Magnesium – Instructions for use

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

4 x 50 mL • REF A-R0200000801
3 x 18,5 mL • REF R3330000022

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of Magnesium in human serum, plasma and urine. The results of the test must always be interpreted in conjunction with the clinical picture. For professional use only.

CLINICAL SIGNIFICANCE
About 55% of the total magnesium present in the human body is found in the bone, while the remaining portion is within the cells, bound to proteins or molecules with a negative charge. About 55% of the magnesium present in the serum is free, 30% is bound to proteins and 15% is in the form of compounds bound to phosphate or citrate ions. It is of fundamental importance in oxidative phosphorylation, in glycolysis and in cellular replication. The reference method for the determination of magnesium in serum and urine makes use of atomic absorption spectrophotometry. For routine diagnostic use, colorimetric assay methods have been developed based on compounding reactions between colouring substances (calmagite, methylthymol blue, titanium yellow, non-sulphonated derivatives of xylidyl-blue, xylidyl-blue). The reagent makes use of xylidyl blue which is more sensitive than other stains. Like the other colouring substances, it also compounds cations other than magnesium, and in particular calcium, and it must therefore be associated with a chelating agent which eliminates this type of interference (1.2).

PRINCIPLE
Xylidyl-blue forms a soluble coloured compound with magnesium in an alkaline ambient, with a maximum absorbance between 505 and 520 nm. The intensity of the colour of the Mg-xylidyl-blue compound is directly correlated to the magnesium concentration in the sample. Calcium interference is eliminated by including a specific chelator in the reagent: diethylene-glycol bis (2-amino-ethylether) N,N-N',N'-tetracetic acid (EDTA).

REAGENTS
A-R0200000801- 4 x 50 mL
Reagent: n° 4 vials x 50.0 mL ready for use
R3330000022 - 3 x 18,5 mL
Reagent: n° 3 vials x 14,0 mL ready for use

Concentrations

Reagent:			
	Conc.	**U.M.**	
TRIS	200	mmol/L	
Sodium carbonate	50.0	mmol/L	
Xylidyl-blue	0.10	mmol/L	
EDTA	0.10	mmol/L	**GHS05***

* *Warning*: **DANGER**
H314 - Causes severe skin burns and eye damage.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
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/doctor.
P321 - Specific treatment (see on this label).
P501 - Dispose of contents/container in accordance with local/ Regional /national / international regulations.

Precautions
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. A slight variation in the composition of the reagent may occur between batches, but this has no effect on the test results.
After opening, the vial are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

SAMPLE COLLECTION
Type of sample and storage
Non-hemolyzed human serum samples or plasma with the use of anticoagulants not containing magnesium-chelating agents should be used. Magnesium is stable in samples for at least 7 days at 2 - 8°C. If urine samples are used, they should be acidified with HCl 0.1 N to reach a pH value of 3 - 4.

Precaution
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Control sera with known levels of Magnesium are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera are available as "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user

Calibration
For calibration use the "Multicalibrator code R0300000006. For ISE srl instruments, the calibration every 10 days it is recommended.

Traceability:
The Magnesium traceability is reported in the package insert supplied with the ""Multicalibrator".

Reaction conditions
Wavelength (primary): 520 nm
Wavelength (secondary): 700 nm
Temperature: 37°C

Technique – Procedure with Serum as starter
Bring the reagents to the reaction temperature.

	U.M.	**Calib.Serum**	**Sample**	**Blank**
Reagent	µL	1000	1000	1000
Calib.Serum	µL	10	-	-
Sample	µL	-	10	-
Blank	µL	-	-	10

Mix then wait 3 minutes before reading.
If the blank reagent exceeds 0,800 D.O. at 520 nm, discard the reagent.
Read the absorbances of the sample (sample D.O.) and of the Calibration Serum (D.O. calibration serum) subtracting the absorbance of the reagent white. The final color is stable 30 minutes away from direct light.
The reaction volumes can be varied proportionately, the calculation remaining unchanged.

Results
The concentration of Magnesium is obtained through the following formula:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibration Serum}} \times \text{Calibrator Concentration} = \text{Magnesium (mg/dL)}$$

NORMAL VALUES
Serum or plasma: 1.53 - 2.55 mg/dL (0.63 - 1.05 mmol/L)
Urine: 75 - 125 mg/dL/24h (3.1 – 5.1 mmol/24 h)
Each laboratory should calculate its own normal values on the basis of its local population.

Sclavo Diagnostics International
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Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Calibrators and controls.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 5.00 mg/dL of Magnesium.

Accuracy-Recovery
Magnesium added to a serum matrix containing known amounts of Magnesium gave an average recovery of 104%.

Interference
Hemolysis of the sample causes interference due to the endoerythrocyte magnesium content.

Precision

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1.07	0.050	4.70%	20
High	mg/dL	4.21	0.070	1.66%	20
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1.07	0.016	1.49%	20
High	mg/dL	4.21	0.124	2.95%	20

Sensitivity
A concentration of 0.1 mg/dL of Magnesium in the sample at λ 505 nm.

Comparative method
The correlation test between the Magnesium method and a commercial method utilizing Xylidyl-blue gave the following results: Y = 0.8984x + 0.09; r = 0.923; Samples tested = no. 71.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
Sclavo Diagnostics International
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

1. Ranson, J.H.C., Curr. Prob. Surg., 16:1 (1979).
2. Salt, W.B., Schenker, S., Medicine, 55:269 (1976).
3. Stefanini, P., Ermini, M., Carboni, M., J. Am. Surg., 110:866 (1965).
4. Henry, R.J., Chiamori, M., Clin. Chem., 6:434 (1960).
5. Kaufman, R.A. and Tietz, N.W., Clin. Chem. 26:846 (1980).
6. Blair, H.E., U.S. Patent No. 4,649,108.
7. Chavez, R.G., et al., U.S. Patent No. 4,963,479.
8. NCCLS document "Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture", 2nd Ed., Harper & Row (1974).
9. Demetriou, J., et al., "Clinical Chemistry: Principles and Techniques", 2nd Ed., Harper & Row (1974).

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance