ISE S.r.l. **Magnesium** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 4x 17,5 mL **R3330000022** REF

Diagnostic reagent for quantitative in vitro determination of magnesium in human serum, plasma, cerebrospinal fluid or urine on photometric systems

TEST PARAMETERS

Method:	Colorimetric, endpoint, increasing / decreasing reaction (depending on wavelength), Xylidylblue
Wavelength:	520 nm, Hg 546 nm (500-550 nm) (increase of absorbance) 628 nm, Hg 623 nm, 570-650 nm (decrease absorbance)
Temperature:	20 – 25°C, 37°C
Sample:	Serum, plasma (do not use EDTA-plasma!), cerebrospinal fluid (CSF), urine
Linearity:	up to 5 mg/dL (2.05 mmol/L)
Sensitivity:	The lower limit of detection is 0.05 mg/dL (0.02 mmol/L)

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Ethanolamine, pH 11.0	750 mmol/L
Xylidyl Blue	110 µmol/L
GEDTA	60 µmol/L
(Glycoletherdiamine tetraacetic acid)	

SUMMARY [1,2]

Deficiency of magnesium is a quite common disorder which can be caused by malnutrition, malabsorption, renal loss and endocrinological disturbances. Complications associated with decreased magnesium cocentrations are neuromuscular irritability (e.g. tremor, seizures) and cardiac symptoms (e.g. tachycardia, arrhythmia). Decreased magnesium concentrations are often related to decreased calcium and potassium levels, taking into account that hypomagnesemia may be the primary cause of hypocalcemia.
Elevated magnesium values can be observed in dehydration, renal disorders and after intake of excessive amounts of antacids and can be associated with weakness of reflexed and low blood pressure.

TEST PRINCIPLE

Magnesium ions react with xylidyl blue to form a coloured complex in alkaline solution. The intensity of the purple colour is proportional to the magnesium concentration in the sample.
Interference by calcium is prevented by the use of GEDTA that complexes calcium ions.

REAGENT PREPARATION

The reagent is ready for use.

REAGENT STABILITY AND STORAGE

Conditions:	Close immediately after use Avoid contamination Do not freeze the reagent.
Storage:	at 2 – 8 °C
Stability:	up to the expiration date

SAMPLE PREPARATION

Urine: Acidify urine with some drops of conc. HCl to pH 3 – 4, then dilute 1+4 with dist. water. Multiply the result by 5.

SAMPLE STABILITY AND STORAGE [3]

Stability:

in serum / plasma:	at 20 – 25 °C	7 days
	at 4 – 8 °C	7 days
	at -20 °C	1 year
in urine:	at 20 – 25 °C	3 days
	at 4 – 8 °C	3 days
	at -20 °C	1 year

Do not use EDTA plasma!

Freeze only once!

Discard contaminated specimens!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit – has to be ordered separately)

Concentration	2 mg/dL (0.82 mmol/L)
Storage:	2 – 25 °C
Stability:	up to the expiration date

Close immediately after use! Avoid contamination!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µl
Std./Cal.	-	10 µl	-
Distilled water	10 µl	-	-
Mix. Incubate for 5 min. at 20 °C – 25 °C or 37 °C. Measure absorbance of standard/calibrator and sample against reagent blank within 60 minutes.			

CALCULATION

serum/plasma:

$$\text{Magnesium [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{conc. Std/Cal [mg/dL]}$$

urine:

$$\text{Magnesium (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{conc. Std/Cal (mg/dL)} \times 5$$

UNIT CONVERSION

mg/dL x 0.4114 = mmol/L

REFERENCE RANGE [1,6] *

Serum or plasma:

Neonates	1.2 – 2.6 mg/dL	0.48 – 1.05 mmol/L
Children	1.5 – 2.3 mg/dL	0.60 – 0.95 mmol/L
Females	1.9 – 2.5 mg/dL	0.77 – 1.03 mmol/L
Males	1.8 – 2.6 mg/dL	0.73 – 1.06 mmol/L

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Urine:	73 – 122 mg/24h	3 – 5 mmol/24 h
CSF:	2.1 – 3.3 mg/dL	0.85 – 1.35 mmol/L

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Linearity, MEASURING RANGE

The test has been developed to determine magnesium concentrations within a measuring range from 0.05 – 5 mg/dL (0.02 – 2.05 mmol/L).
If values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the results multiplied by 5.

SENSITIVITY/LIMIT OF DETECTION
The lower limit of detection is 0.05 mg/dL (0.02 mmol/L)

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1.88	0.02	0.92
Sample 2	2.34	0.02	0.87
Sample 3	4.02	0.03	0.83

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1.84	0.02	1.09
Sample 2	2.38	0.03	1.12
Sample 3	4.11	0.06	1.43

SPECIFICITY/INTERFERENCES
no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Triglycerides	2000 mg/dL
Calcium	25 mg/dL

Hemoglobin interferes because magnesium is released by erythrocytes. For further information on interfering substances refer to Young DS [7].

METHOD COMPARISON

A comparison of this Magnesium (y) and a commercially available test (x) using 81 samples gave following results:
y = 1.01 x – 0.03 mg/dL; r= 0.999.

QUALITY CONTROL

All control sera with Magnesium values determined by this method can be used.
Each laboratory should establish corrective action in case of deviations in control recovery.

CALIBRATION

The assay requires the use of a magnesium standard or calibrator.

WARNINGS AND PRECAUTIONS

1. Reagent: Danger.
   H315: Causes skin irritation.
   H318: Causes serious eye damage.
   P264: Wash hands and face thoroughly after handling.
   P280: Wear protective gloves/protective clothing/eye protection/face protection.
   P302+P352: If on skin: Wash with plenty of water/soap.
   P305+P351+P33/: 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 / physician.
   P308+P313: If exposed or concerned: Get medical advice/attention
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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Symbols on labels and packaging

IVD	=	In vitro diagnostic medical device
REF	=	Catalog Number
LOT	=	Lot Number
	=	Manufacturer
	=	Expiration date
	=	Temperature limitation
	=	Instruction for use

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