MAGNESIUM

Xylidyl Blue

Diagnostic reagent for determination of Magnesium concentration.

Liquid. Mono Reagent. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2280	5 x 50 mL	T2280	2703 Tests	BY2281	3535 Tests	M2280	2525 Tests
A2281	5 x 25 mL	T2281	811 Tests	N2280	758 Tests	M2281	1515 Tests
A2280N	500 mL	S2280	1636 Tests	N2281	424 Tests	L2280	5000 Tests
A2281N	200 mL	S2281	1636 Tests	K2280	2273 Tests	L2281	2667 Tests
TB2280	400 mL	BY2280	5051 Tests	K2281	1091 Tests	TB281	150 mL
TB2281	150 mL	DM2280	990 Tests	R2281	1364 Tests	R2280	990 Tests
M4280	2700 Tests	M4281	1650 Tests	PS2280	876 Tests		

INTENDED USE

The test is applied for the quantitative determination of magnesium in serum and plasma heparinate.

TEST PRINCIPLE

Xylidyl blue combines with magnesium at alkaline pH to form a purple complex, the absorbance of which is measured at 546 nm. Interference from other cautions is avoided by specific chelating agents.

TEST PARAMETERS

Method : Colorimetric, Endpoint,
Wavelength : 546 nm (540-550nm)
Temperature : Room temperature, 25, 30 or 37°C
Sample : Serum
Linearity : 0.45 mEq/L - 6 mEq/L

REAGENT COMPOSITION

Xylidyl blue	≤ 0.12 mM,
NaCl	≤ 0.90 M,
EGTA	≤ 0.26 mM,
Triethanolamine	≤ 0.8 mM,
Good's buffer	pH 11.0,
Surfactant,	
Preservative.	

REAGENT PREPARATION

Reagents are ready to use.

Stability of unopened vials is up to expiration date on labels at 2-8°C.

REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 60 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred), plasma heparinate are collected by standard procedures. Do not use citrate, oxalate and EDTA as anticoagulant. The specimen should be drawn without venous stasis if possible. Do not use samples from patients in therapy with EDTA. Remove serum from clot without delay. Serum or plasma samples are stable at 2-8°C for one week, 7 days at 20 - 25°C and 1 year at -20°C.

Urine samples have to be acidified in order to avoid precipitation (add 15 ml of concentrated HCl to 24/hours urine).
Acidified urine is unsuitable for creatinine determination.

Dilute sample urine 1:2 with redistilled water and multiply results by two.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Serum/plasma sample:
Magnesium mEq/L = Ax/As x 2 (standard value)

Urine sample: magnesium mEq/L = Ax/As x 2 x 2 (standard value and dilution factor)

24 hours urine sample:
Magnesium mEq/24h = Ax/As x 2 x 2 x urine volume. (Standard Value, Dilution Factor And Diuresis In Decilitres)

Unit Conversion

mg/dL x 0.4113 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Newborn
2-4 d : 1.20-1.80 mEq/L (0.60 - 0.90 mmol/L)
5 mo - 6 yrs : 1.42-1.88 mEq/l (0.71 - 0.94 mmol/L)
6 - 12 yrs : 1.38-1.74 mEq/l (0.69 - 0.87 mmol/L)
12 - 20 yrs : 1.35-1.77 mEq/l (0.67 - 0.88 mmol/L)

Adult : 1.30-2.10 mEq/l (0.65 - 1.05 mmol/L)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.

We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Magnesium Standard or a Magnesium Calibrator. We recommend:

ARCHEM Standard
Cat.No. A3960 (Conc. 2 mg/dL (0,822 mmol/L)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is **30 days.**

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 0.45 mEq/L

High Linearity: The method is linear up to 6 mEq/L.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
2.09 mEq/L	0.03	1.29%	10
3.43 mEq/L	0.05	1.38%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
2.07 mEq/L	0.03	1.33%	20
3.41 mEq/L	0.04	1.28%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 0.32 mEq/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 43 mg/dL
Lipids	≤ 1100 mg/dL
Calcium	≤ 33 mg/dL

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards

QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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