

Magnesium XL FS*

Order Information

Cat. No.	Kit size	Instrument	
1 4610 99 10 971	R 3 x 13.8 mL	BX-3010	225 (3 x 75)
		BX-4000	171 (3 x 57)

Intended Use

Diagnostic reagent for quantitative in vitro determination of magnesium in human serum or heparin plasma on automated Sysmex BX-Series.

Summary

The essential trace element magnesium is the fourth most common cation in the human body and the second most common intracellular cation. It is mainly localized in the skeletal system (53%), muscles (27%) and in non-muscular tissue (19%). Only 1% of the total body magnesium stores is located in extracellular fluid [1]. Magnesium is a pivotal cofactor in many enzymatic processes. Furthermore, it is important in processes like oxidative phosphorylation, glycolysis, cell replication, nucleotide metabolism and protein biosynthesis [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 concentrations 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. Additionally, enhanced magnesium concentrations can be associated with weakness of reflexes and low blood pressure [1,2].

Method

Photometric test using xylidyl blue

Magnesium ions form a purple colored complex with xylidyl blue in alkaline solution. In presence of GEDTA, which complexes calcium ions, the reaction is specific. The intensity of the purple color is proportional to the magnesium concentration.

Reagents

Components and Concentrations

Ethanolamine	pH 11.0	750 mmol/L
Glycoetherdiamine-tetraacetic acid (GEDTA)		60 µmol/L
Xylidyl blue		110 µmol/L

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- Components contained in Magnesium XL FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ Reagent: Danger. Contains Ethanolamine. H315 Causes skin irritation. H318 Causes serious eye damage. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/doctor.

- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed

with the patient's medical history, clinical examinations and other findings.

- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Use TruLab N and TruLab P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 5 mg/dL (2.05 mmol/L), linearity is given within ± 5%.	
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.23 mg/dL (0.09 mmol/L)
Onboard stability	3 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration
Ascorbic acid	30 mg/dL	2.14 mg/dL (0.880 mmol/L)
Bilirubin (conjugated)	60 mg/dL	2.14 mg/dL (0.882 mmol/L)
Bilirubin (unconjugated)	60 mg/dL	2.13 mg/dL (0.874 mmol/L)
Hemolysis	200 mg/dL	2.41 mg/dL (0.993 mmol/L)
Lipemia (triglycerides)	1800 mg/dL	2.33 mg/dL (0.957 mmol/L)

For further information on interfering substances, refer to the literature [5-7].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.78	2.46	5.06
Mean [mmol/L]	0.733	1.01	2.08
CV [%]	2.40	1.48	0.975
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.79	2.27	5.04
Mean [mmol/L]	0.736	0.935	2.08
CV [%]	3.30	2.25	1.53

Method comparison (n=111)	
Test x	DiaSys Magnesium XL FS (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Magnesium XL FS (BX-4000)
Slope	1.05
Intercept	-0.059 mg/dL (-0.024 mmol/L)
Coefficient of correlation	0.992

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor

Magnesium [mg/dL] x 0.4114 = Magnesium [mmol/L]

Reference Range

Serum/Plasma [1]:

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
Women	1.9 – 2.5 mg/dL	0.77 – 1.03 mmol/L
Men	1.8 – 2.6 mg/dL	0.73 – 1.06 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 03 05]. Available from: <https://www.clinical-laboratory-diagnostics.com>
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395-1457.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.
4. W.G. Guder, F. da Fonseca-Wollheim, W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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www.diasys-diagnostics.com

* Fluid Stable

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																										
Method No.	*	Method Name	MG	Reagent Name	Reagent (µL)	Water (µL)																								
Print Name	Magnesium	MethodColor		R1	MG	150																								
Sample Type	Serum			R2	Disable																									
Unit	mg/dL			Diluent	Disable																									
Assay Type	End			Sample Ppt. Wash	Disable																									
Measuring points		Start	End	Stirring Speed R1	Low	R2																								
	1	45	46																											
	2	Disable																												
Wave Length	Prim.	546	Sec.	700																										
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4">Normal Range</th> </tr> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>							Normal Range				No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
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1	Male-G1	*	*																											
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3	Male-G3	*	*																											
4	Female-G1	*	*																											
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range	(Conc)	0.23 - 5.0																								
<input type="checkbox"/> Diluent	Low 0.0 < Normal 1.5 < High 0.0				(mAbs/10)	* - *																								
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)		* - * %																								
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Abnormal Range	(Conc)	* - *																								
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc)	* - *																								
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Decimal Point	2	Profile SI																								
Disable																														
*Entered by user																														

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	MG	Sample	Serum	
Limit Checks <input checked="" type="checkbox"/> Duplicate Limit 250 mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit 1500 mAbs/10 <input checked="" type="checkbox"/> Linearity Limit % (mAbs/10)/min <input type="checkbox"/> Prozone Limit Higher % SL1-S - SL1-F SL2-S - SL2-F Sensitivity mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction Increase Limit 25000 mAbs/10				Blank measurement Blank measurement: Disable reagent blank and C1 blank Measurement of Reagent Blank during Run: None Reagent blank measurement at calibration: Reagent blank (No sample) The number of measurement: Duplicate Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit 50 mAbs/10		
Instrument Factor a 1.00 b 0.00						

Magnesium XL FS

Chemistry Code 100 61

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

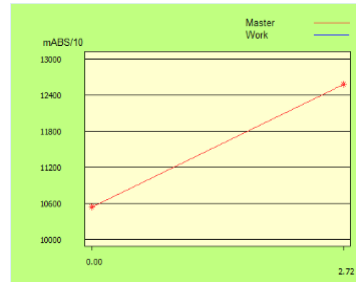
Reagent Lot

Calibrator Name

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	* <input type="text"/>	Name	<input type="text" value="MG"/>	Reagent Name	<input type="text"/>																				
Print Name	<input type="text" value="Magnesium"/>	R1	<input type="text" value="MG"/>	Reagent (µL)	<input type="text" value="200"/>																				
Sample	<input type="text" value="Serum"/>	R2	<input type="text"/>	Water (µL)	<input type="text"/>																				
Unit	<input type="text" value="mg/dL"/>	<input checked="" type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
Assay Type	<input type="text" value="End"/>	Diluent	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
Measuring points	Start	End	Decimal Points	<input type="text" value="0"/>																					
	1	<input type="text" value="67"/> - <input type="text" value="68"/>																							
<input type="checkbox"/> Enable	2	<input type="text"/> - <input type="text"/>																							
Wave Length	Prim. <input type="text" value="546"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="700"/>																					
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4	Female-G1	*	*																						
<input type="checkbox"/> Normal Dilution <input type="text" value="2.0"/>		<input type="checkbox"/> Sampling Sample (µL) <input type="text"/> Diluent (µL) <input type="text"/>		Technical Range (Conc) <input type="text" value="0.23"/> - <input type="text" value="5.0"/> (mAbs/10) <input type="text"/> - <input type="text"/>																					
<input type="checkbox"/> Rerun (High/Prozone) <input type="text"/>		<input type="checkbox"/> Dilution <input type="text" value="2.0"/>		<input type="checkbox"/> Rerun (Low) <input type="text"/>																					
<input type="checkbox"/> Dilution <input type="text" value="2.0"/>		SPT Wash <input type="checkbox"/> Enable <input type="text"/>		Reagent Name <input type="text"/>																					
		Stirring Speed R1 <input type="text" value="Low"/> R2 <input type="text"/>																							

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters					
Method No.	* <input type="text"/>	Name	<input type="text" value="MG"/>	Sample	<input type="text" value="Serum"/>		
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;"> Limit Checks <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="250"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="1500"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text"/> % <input type="text"/> (mAbs/10)/min <input type="checkbox"/> Prozone Limit <input type="text"/> % <input type="text" value="Upper"/> SL1-S <input type="text"/> - SL1-F <input type="text"/> SL2-S <input type="text"/> - SL2-F <input type="text"/> Sensitivity <input type="text"/> mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Reaction <input type="text" value="Increase"/> Limit <input type="text" value="25000"/> mAbs/10 </td> <td style="width:50%;"> Blank measurement Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/> Measurement of Reagent Blank during Run: <input type="text" value="None"/> Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/> The number of measurement: <input type="text" value="Duplicate"/> Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="50"/> mAbs/10 </td> </tr> </table>						Limit Checks <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="250"/> mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit <input type="text" value="1500"/> mAbs/10 <input checked="" type="checkbox"/> Linearity Limit <input type="text"/> % <input type="text"/> (mAbs/10)/min <input type="checkbox"/> Prozone Limit <input type="text"/> % <input type="text" value="Upper"/> SL1-S <input type="text"/> - SL1-F <input type="text"/> SL2-S <input type="text"/> - SL2-F <input type="text"/> Sensitivity <input type="text"/> mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Reaction <input type="text" value="Increase"/> Limit <input type="text" value="25000"/> mAbs/10	Blank measurement Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/> Measurement of Reagent Blank during Run: <input type="text" value="None"/> Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/> The number of measurement: <input type="text" value="Duplicate"/> Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="50"/> mAbs/10
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Instrument Factor a <input type="text" value="1.00"/> b <input type="text" value="0.00"/>							

<u>Registration Calibration</u>		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																	
Method <input type="text" value="*"/> Name <input type="text" value="MG"/>	R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/>																																																		
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<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">WORK</th> <th style="width: 15%;">MASTER</th> <th style="width: 15%;">Lot No. (S)</th> <th style="width: 10%;"><input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td>0</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All	S1	0	Automatic entry	Automatic entry			S2	*	Automatic entry	Automatic entry			S3	*					S4	*					S5	*					S6	*					S7	*				
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