Magnesium – Method Xylidyl-blue
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182510	n° 12 vials x 20 mL
	REF B75182511	n° 8 vials x 10 mL
CHEMILAB	REF B81180141	n° 2 vials x 21 mL
	REF B81180142	n° 3 vials x 28 mL

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 context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE
Magnesium is the second most abundant intracellular cation in the human body after potassium, and is essential in a large number of enzymatic and metabolic processes. It is a cofactor of all enzymatic reactions involving ATP and includes the membrane that maintains the electrical excitability of the muscle and nerve cell. A low level of magnesium is found in malabsorption syndrome, diuretic or aminoglucoside therapy; hyperparathyroidism or diabetic acidosis. High magnesium values can be observed in dehydration, kidney disorders and after taking excessive amounts of antacids and may be associated with weakness of reflexes and low blood pressure. Clinical diagnosis should not be made on a single test result; It should integrate clinical data and other laboratory data.

PRINCIPLE OF THE METHOD
Method Xylidyl-blue. Xylidyl-blue forms a soluble coloured compound with magnesium in an alkaline ambient, with a maximum absorbance between 510 and 520 nm. The intensity of the colour of the Mg-xylidyl-blue compound is directly correlated to the magnesium concentration in the sample. The interference of calcium is eliminated by the addition of a chelating reagent specific: diethylene glycol bis (2-amino-ethyl ether) N, N-N ', N'-tetra acetic acid (EGTA).

Storage and stability
= Storage temperature 2-8°C
Stored unopened at the indicated temperature avoiding direct light, evaporation and contamination, reagents are stable until the expiration date printed on the label.

Concentrations

Reagents:			
	Conc.	U.M.	
TRIS	200	mmol/L	
Na_2CO_3	50.0	mmol/L	
Xylidyl-blue	0.10	mmol/L	
EGTA	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.

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls, calibrators and pipettes with adequate volume

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles)
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting 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.

PROCEDURE
Quality control
Control sera with a known titer of Magnesium are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration
For calibration use the "Calibrator serum Sclavo" code B35181702.

Traceability
The Magnesium traceability is reported in the package insert supplied with the "Calibrator Serum".

SAMPLE
Type of sample and storage
Non-haemolyzed 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 1.

PREPARATION OF THE REAGENT
Ready-to-use liquid reagent.
After opening, the reagent is stable for 30 days when the bottle is closed and kept at a temperature of 2-8°C away from direct light. Do not mix different batches, operate away from direct light. Slight variations in color from batch to batch, will not affect test results.

Automation
The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1/ C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD
The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions
Wavelength (primary): 520 nm
Temperature: 37°C
Reaction: End-Point (Increasing reaction)

Technical – procedure with Serum as starter
Bring the reagents to the reaction temperature and operate away from direct light.

	U.M.	Blank	Calibr. Serum	Sample
Reagent	µL	1000	1000	1000
Calibr. Serum	µL	-	10	-
Sample	µL	-	-	10
Blank	µL	10	-	-

If the blank overcomes 0.800 O.D. at 520 nm discard the reagent. Mix well and let stand for 3 minutes before reading at 37°C. Read the absorbance of sample (O.D. sample) and calibrator serum (O.D. calibrator serum) against reagent blank. Final colour is stable for at least 30 minutes, avoiding direct light.
The reaction volumes may be varied proportionally without alteration of results.

Sclavo Diagnostics International
Loc. Pian dei Mori, via Po n° 26-28 • 53018 (SI) (Italy)
Phone +39 0577 390 41 • fax +39 0577 390 444
www.sclavodiagnostics.com

Results:
Manual Method
Calculation of Magnesium concentration:
O.D. Sample (- Blank) x Calibr. Serum Concentration = Magnesium (mg/dL)
O.D. Calbr Serum (- Blank)

Automation
The results are automatically calculated by the analyzer based on the calibration curve/line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration curve/line is obtained through a special validated algorithm.

REFERENCE RANGE
Serum or plasma: 1,53 - 2,55 mg/dL (0,63 - 1,05 mmol/L)
Urine Random: 2.1 – 23.2 mg/dL (males < 40 years)
0.6 – 13.7 mg/dL (males i > 40 years)
1.2 – 18.7 mg/dL (females < 40 years)
0.4 – 15.0 mg/dL (females > 40 years)
Urine 24h: 6-10 mEq/day
Each laboratory should establish its own normal values according to the population in which it operates.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 5.5 mg/dL (2.26 mmol/L) of Magnesium. If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result for the dilution factor.

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

Recovery
Commercial control sera were analyzed with the kit in question following the guidelines of the CLSI protocol. The data obtained are shown in the table below.
Serum – Plasma

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	1.13	0.01	0.88	97.8 %
High	5	3.79	0.05	1.32	90.5 %

Urine

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	1.75	0.01	1.10	101.6 %
High	5	3.47	0.05	1.70	100.1 %

Precision of the method
Precision tests performed with control sera on automatic analyzers.

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	2.75	0.04	1.45	30
High	mg/dL	5.38	0.13	2.42	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	2.74	0.106	3.87	20
High	mg/dL	5.30	0.243	4.58	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is of about 0.23 mg/dL. at the conditions established for this test.

Comparison between methods
The Sclavo method for Magnesium was compared with a similar commercially available method. analyzing 60 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	-0.207
Slope	1.074
Correlation Coeff. (R)	0.998

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

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REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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