Gülbahar O, et al. Heart fatty acid binding protein and myoglobin after reperfusion of acute myocardial infarction *Acta Cardiol* 2007;62(5):473-478
- 16 Thygesen K, Alpert JS, Chaitman BR, et al., Fourth Universal Definition of Myocardial Infarction (2018). *Glob Heart* 2018;13(4):305-338.
- 17 Fan J, Ma J, Xia N, et al., Clinical Value of Combined Detection of CK-MB, MYO, cTnl and Plasma NT-proBNP in Diagnosis of Acute Myocardial Infarction. *Clin Lab* 2017;63(3):427-433.
- 18 Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. *J Clin Chem Clin Biochem* 1988 Nov;26(11):783-790.

For further information, please refer to the appropriate user guide or operator's manual for the analyzer concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

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 (for USA: see navifyportal.roche.com for definition of symbols used):

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume for reconstitution
	Global Trade Item Number

COBAS, NAVIFY, ELECSYS and PRECICONTROL are trademarks of Roche. INTRALIPID is a trademark of Fresenius Kabi AB.

All other product names and trademarks are the property of their respective owners.

Additions, deletions or changes are indicated by a change bar in the margin.

© 2024, Roche Diagnostics

0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
 +800 5505 6606

