

MAGNESIUM XL

MX 0300 CH	6 x 50 ml
MX 0500 CH	4 x 125 ml

INTENDED USE

Reagent for quantitative in vitro determination of magnesium in biological fluids.

SUMMARY OF TEST

Magnesium is not a true trace element. It is the fourth most abundant cation in the body and within the cell is second only to potassium. The adult human body (70 kg) contains 21 to 28 g of magnesium (approximately 1 mol). Magnesium catalyzes or activates more than 300 enzymes in the body. Magnesium acts as an essential cofactor for enzymes concerned with cell respiration, glycolysis, and transmembrane transport of other cations such as calcium and sodium. The permeability characteristics and electric properties of membranes are affected by magnesium.

PRINCIPLE OF THE METHOD

Xylidyl blue combines with magnesium at alkaline pH to form a purple complex, the absorbance of which is measured at 546 nm. Interference from other cations are avoided by specific chelating agents.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

MG-X R1 **0300: 6 x 50 ml (liquid) blue cap**
0500: 4 x 125 ml (liquid) blue cap

Composition: xylidyl blue 0.11 mM, NaCl 0.86 M, EGTA 0.25 mM, triethanolamine 0.7 mM, Good's buffer pH 11.0, surfactant, preservative.

Standard: magnesium solution 2 meq/l - 5 ml

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Reagent R1: ready to use.

Stability of unopened vials: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

MG- X R1: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

SPECIMEN

Serum (preferred), plasma heparinate. Do not use citrate, oxalate and EDTA as anticoagulant. The specimen should be drawn without venous stasis if possible. Do not use samples from patients in therapy with EDTA. Remove serum from clot without delay.

Serum or plasma samples are stable at 2-8°C for one week.

Urine samples have to be acidified in order to avoid precipitation (add 15 ml of concentrated HCl to 24/hours urine). Acidified urine are unsuitable for creatinine determination. Dilute sample urine 1:2 with redistilled water and multiply results by two.

TEST PROCEDURE

Wavelength:	546 nm (allowed 540 ÷ 550 nm)
Lightpath:	1 cm
Temperature:	25, 30 or 37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 µl

Mix, incubate at 25, 30 or 37°C for 2 minutes.
Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

serum/plasma sample:

magnesium meq/l = Ax/As x 2 (standard value)

urine sample:

magnesium meq/l = Ax/As x 2 x 2 (standard value and dilution factor)

24 hours urine sample:

magnesium meq/24h = Ax/As x 2 x 2 x urine volume (standard value, dilution factor and diuresis in decilitres)

EXPECTED VALUES

newborn 2-4 d:	1.20 - 1.80 meq/l	(0.60 - 0.90 mmol/l)
5 mo - 6 yrs:	1.42 - 1.88 meq/l	(0.71 - 0.94 mmol/l)
6 - 12 yrs:	1.38 - 1.74 meq/l	(0.69 - 0.87 mmol/l)
12 - 20 yrs:	1.35 - 1.77 meq/l	(0.67 - 0.88 mmol/l)
Adult:	1.30 - 2.10 meq/l	(0.65 - 1.05 mmol/l)

Urine: 6.0 - 10.0 meq/24h (3.0 - 5.0 mmol/24h)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QUANTINORM CHEMA

with normal or close to normal control values

QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 6 meq/l.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)

the limit of detection is 0.32 meq/l.

Interferences

no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 43 mg/dl
lipids	≤ 1100 mg/dl
calcium	≤ 33 mg/dl

Precision

intra-assay (n=10)	mean (meq/l)	SD (meq/l)	CV%
campione 1	2.09	0.03	1.29
campione 2	3.43	0.05	1.38

inter-assay (n=20)	mean (meq/l)	SD (meq/l)	CV%
campione 1	2.07	0.03	1.33
campione 2	3.41	0.04	1.29

Methods comparison

a comparison between Chema and a commercially available product gave the following results:

Magnesium XL Chema = x
Magnesium competitor = y
n = 86

$$y = 0.999x + 0.023 \text{ meq/l} \quad r^2 = 0.98$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

P. Burcar, A. Boyle, R. Mosher. - Clin.Chem. 10/11, 1028-1038 (1964).

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

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SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use