

Magnesium XL FS*

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

Order Information

Cat. No.	Kit size	Number of tests
1 4610 99 10 971	R 3 x 13.8 mL	BX-3010 3 x 75 tests BX-4000 3 x 57 tests

Method

Photometric test using xylidyl blue

Principle

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
GEDTA (Glycoetherdiamine tetraacetic acid)		60 µmol/L
Xylidyl blue		110 µmol/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagent!

Warnings and Precautions

1. Reagent 1 Danger. 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 or doctor/physician.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets 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.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum and plasma (do not use EDTA plasma!)

Stability [1]:

in serum/plasma	7 days at	20 – 25°C
	7 days at	4 – 8°C
	1 year at	-20°C

Freeze only once.

Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. For internal quality control DiaSys TruLab N and P controls should be assayed. The assigned values of the calibrator have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Each laboratory should establish corrective action in case of deviations in control recovery.

		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 5.0 mg/dL (2.05 mmol/L) magnesium (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) Mg
On-board stability	3 weeks
Calibration stability	3 weeks

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

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	2.14 mg/dL (0.880 mmol/L)
Hemoglobin	up to 200 mg/dL	2.41 mg/dL (0.993 mmol/L)
Bilirubin, conjugated	up to 60 mg/dL	2.14 mg/dL (0.882 mmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	2.13 mg/dL (0.874 mmol/L)
Lipemia (triglycerides)	up to 1800 mg/dL	2.33 mg/dL (0.957 mmol/L)

For further information on interfering substances refer to Young DS [7].

Precision BX-3010			
Within run (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
Coefficient of variance [%]	2.40	1.48	0.975
Between run (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
Coefficient of variance [%]	3.30	2.25	1.53

Method comparison (n=111)	
Test x	Magnesium XL FS (BioMajesty 6010C)
Test y	Magnesium XL FS (BX-4000)
Slope	1.05
Intercept	-0.059 mg/dL (-0.024 mmol/L)
Coefficient of correlation	0.992

Conversion factor

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

Reference Range [2,3]

Serum/Plasma:

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. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001: 38-39, 50-51.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 339-40.
3. Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH: 1986. p. 166.
4. 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.
5. Mann CK, Yoe JH. Spectrophotometric determination of magnesium with 1-Azo-2-hydroxy-3-(2.4-dimethyl-carboxanilido)-naphthalene-1'-(2-hydroxybenzene). Anal Chim Acta 1957; 16 : 155-60.
6. Bohoun C. Microdosage du magnesium dans divers milieux biologiques. Clin Chim Acta 1962; 7: 811-7.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

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

*Entered by user

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

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

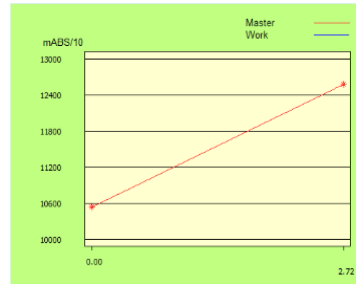
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Magnesium XL FS

Chemistry Code 100 61

Chemistry Parameters			Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																							
Method	*	Name MG		Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Magnesium		R1	MG	200																					
Sample	Serum		R2	<input type="checkbox"/> Enable																						
Unit	mg/dL																									
Assay Type	End		Diluent	<input type="checkbox"/> Enable																						
Measuring points	Start	End	Decimal Points	0																						
	1	67 - 68																								
<input type="checkbox"/> Enable	2																									
Wave Length	Prim.	546	Sec	<input type="checkbox"/> Disable	700																					
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1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
<input type="checkbox"/> Normal Dilution		Sampling 2.0	Sample (µL)	Diluent (µL)	Technical Range (Conc) 0.23 - 5.0 (mAbs/10)																					
<input type="checkbox"/> Rerun (High/Prozone)																										
<input type="checkbox"/> Dilution		2.0																								
<input type="checkbox"/> Rerun (Low)																										
<input type="checkbox"/> Dilution		2.0																								
				SPT Wash	<input type="checkbox"/> Enable	Reagent Name																				
				Stirring Speed	R1	Low R2																				

*Entered by user

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

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method Name

Sample

Sampling

Check Interval days

Auto

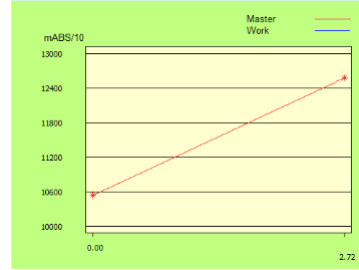
Auto Interval hours

Type Lot

Material Name

R Lot No. R1
R2

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K S1 Blank Reagent Blank for S1

*Entered by user