Magnesium Assay Kit (Mg)

Method: Colorimetry

Cat .No.	Size	Instrument
GB410E	6×50 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS411E	6×50 ml	For Hitachi917 & OlympusAU640/400/600
GX411E	1×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GD411E	36×4.3 ml	For DATE DENENSION

INTENDED USE

For the quantitative *in vitro* determination of Magnesium in human serum.

CLINICAL SIGNIFICANCE

Magnesium is one of the major intracellular cations in the body. Its action is closely related to that of calcium. Magnesium deficiency, hypomagnesaemia can result in various neuromuscular disorders, weakness, tremors, tetany and convulsions. It is associated with hypocalcaeia, intravenous therapy, diabetes mellitus, alcoholism, dialysis and pregnancy. Increased serum magnesium levels are associated with dehydration, severe diabetic acidosis and Addison's Disease. Conditions that interfere with glomerular filtration as in renal failure result in retention of magnesium and hence elevation of serum levels.

ASSAY PRINCIPLE

Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the colour intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA.

SAMPLE COLLECTION AND PREPARATION

Serum is the recommended sample. Stable for 7 days when stored at 2-8℃

REAGENT COMPOSITION

Contents	Concentration of Solutions
Tris Buffer	0.2 mmol/L
Xylidyl Blue	0.1 mmol/L, PH 10.7
K_2CO_3	77 mmol/L
EGTA	40 μmol/L
Stabilizer	

STABILITY AND PREPARATION OF REAGENTS

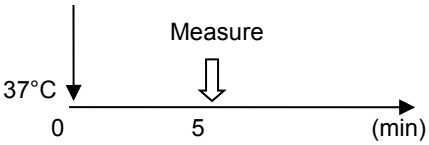
All reagents are ready to use.
Stable up to expiry date when stored at 2-8 °C.
The reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers

Assay Mode: END, 0-27
Wave Length (main/sub): 505 nm/800 nm

Sample:3 μl
R1: 300 μl



1. Mix 3 μl sample with 300 μl R1 and incubate at 37°C for 5 minutes
2. Measure final absorbance of the sample and standard against the reagent blank.
3. Calculate concentration.

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}}{\Delta A_{calibrator}} \times \text{Calibrator value}$$

CALIBRATION

Recommend Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiray date of kit and contents.

REFERENCE VALUE

Serum: 0.7-1.1 mmol/L.
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 3.04 mmol/L. If the samples above this concentration should be diluted 1:1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

PRECISION

The CV of the test should be ≤5%

Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	0.93	1.84
SD	0.012	0.016
CV	1.27%	0.89%
Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	0.96	1.82
SD	0.015	0.033
CV	1.57%	1.81%

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CE For professional use

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SENSITIVITY
The minimum detectable level has been determined as 0.061 mmol/L.

INTERFERENCE
The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin:	500 mg/dl
Intralipid:	100 mg/dl
Total Bilirubin:	90 mg/dl
Ascorbic Acid:	45 mg/dl
Ca^{2+}:	4 mmol/l

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
y = 0.969x+0.0383, R^2=0.9946; 110 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Solution contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Sunahara , et al,. United States Patent(5108905), Method of assaying *magnesium* in human body fluid, April 28, 1992
2. Kondou ,et al,. United States Patent(5,683,889), Reagent for measurement of *magnesium* ion, November 4, 1997
3. Murachi ,et al,. United States Patent(4778754), Reagent for determining the amount of *magnesium* ions, October 18, 1988
4. Fischer ,et al,. United States Patent(4275031), Agent and process for carrying out colorimetric or photometric determinations, June 23, 1981
5. Furuta ,et al,. United States Patent(5968833),Test piece and method of use for measuring *magnesium* in biological fluid, October 19, 1999.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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