TRUEchemie Magnesium Test Kit (Xylidyl Blue)

for quantitative determination of Magnesium in serum or plasma

INTENDED USE

The TRUEchemie Magnesium Test Kit (Xylidyl Blue) is used for the quantitative determination of Magnesium in serum or plasma.

INTRODUCTION

Magnesium is one of the most abundant cations in the body involved in many biochemical reactions. Many enzymes such as alkaline phosphatase (ALP) require magnesium as activator. Magnesium is also necessary for the stability of conformational structure for many macromolecules such as DNA, RNA, etc.
Although little is known about the regulation of magnesium levels in blood, it has been reported that para-thyroid gland is involved. Increased level of magnesium has been observed in Addison's disease, diabetic acidosis, renal failure and vitamin D intoxication, and decreased level of magnesium are observed in diabetes, diuretics, hyperthyroidism, hyperalimentation, alcoholism, myocardial infarction, congestive heart failure and liver cirrhosis.

PRINCIPLE

Magnesium reacts with xylidyl blue to form a colored compound in alkaline solution. The intensity of the color formed is proportional to the magnesium in the sample.

Xylidyl Blue + Magnesium $\xrightarrow{OH^-}$ Xylidyl blue-Magnesium complex
(Bluish-purple)

PACK SIZE

Kit Size	50 T
Cat. No.	ADX435
1) Magnesium Reagent	50 x 1 ml
2) Magnesium Standard (2 mg/dL)	1 x 2 ml

REAGENT COMPOSITION

1) Magnesium Reagent

Buffer (pH 11.2 at 250 C)	:	68 mmol/L
Xylidyl blue	:	0.09 mmol/L
EGTA	:	0.13mmol/L
Surfactant	:	< 2% (w/v)
2) Magnesium Standard	:	2 mg/dL

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. To avoid contamination, use clean laboratory wares. It is recommended to use disposable tubes. Use clean, dry disposable pipette tips for dispensing. Reagent and standard bottles should be closed immediately after use. Avoid direct exposure to light.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
4. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 15-30°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

1. Serum, heparin and plasma are suitable for samples. Whole blood, hemolysis not recommended for use as a sample. Freshly drawn serum is the preferred specimen.
2. Use the suitable tubes or collection containers and follow the instruction of the manufacturer; avoid effect of the materials of the tubes or other collection containers.
3. Centrifuge samples containing precipitate before performing the assay.
4. Stability:
   Plasma must be assayed fresh.
   Serum: 7 days at 4-8 ºC
   1 year at -20 ºC

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 546 nm.

TEST PROCEDURE

Wavelength	:	546 nm
Temperature	:	37°C

Prewarm the Reagent to reaction temperature.

	Blank (µl)	Standard (µl)	Sample (µl)
Magnesium Reagent	1000	1000	1000
Magnesium Standard	--	10	--
Sample	--	--	10

Incubate all tubes at Room temperature for 3 minutes. After incubation, zero the photometer with the reagent blank at 546 nm. Read and record the incubated standards and samples.

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Newborns	: 1.8 - 2.8 mg/dL
Children	: 1.7 - 2.3 mg/dL
Adults	: 1.6 - 3.0 mg/dL

It is strongly recommended that each laboratory establishes its own normal range.

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.02 mg/dL
Linearity: upto 8.5 mg/dL under the described assay conditions. If the concentration is greater than linearity (8.5 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	1.98	0.04	2.00
Control Level - 2	4.28	0.05	1.21

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	1.99	0.03	1.61
Control Level - 2	4.31	0.04	1.00

The reagent was tested for 12 days, using two different Magnesium concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Magnesium reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.97 and the regression equation is y=0.987x+0.043. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Hemoglobin levels up to 500 mg/dL,
Lipemia levels up to 500 mg/dL,
Ascorbic acid levels up to 50 mg/dL,
Bilirubin levels up to 20 mg/dl were found to exhibit negligible interference.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	2
Wave length	:	546 nm
Units	:	mg/dL
Flow cell Temp.	:	37°C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	3 min. at Room Temperature
Low Normal	:	1.6
High Normal	:	3.0
Sensitivity	:	0.02
Linearity	:	8.5
Reaction slope	:	Increasing

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed.Frankfurt: TH-Books Verlagsgesellschaft; 1998.
2. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes; Preanalytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.
3. CLSI. Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline. CLSI document EP5-A [ISBN 1-56238-368-X]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA
4. Bagniski, E.S., et al, Selected Methods of Clinical Chemistry, Vol. 9, Washington (DC), AACC, pp. 227-281 (1982)
5. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight

Do not use if package is damaged — Contains sufficient for <n> tests

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