Tài liệu hướng dẫn sử dụng tiếng Anh của trang thiết bị y tế

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 27 tháng 10 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

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Magnesium

Xylidyl blue

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

Reagent with ATCS*

REF	Kit Size	Configuration
D01241B	1 x 1 L	Single Reagent
D01243	5 x 100 mL	Single Reagent
D01245	5 x 50 mL	Single Reagent
D01256	5 x 25 mL	Single Reagent
D01246	5 x 10 mL	Single Reagent
D78911	10 x 50 mL	Single Reagent
D0434917	9 x 65 mL	Single Reagent
DA0838	5 x 50 mL	Single Reagent
DT1038	4 x 50 mL	Single Reagent
DK0736	5 x 50 mL	Single Reagent
DE1838	5 x 20 mL	Single Reagent
DB20328	10 x 50 mL	Single Reagent

* Advanced Turbidity Clearing System; minimzes turbidity caused by lipemia.

Additionally available:

D95339	1 x 3 mL	Magnesium Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P
D08581	12 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08581SV	1 x 5 mL	Urine Ctrl. normal	Diacon Urine Level 1
D08582	12 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2
D08582SV	1 x 5 mL	Urine Ctrl. abnormal	Diacon Urine Level 2

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Colorimetric, endpoint, increasing/decreasing reaction (depending on wavelength), Xylidyl blue
Wavelength	520 nm, Hg 546 nm, 500 – 550 nm (Increase of absorbance) 628 nm, Hg 623 nm, 570 – 650 nm (Decrease of absorbance)
Optical path	1 cm
Temperature	20 – 25 °C / 37 °C
Sample	Serum, plasma (do not use EDTA-plasma!), cerebrospinal fluid (CSF), urine

INTENDED USE

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

DIAGNOSTIC SIGNIFICANCE [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 concentrations 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 purple 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 COMPOSITION

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

MATERIAL REQUIRED BUT NOT PROVIDED

- NaCl solution (9 g/L).
- Clinical chemistry analyser.

REAGENT PREPARATION

The reagent provided is ready to use.

STORAGE AND STABILITY

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

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.
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 or doctor/physician.
Special labelling: Contains Ethanolamine.

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!

SPECIMEN COLLECTION AND STORAGE

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.

Stability [3]:

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!
Only freeze once!
Discard contaminated specimens!

STANDARD

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

Concentration	2 mg/dL (0.82 mmol/L)
Storage:	2 – 8 °C
Stability:	up to the indicated expiration date

Protect from light!
Close immediately after use! Avoid contamination!

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.			

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

Calculation
With Standard or calibrator:

Serum/plasma:

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

Urine:

$$\text{Magnesium [mg/dL]} = \frac{\text{A Sample}}{\text{A Std / Cal}} \times \text{Conc. of Std / Cal [mg/dL]} \times 5$$

Unit Conversion
Magnesium [mg/dL] x 0.4114 = Magnesium [mmol/L]

QUALITY CONTROL AND CALIBRATION

All control sera with magnesium values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range) as well as the Dialab urine controls **Diacon Urine Level 1** (control urine normal) and **Level 2** (control urine abnormal).
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.
We recommend the Dialab **Magnesium Standard** and the Dialab multi calibration serum **Diacal Auto**.

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 Dialab 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.

TRACEABILITY

The assigned values of Diacal Auto have been made traceable to the reference method Atomic Absorption Spectrometry (AAS).

EXPECTED VALUES [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
Women	1.9 – 2.5 mg/dL	0.77 – 1.03 mmol/L
Men	1.8 – 2.6 mg/dL	0.73 – 1.06 mmol/L
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.

LIMITATIONS

- Eventual Magnesium, Xylidyl blue carry-over to reagents Alkaline Phosphatase (opt DGKC), Alkaline Phosphatase (mod. IFCC), LDH-L (IFCC), LDH-P (opt. DGKC), Phosphorus Inorganic (Molybdate), Bilirubin Auto Total (DCA) and Carbon Dioxide (PEP-C). The actual carry-over depends on the analyser.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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