Cat. No 4-529

DIAGNOSTIC KIT FOR DETERMINATION OF MAGNESIUM CONCENTRATION

HC – 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	6 x 97 ml

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagents in open bottles are stable for 5 weeks on board the analyser at 2-10°C. 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 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.

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 2-8ºC. For longer storage samples should be frozen at -20ºC.
24-hours urine samples can be stored up to 7 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
The reagent is ready to use. Avoid foaming.
This reagent may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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 CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) or LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended. Calibrators and deionised water should be used for calibration.
The calibration curve should be prepared every 2 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.12 mg/dl (0.049 mmol/l).
- **Linearity:** up to 9 mg/dl (3.69 mmol/l).
- **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	2.02	0.04	2.07
level 2	4.17	0.04	1.04

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	2.03	0.03	1.43
level 2	4.11	0.11	2.58

- **Method comparison**

A comparison between magnesium values determined at Hitachi 912 (y) and at ADVIA 1650 (x) using 101 samples gave following results:
y = 0.9533 x + 0.0956 mg/dl;
R = 0.9519 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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