0006481647190c501V5.0

MG2

cobas®

Magnesium Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
06481647 190	Magnesium Gen.2 250 tests	System-ID 07 7486 3	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 401	
10759350 360	Calibrator f.a.s. (12 x 3 mL, for USA)	Code 401	
12149435 122	Precinorm U plus (10 x 3 mL)	Code 300	
12149435 160	Precinorm U plus (10 x 3 mL, for USA)	Code 300	
12149443 122	Precipath U plus (10 x 3 mL)	Code 301	
12149443 160	Precipath U plus (10 x 3 mL, for USA)	Code 301	
10171743 122	Precinorm U (20 x 5 mL)	Code 300	
10171735 122	Precinorm U (4 x 5 mL)	Code 300	
10171778 122	Precipath U (20 x 5 mL)	Code 301	
10171760 122	Precipath U (4 x 5 mL)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

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

MG-2: ACN 701 (serum and plasma)

MGU-2: ACN 704 (urine)

SMG2: ACN 688 (STAT, serum and plasma, reaction time: 4)

SMG2U: ACN 689 (STAT, urine, reaction time: 4)

For **cobas c** 502 analyzer:

MG-2: ACN 8701 (serum and plasma)

MGU-2: ACN 8704 (urine)

SMG2: ACN 8688 (STAT, serum and plasma, reaction time: 4)

SMG2U: ACN 8689 (STAT, urine, reaction time: 4)

Intended use

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

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

Magnesium along with potassium is a major intracellular cation. Mg^{2+} is a cofactor of many enzyme systems. Thus, all ATP-dependent enzymatic reactions require Mg^{2+} as a cofactor in the ATP-magnesium complex. Approximately 69 % of magnesium ions are stored in bone. The rest are part of the intermediary metabolism, about 70 % being present in free form while the other 30 % is bound to proteins (especially albumin), citrates, phosphate, and other complex formers. The Mg^{2+} serum level is kept constant within very narrow limits (0.65-1.05 mmol/L). Regulation takes place mainly via the kidneys, especially via the ascending loop of Henle.

This assay is used for diagnosing and monitoring hypomagnesemia (magnesium deficiency) and hypermagnesemia (magnesium excess). Numerous studies have shown a correlation between magnesium deficiency and changes in calcium-, potassium- and phosphate-homeostasis which are associated with cardiac disorders such as ventricular arrhythmias that cannot be treated by conventional therapy, increased sensitivity to digoxin, coronary artery spasms, and sudden death. Additional concurrent symptoms include neuromuscular and neuropsychiatric disorders. Hypermagnesemia is found in acute and chronic renal failure, magnesium excess, and magnesium release from the intracellular space.

In addition to atomic absorption spectrometry (AAS), complexometric methods can also be used to determine magnesium.

The method described here is based on the reaction of magnesium with xylidyl blue in alkaline solution containing EGTA to mask the calcium in the sample.

Urine magnesium levels are determined in magnesium depletion tests.

Test principle[5]

Colorimetric endpoint method

- Sample and addition of R1
- Addition of R2 and start of reaction:

  In alkaline solution, magnesium forms a purple complex with xylidyl blue, diazonium salt. The magnesium concentration is measured photometrically via the decrease in the xylidyl blue absorbance.

Reagents - working solutions

R1 TRIS[a] /6-aminocaproic acid buffer: 500 mmol/L, pH 11.25; EGTA: 129 µmol/L; preservative

R2 Xylidyl blue: 0.28 mmol/L; detergent; preservative

a) TRIS = Tris(hydroxymethyl)-aminomethane

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: For prescription use only.

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

Warning

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Prevention:

P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.

Product safety labeling primarily follows EU GHS guidance.
Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling
Ready for use

Storage and stability

MG

Shelf life at 15-25 °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
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 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.

Chelating anticoagulants such as EDTA, fluoride and oxalate must be avoided.

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.

Stability in *serum/plasma:*[6]	7 days at 15-25 °C
	7 days at 2-8 °C
	1 year at (-15)-(-25) °C

Urine:

Urine samples should be acidified to pH 1 with concentrated HCl to prevent precipitation of magnesium ammonium phosphate. Collect urine samples in metal-free container.[3] Urine samples are automatically prediluted with 0.9 % NaCl by the instrument.

Stability in *urine:*[6]	3 days at 15-25 °C
	3 days at 2-8 °C
	1 year 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 / 6-17 (STAT 4 / 6-17)	
Wavelength (sub/main)	505/600 nm	
Reaction direction	Decrease	
Units	mmol/L (mg/dL, mval/L)	
Reagent pipetting		Diluent (H_2O)
R1	97 µL	–
R2	97 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	9 µL	20 µL	100 µL
Increased	3 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-25 (STAT 4 / 10-25)	
Wavelength (sub/main)	505/600 nm	
Reaction direction	Decrease	
Units	mmol/L (mg/dL, mval/L)	
Reagent pipetting		Diluent (H_2O)
R1	97 µL	–
R2	97 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	9 µL	20 µL	100 µL
Increased	3 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-25 (STAT 4 / 10-25)	
Wavelength (sub/main)	505/600 nm	
Reaction direction	Decrease	
Units	mmol/L (mg/dL, mval/L)	
Reagent pipetting		Diluent (H_2O)
R1	97 µL	–

MG2

Magnesium Gen.2

R2	97 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3 µL	–	–
Decreased	9 µL	20 µL	100 µL
Increased	6 µL	–	–

Application for urine

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 6-17 (STAT 4 / 6-17)
Wavelength (sub/main)	505/600 nm
Reaction direction	Decrease
Units	mmol/L (mg/dL, mval/L)
Reagent pipetting	Diluent (H_2O)
R1	97 µL -
R2	97 µL -

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	14 µL	140 µL
Decreased	3 µL	14 µL	140 µL
Increased	6 µL	14 µL	140 µL

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-25 (STAT 4 / 10-25)
Wavelength (sub/main)	505/600 nm
Reaction direction	Decrease
Units	mmol/L (mg/dL, mval/L)
Reagent pipetting	Diluent (H_2O)
R1	97 µL -
R2	97 µL -

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	14 µL	140 µL
Decreased	3 µL	14 µL	140 µL
Increased	6 µL	14 µL	140 µL

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-25 (STAT 4 / 10-25)
Wavelength (sub/main)	505/600 nm
Reaction direction	Decrease
Units	mmol/L (mg/dL, mval/L)
Reagent pipetting	Diluent (H_2O)
R1	97 µL -
R2	97 µL -

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	6 µL	14 µL	140 µL
Decreased	3 µL	14 µL	140 µL
Increased	12 µL	14 µL	140 µL

Calibration

Calibrators	S1: H_2O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point calibration • after reagent lot change • as required following quality control procedures

Traceability: This method has been standardized against atomic absorption spectrometry.

For the USA, this method has been standardized against SRM 956.

Quality control

Serum/plasma

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

Urine

Quantitative urine controls are recommended for routine quality control.

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.

Conversion factors:	mmol/L x 2.43 = mg/dL
	mg/dL x 0.411 = mmol/L
	mval/L x 0.5 = mmol/L
	mval/L x 1.22 = mg/dL
	mval/L = mEq/L

Note: If the unit is changed from the primary unit mmol/L to mg/dL or to mVal/L the fields for sensitivity limit have to be checked and the following numbers have to be entered manually:

2. Unit mg/dL Sens Low = - 5967 Sens High = - 2547

3. Units mVal/L Sens Low = - 7250 Sens High = - 3095

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at a magnesium concentration of 0.7 mmol/L (1.7 mg/dL, 1.4 mval/L).

Serum/plasma

Icterus:[7] No significant interference up to an I index of 60 for conjugated bilirubin and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L).

Hemolysis:[7] No significant interference up to an H index of 800 (approximate hemoglobin concentration: 496 µmol/L (800 mg/dL)).

Hemolysis elevates results depending on the content of the analyte in the lysed erythrocytes.

Lipemia (Intralipid):[7] No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[8,9]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[10]

Urine

Drugs: No interference was found at therapeutic concentrations using common drug panels.[9]

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/Multiclean/SCCS or 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

Serum/plasma

0.10-2.0 mmol/L (0.243-4.86 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Urine

0.56-11.0 mmol/L (1.36-26.7 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Limit of Blank (LoB) and Limit of Detection (LoD)

Serum/plasma

LoB = 0.05 mmol/L (0.12 mg/dL)

LoD = 0.10 mmol/L (0.243 mg/dL)

Urine

LoB = 0.28 mmol/L (0.68 mg/dL)

LoD = 0.56 mmol/L (1.36 mg/dL)

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A 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 %).

Expected values[11]

Serum/plasma:

Newborn:	0.62-0.91 mmol/L	(1.5-2.2 mg/dL)
5 months-6 years:	0.70-0.95 mmol/L	(1.7-2.3 mg/dL)
6-12 years:	0.70-0.86 mmol/L	(1.7-2.1 mg/dL)
12-20 years:	0.70-0.91 mmol/L	(1.7-2.2 mg/dL)
Adults:	0.66-1.07 mmol/L	(1.6-2.6 mg/dL)
60-90 years:	0.66-0.99 mmol/L	(1.6-2.4 mg/dL)
> 90 years:	0.70-0.95 mmol/L	(1.7-2.3 mg/dL)

Urine (24 h):

3.0-5.0 mmol/d (72.9-121.5 mg/d)

Roche has not evaluated reference ranges in a pediatric population.

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 accordance with the CLSI (Clinical and Laboratory Standards Institue) EP5 requirements with repeatability and intermediate precision (2 aliquots per run, 2 runs per day, 21 days).
The following results were obtained:

Serum/plasma

Repeatability	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Precinorm U	0.891 (2.17)	0.008 (0.02)	0.9
Precipath U	1.73 (4.20)	0.01 (0.02)	0.8
Human serum 1	0.588 (1.43)	0.006 (0.01)	1.1
Human serum 2	0.797 (1.94)	0.007 (0.02)	0.8
Human serum 3	1.35 (3.3)	0.01 (0.0)	0.7
Intermediate precision	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Precinorm U	0.891 (2.17)	0.009 (0.02)	1.0
Precipath U	1.73 (4.20)	0.02 (0.05)	1.0
Human serum 1	0.588 (1.43)	0.008 (0.02)	1.3
Human serum 2	0.797 (1.94)	0.009 (0.02)	1.1
Human serum 3	1.35 (3.3)	0.01 (0.0)	0.9

Urine

Repeatability	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Liquicheck 1	2.16 (5.25)	0.03 (0.07)	1.4
Liquicheck 2	5.16 (12.5)	0.04 (0.1)	0.8
Human urine 1	1.50 (3.65)	0.03 (0.07)	1.8
Human urine 2	6.29 (15.3)	0.05 (0.1)	0.8
Human urine 3	9.59 (23.3)	0.06 (0.2)	0.6
Intermediate precision	*Mean*	*SD*	*CV*
	mmol/L (mg/dL)	*mmol/L (mg/dL)*	*%*
Liquicheck 1	2.16 (5.25)	0.03 (0.07)	1.5
Liquicheck 2	5.16 (12.5)	0.06 (0.2)	1.1
Human urine 1	1.50 (3.65)	0.03 (0.07)	2.1
Human urine 2	6.29 (15.3)	0.06 (0.2)	0.9
Human urine 3	9.59 (23.3)	0.07 (0.2)	0.8

Method comparison

Magnesium values for human serum/plasma and urine 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).

Serum/plasma

Sample size (n) = 75

Passing/Bablok[12]	Linear regression
y = 1.029x - 0.015 mmol/L	y = 1.031x - 0.019 mmol/L
τ = 0.985	r = 0.999

The sample concentrations were between 0.308 and 1.67 mmol/L (0.748 and 4.06 mg/dL).

Urine

Sample size (n) = 57

Passing/Bablok[12]	Linear regression
y = 1.025x + 0.043 mmol/L	y = 1.025x + 0.038 mmol/L
τ = 0.994	r = 1.00

The sample concentrations were between 0.630 and 10.5 mmol/L (1.53 and 25.5 mg/dL).

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.

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

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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