MAGNESIUM (Mg)

XYLIDYL BLUE
COLORIMETRIC METHOD
RX SERIES

INTENDED USE

A magnesium test system is a device intended for the quantitative *in vitro* determination of magnesium concentration in serum, plasma and urine. This product is suitable for use on the RX **series** instruments, which includes the RX **daytona** and RX **imola**.

Cat. No.		
MG 3880	R1. Colour Reagent	6 x 20 ml

GTIN: 05055273204629

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 hypocalcaemia, 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.

PRINCIPLE[1-5]

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.

SPECIMEN COLLECTION AND PREPARATION [6, 7]

Serum, Plasma (not EDTA plasma) or urine. 24 hour urine collection may contain sediment that absorbs magnesium. Add drops of concentrated hydrochloric acid (pH 3 - 4) to dissolve the sediment. Urine samples are diluted 1+4 with saline on-board the analyser. Results are automatically recalculated. Serum, plasma and urine are stable for 7 days at +2 to +25°C.

REAGENT COMPOSITION

Contents Of Solutions	Initial Concentrations
R1. Colour Reagent	
Xylidyl blue	0.1 mmol/l
Tris Buffer	0.2 mmol/l
Potassium Carbonate	77 mmol/l
EGTA	0.04 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This kit contains components classified as hazardous in accordance with the Regulation (EC) No.1272/2008:

Signal Word(s) Danger

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.

Precautionary statement(s)

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of in compliance with all local, regional, national and international regulations.

Solution R1 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.

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.

Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

Supplied ready to use. Stable up to expiry date when stored at +2 to +8°C.

R1 = Colour Reagent
R2 = None

MATERIALS PROVIDED

Colour Reagent

WASH PROGRAM

The magnesium determination should be set up with an acid wash, via Maintenance/Wash screen on the RX **daytona**, or via Parameter/Wash screen on the RX **imola**.

Method 1	Method 2	R1→R1	R1→R2	R2→R1	R2→R2
*	MG	**Reagent Type** Wash Solution **Reagent Name** Acid Wash	Disable	**Reagent Type** Wash Solution **Reagent Name** Acid Wash	Disable

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Acid Wash Solution (Cat. No. WS 3853)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The tests should also not be in first and last position in the running order. This can be updated in the Parameter (F6) order screen**.**

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland, +44 (0) 28 9445 1070.

NOTE:

All equipment used must be free from magnesium contamination. Fluctuations in blank values of more than 10% in a series are more than likely due to magnesium contamination of the equipment.

CALIBRATION

0.9% NaCl as zero calibrator and Randox calibration sera level 3 are recommended for calibration.
Perform a new calibration:
- A reagent bottle is replaced by a new reagent bottle and the previous reagent bottle was recalibrated during use.
- When a reagent bottle of a new lot is loaded.
- At the end of the calibration interval.
- When indicated by quality control results.

STANDARDISATION

Randox Calibration Serum Level 3 is traceable to Magnesium reference material NIST 909b.

QUALITY CONTROL

Randox Assayed Multi-sera, 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 cleanliness of all equipment in use.
3. Check water. Contaminants, i.e. bacterial growth, may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCE

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	890 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipids	400 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [8]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES [9,10]

	ADULTS	
Serum/Plasma	0.7 - 1.1 mmol/l	(1.70 - 2.70 mg/dl)
Urine	2.1 - 8.2 mmol/24hrs/d	(50 - 200 mg/24hrs)

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

The following performance characteristics were obtained using a RX **daytona** analyser.

SERUM LINEARITY

This method is linear up to 3.27 mmol/l (8.01 mg/dl).

SENSITIVITY

The minimum detectable concentration of magnesium with an acceptable level of precision was determined as 0.280 mmol/l (0.681 mg/dl).

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	0.351	0.879	1.73
SD	0.015	0.024	0.033
CV(%)	4.19	2.68	1.91
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	0.337	0.903	1.75
SD	0.013	0.018	0.039
CV(%)	3.89	1.97	2.22
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y =1.04X - 0.01
and a correlation coefficient of 1.00

56 patient samples were analysed spanning the range 0.32 to 3.20 mmol/l.

URINE LINEARITY

This method is linear up to 21.4 mmol/l (52.0 mg/dl).

SENSITIVITY

The minimum detectable concentration of magnesium with an acceptable level of precision was determined as 0.199 mmol/l (0.484 mg/dl).

PRECISION

Intra precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.02	5.36	12.2
SD	0.057	0.107	0.465
CV(%)	5.60	2.00	3.82
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.31	7.32	15.9
SD	0.056	0.167	0.316
CV(%)	4.28	2.29	1.99
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y =0.91X + 0.23
and a correlation coefficient of 1.00

50 patient samples were analysed spanning the range 0.30 to 20.94 mmol/l.

REFERENCES

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The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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