DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

MAGNESIUM

Xylidyl blue with ATCS*

Single Reagent

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

Ref.No.	Kit Size	Content
DIA010172	5 x 25 ml	Single Reagent
DIA010173	5 x 50 ml	Single Reagent
DIA010174	5 x 100 ml	Single Reagent

Additionally offered:

DIA060080	1 x 3 mL	**Magnesium STANDARD**
DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)
DIA030030	1 x 5 mL	**Diacon Urine Level 1** (Control Normal)
DIA030035	1 x 5 mL	**Diacon Urine Level 2** (Control Abnormal)

* **A**dvanced **T**urbidity **C**learing **S**ystem; minimzes turbidity caused by lipemia

TEST PARAMETERS

Method: Colorimetric, endpoint, increasing reaction, Xylidylblue

Wavelength: 520 nm, Hg 546 nm(500-550 nm)

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
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.

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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 Diagnostica 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.
We recommend the Diagnostica 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 Diagnostica 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 Diagnostica**Magnesium Standard** and the Diagnostica multi calibration serum **Diacal Auto**.
The assigned values of Diacal Auto have been made traceable to the reference method Atomic Absorption Spectrometry (AAS).

AUTOMATION

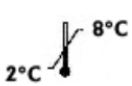
Special applications for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent: Danger.
   H315: Causes skin irritation.
   H318: Causes serious eye damage.
   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.
   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.

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