

DIAGNOSTIC KIT FOR DETERMINATION OF MAGNESIUM CONCENTRATION



ACCENT-200 MG

INTRODUCTION

Magnesium in human organism occurs mainly in bone (about 50%) but is present also intracellularly in other tissues. Magnesium serves as a cofactor for multiple enzymatic reactions involved in nucleic acids synthesis, transport and production of energy. Magnesium is important in neuromuscular conduction and activation. Reduced magnesium level generates: concentration disturbances, fatigue, muscle tremor, anxiety state.

METHOD PRINCIPLE

Magnesium forms a purple coloured complex in alkaline solution. In the presence of EGTA, the reaction is specific. The intensity of the purple colour is proportional to the magnesium concentration.

REAGENTS

Package

1-Reagent 2 x 14.5 ml

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. After first opening the reagent's stability on board of the analyser at 2-10°C is 3 weeks. The reagent is air sensitive, to extend reagents stability it is recommended to keep reagent's bottles recapped on the board of analyser. Protect from light and avoid contamination!

Concentrations in the test

xylidyl blue	0.15 mmol/l
EGTA	0.1 mmol/l
buffer (pH 11.5)	
detergent	

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- The reagent contains sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- It is recommended to use disposable plastic materials. If it is not possible, the glassware should be washed with 1% HCl solution and rinsed with plenty of distilled water.
- It is recommended to precede the MG test by wash cycle with ACCENT-200 ACID WASHING SOLUTION (Cat. no 3-109) using APPLICATION for WASHING in order to avoid interference with other tests.
- 1-Reagent meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

1-Reagent contains potassium hydroxide.

Danger



H314 Causes severe skin burns and eye damage.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with 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.

P310 Immediately call a POISON CENTER or doctor.

SPECIMEN

Serum, heparinized plasma free from hemolysis, 24-hours urine.

Recommended anticoagulants: heparine lithium, sodium or ammonium salt.

Serum should be separated from red blood cells as soon as possible after blood collection, because erythrocytes contain approximately 3 times the magnesium concentration found in normal serum.

Urine preparation: Acidify urine with some drops of concentrated hydrochloride acid to pH 1.0. Then dilute 1 part of acidified urine with 4 parts of distilled water. Multiply the result by 5. Mix well samples before analysis.

Serum and plasma can be stored up to 7 days at 2-8°C. For longer storage samples should be frozen at -20°C.

24-hours urine samples can be stored up to 7 days at 2-8°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

This reagent may be used in automatic analysers: ACCENT-200, ACCENT-200 II GEN, ACCENT-220S and BS-120 / BS-130.

1-Reagent is ready to use. Avoid foaming.

Actions required:

Use the reagent in conjunction with APPLICATION for WASHING (see page 3,4 of this instruction for use). A bottle of cleaning solution ACCENT-200 ACID WASHING SOLUTION (Cat. No 3-109) must be also put in reagent tray.

Deionised water is recommended as a reagent blank.

REFERENCE VALUES ⁶

serum / plasma	mg/dl	mmol/l	
newborn 2 – 4 d	1.5 – 2.2	0.62 – 0.91	
children 5 mo – 6 y	1.7 – 2.3	0.70 – 0.95	
	6 – 12 y	1.7 – 2.1	0.70 – 0.86
	12 – 20 y	1.7 – 2.2	0.70 – 0.91
adults	1.6 – 2.6	0.66 – 1.07	
24-hours urine:	mg/24h	mmol/24h	
	72.9 – 145.8	3 – 5	

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the following controls for each batch of samples:

CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) - for determination in serum;

CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) - for determination in urine.

For the calibration of automatic analysers: ACCENT-200, ACCENT-200 II GEN, ACCENT-220S, BS-120 / BS-130, the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177). Deionised water should be used as a calibrator 0.

The calibration curve should be prepared every week, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

The following results have been obtained using automatic analysers ACCENT-200 and/or ACCENT-200 II GEN, and/or ACCENT-220S. Results may vary if a different instrument or a manual procedure is used.

▪ **Sensitivity**

0.12 mg/dl (0.05 mmol/l) - ACCENT 200
0.12 mg/dl (0.05 mmol/l) - ACCENT 200 II GEN
0.12 mg/dl (0.05 mmol/l) - ACCENT 220S

▪ **Linearity**

up to 5.0 mg/dl (2.05 mmol/l) - ACCENT 200
up to 5.0 mg/dl (2.05 mmol/l) - ACCENT 200 II GEN
up to 5.0 mg/dl (2.05 mmol/l) - ACCENT 220S

▪ **Specificity / Interferences**

Haemoglobin up to 0.313 g/dl, ascorbate up to 62 mg/l, bilirubin up to 15 mg/dl, triglycerides up to 1000 mg/dl and calcium up to 20 mg/dl do not interfere with the test.

▪ **Precision**

Repeatability (run to run) n=10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.97	0.02	1.22
level 2	4.26	0.03	0.63
Reproducibility (day to day) n=10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	2.06	0.05	2.31
level 2	4.21	0.09	2.04

▪ **Method comparison**

A comparison between magnesium values determined at **ACCENT-200** (y) and at **ADVIA 1650** (x) using 25 samples gave following results:

$$y = 0.9218x + 0.0901 \text{ mg/dl};$$

$$R = 0.964 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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