

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
20737593 322	Magnesium (175 tests)	System-ID 07 3759 3 COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	System-ID 07 3718 6
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	System-ID 07 7999 7
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6
12149443 160	Precipath U plus (10 × 3 mL, for USA)	System-ID 07 8000 6
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	System-ID 07 7469 3
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	System-ID 07 7470 7

English

System information

Test MG, test ID 0-059; test MGU, test ID 0-159

Intended use

In vitro test for the quantitative determination of magnesium in human serum, plasma, and urine on COBAS INTEGRA systems.

Summary^{1,2,3,4}

Magnesium is the fourth most abundant cation in the body, with about 50 % present in the bones associated with calcium and phosphate. Much of the remaining magnesium is intracellular and only a small amount is found in extracellular fluid. Magnesium functions as an activator for various physiochemical processes, including phosphorylation, protein synthesis, and DNA metabolism. It is also involved in neuromuscular conduction and excitability of skeletal and cardiac muscle.

Ingested magnesium is absorbed in the intestine and the amount absorbed is inversely related to the total magnesium intake. The kidneys effectively control magnesium homeostasis through tubular reabsorption, which conserves magnesium when intake is low and excretes excess when intake is high.

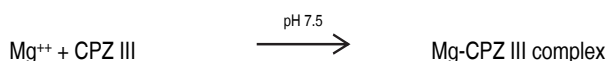
Increased serum magnesium concentrations occur in renal failure, acute diabetic acidosis, dehydration, or Addison's disease. Hypermagnesemia has a depressing effect on the central nervous system, causing general anesthesia and respiratory failure. It alters the conduction mechanism of the heart, causing cardiac arrest. Hypomagnesemia may be observed in chronic alcoholism, malabsorption, severe diarrhea, acute pancreatitis, diuretic therapy, prolonged parenteral fluid therapy without magnesium supplementation, and kidney disorders such as glomerulonephritis and tubular reabsorption defects. Decreased serum magnesium concentrations may result in tetany, convulsions, and cardiac arrhythmias.

Urine magnesium levels are determined in magnesium depletion tests.

Test principle

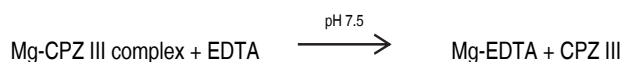
Colorimetric method with Chlorophosphonazo III.⁵

Chlorophosphonazo III (CPZ III) binds to magnesium and causes an absorbance increase at 659 nm. EGTA (ethylenedis(oxyethylenetriolo) tetra-acetic acid) is used to inhibit calcium binding to CPZ III.



Nonspecific absorbance interferences are reduced by the addition of EDTA (ethylenediaminetetra-acetic acid), which removes magnesium from the

magnesium-CPZ III complex and allows for an accurate sample blank measurement.



The difference in absorbance between the magnesium-CPZ III complex and the EDTA treated complex is the absorbance due to magnesium alone.

Reagents - working solutions

R1 TES^a: 145 mmol/L; pH 7.5; Chlorophosphonazo III: 0.2 mmol/L; EGTA: 10 mmol/L; preservative

SR TES^a: 100 mmol/L; pH 7.5; EDTA: 16 mmol/L; preservative

a) N-tris(hydroxymethyl)methyl-2-aminoethanesulfonic acid

R1 is in position B and SR is in position C.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

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:

P280 Wear eye protection/ face protection.

P280 Wear protective gloves.

Response:

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it 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

Shelf life at 15-25 °C See expiration date on
cobas c pack label

COBAS INTEGRA 400 plus system

On-board in use at 10-15 °C 8 weeks

COBAS INTEGRA 800 system

On-board in use at 8 °C 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 magnesiumammonium phosphate. Collect urine samples in metal-free container.³ Urine samples are automatically prediluted 1:5 (1+4) with water 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.

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.

Applications for serum, plasma, and urine**COBAS INTEGRA 400 plus test definition**

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction direction	Decrease
Wavelength A	652 nm
Calc. first/last	33/40
Unit	mmol/L
<i>Serum, plasma</i>	
Reaction mode	R1-S-SR
<i>Urine</i>	
Reaction mode	D-R1-S-SR

Predilution factor 5

Pipetting parameters

<i>Serum, plasma, and urine</i>		Diluent (H ₂ O)
R1	165 µL	
Sample	2 µL	50 µL
SR	28 µL	
Total volume	245 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction direction	Decrease
Wavelength A	659 nm
Calc. first/last	43/49
Unit	mmol/L
<i>Serum, plasma</i>	
Reaction mode	R1-S-SR
<i>Urine</i>	
Reaction mode	D-R1-S-SR
Predilution factor	5

Pipetting parameters

<i>Serum, plasma, and urine</i>		Diluent (H ₂ O)
R1	165 µL	
Sample	2 µL	50 µL
SR	28 µL	
Total volume	245 µL	

Calibration

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and 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 929 (IDMS).

Quality control

Quality control <i>serum, plasma</i>	Precinorm U, Precinorm U plus or PeciControl ClinChem Multi 1 Precipath U, Precipath U plus or PeciControl ClinChem Multi 2
Quality control <i>urine</i>	Quantitative urine controls are recommended for routine quality control.
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.

Calculation

COBAS INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factors:

mmol/L × 2.43 = mg/dL
mEq/L × 0.5 = mmol/L
mEq/L × 1.22 = mg/dL

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Serum/plasma

Icterus:⁷ 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:⁷ No significant interference up to an H index of 550 (approximate hemoglobin concentration: 341 µmol/L or 550 mg/dL). Hemolysis elevates results depending on the content of 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.

Therapeutic drug interference was tested according to the recommendations of the VDGH⁹. No interferences were found.

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

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.⁸

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

b) Verband der Diagnostica und Diagnostica Geräte Hersteller. Refer to "section 1 / Introduction" of this Method Manual for a list of drugs tested and their concentrations.

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

Serum/plasma

0.15-2.5 mmol/L (0.3-5 mEq/L)

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.

Urine

0.75-12.5 mmol/L (1.5-25 mEq/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Lower limits of measurement

Lower detection limit of the test:

Serum/plasma:

0.15 mmol/L (0.3 mEq/L)

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 = 30).

Urine:

0.75 mmol/L (1.5 mEq/L)

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 = 30).

Expected values⁹

Serum/plasma

Newborn:	0.62-0.91 mmol/L	(1.24-1.82 mEq/L)
5 months-6 years	0.70-0.95 mmol/L	(1.40-1.90 mEq/L)
6-12 years	0.70-0.86 mmol/L	(1.40-1.72 mEq/L)
12-20 years	0.70-0.91 mmol/L	(1.40-1.82 mEq/L)
Adults:	0.66-1.07 mmol/L	(1.32-2.14 mEq/L)
60-90 years	0.66-0.99 mmol/L	(1.32-1.98 mEq/L)
> 90 years	0.70-0.95 mmol/L	(1.40-1.90 mEq/L)

Urine (24 h) 3.0-5.0 mmol/d (6.0-10.0 mEq/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 COBAS INTEGRA 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 and intermediate precision (2 aliquots per run, 2 runs per day, 20 days). The following results were obtained:

Serum/Plasma

	Level 1	Level 2
Mean	1.4 mmol/L (2.8 mEq/L)	2.2 mmol/L (4.4 mEq/L)
CV repeatability	2.8 %	2.1 %
CV intermediate precision	2.9 %	2.3 %

Urine

	Level 1	Level 2
Mean	2.24 mmol/L (4.48 mEq/L)	4.85 mmol/L (9.70 mEq/L)
CV repeatability	5.2 %	4.0 %
CV intermediate precision	4.5 %	3.8 %

Method comparison

Magnesium values for human samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Magnesium reagent (y) were compared with those determined using reagents for magnesium on a COBAS MIRA analyzer (x) and a commercially available alternative clinical chemistry system (x). Samples were measured in duplicate. Sample size (n) represents all replicates.

Serum/plasma

		COBAS MIRA analyzer	Alternative system
Sample size	(n)	200	200
Corr. coefficient	(r)	0.969	0.994
	(r _s)	0.960	0.989
Linear regression		y = 0.95x + 0.11 mmol/L	y = 1.02x - 0.01 mmol/L

MG**Magnesium**

Passing/Bablok¹⁰ $y = 0.99x + 0.08 \text{ mmol/L}$ $y = 1.03x - 0.02 \text{ mmol/L}$

The sample concentrations were between 0.2 and 2.3 mmol/L (0.4 to 4.6 mEq/L).

Urine

		COBAS MIRA analyzer	Alternative system
Sample size	(n)	110	110
Corr. coefficient	(r)	0.995	0.997
	(r _s)	0.995	0.997
Linear regression		$y = 1.08x - 0.21 \text{ mmol/L}$	$y = 1.11x + 0.03 \text{ mmol/L}$
Passing/Bablok ¹⁰		$y = 1.08x - 0.20 \text{ mmol/L}$	$y = 1.10x + 0.03 \text{ mmol/L}$

The sample concentrations were between 1.15 and 11.6 mmol/L (2.30 to 23.2 mEq/L).




References

- 1 Jacob RA. Trace elements. In: Tietz NW, ed. Fundamentals of Clinical Chemistry. 3rd ed. Philadelphia: WB Saunders 1987;517-532.
- 2 Tsang R, Marder H. Bone disease. In: Kaplan LA, Pesce AJ, eds. Clinical Chemistry, theory, analysis, and correlation. St. Louis: Mosby Company 1984;439-459.
- 3 Tietz NW, ed. Clinical Guide to Laboratory Tests. 2nd ed. Philadelphia: WB Saunders 1990;380-383.
- 4 Ryan MF. The role of magnesium in clinical biochemistry: an overview. Ann Clin Biochem 1991;28:19-26.
- 5 Ferguson JW, Richard JJ, O'Laughlin JW, et al. Simultaneous spectrophotometric determination of calcium and magnesium with Chlorophosphonazo III. Anal Chem 1964;63:796-799.
- 6 Use of Anticoagulants in Diagnostic Laboratory Investigations. WHO Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
- 7 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.
- 8 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.
- 9 Wu AHB, ed. Tietz Clinical Guide to Laboratory Tests, 4th ed. Philadelphia, PA: WB Saunders Company 2006:706-709.
- 10 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.

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.

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

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Substrates

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