ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

FIELD SAFETY NOTICE (FSN)
In addition to the two (2) safety notices of March and October 2022 related to the MAGNESIUM XB reagent.

January 4th, 2023

Dear Distributor, Dear valued Customer,

Our traceability indicates that you may have received the following products:

Commercial Designation	*References*	*Batch numbers*	*Expiration dates*
MAGNESIUM XB	MGXB-0250	21-0121	2023-01-31
		21-0320	2023-03-31
		21-0484	2023-04-30
		21-0749	2023-07-31
		21-1164	2023-10-31
		*20-0816	2022-06-30
		*20-1073	2022-06-30
		*20-1192	2022-10-31
		**21-0660	2023-06-30
		**21-0939	2023-09-30
		**22-0087	2024-01-31
	MGXB-0600	21-0413	2023-03-31
		21-0483	2023-03-31
		21-0505	2023-04-30
		21-0750	2023-05-31
		21-0753	2023-07-31
		21-0902	2023-07-31
		21-1165	2023-10-31
		*20-0817	2022-06-30
		*20-1056	2022-06-30
		*20-1193	2022-06-30
		*20-1194	2022-06-30
		**21-0661	2023-06-30
		**21-0938	2023-09-30
		**22-0088	2024-01-31

Table 1: Batch list for the references MGXB-0250 and MGXB-0600

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Commercial Designation	*References*	*Batch numbers*	*Expiration dates*
MAGNESIUM XB	MGXB-M430	21-0321	2023-03-31
		**21-0940	2023-09-30
		**21-0086	2024-01-31

Table 2: Batche list for the reference MGXB-M430

The purpose of this notification is to follow-up on March and October 2022 communications informing you that the linearity of the products listed in Tables 1&2 may not be in accordance with the IFU; and to provide you with instructions on the actions to be taken by your laboratory.

* lots notified on March 2022

** lots notified on October 2022

Explanations

This letter is to notify you that the linearity claims of MAGNESIUM XB (ref. MGXB-0250, MGXB-0600 and MGXB-M430) may not be met.
Internal tests demonstrated a risk of underestimation.

The above mentioned 28 batches correspond to all batches manufactured prior batch 22-0178. From batch 22-0178 the manufacturing process (cause of this over the time linearity issue) has been modified.

Patient Impact

The biases observed should not significantly impact the clinical management of patients, given that the pathological findings remain identified as pathological (> 2.6 mg/dL or 1.07 mmol/L for serum sample; and > 8.1 mg/dL or 3.3 mmol/L for urine sample). Therefore, the overall risk to health is negligible and this is the reason why ELITech Clinical Systems SAS **is not recommending a review of previously generated results**.
Any clinical impact though would be mitigated by consideration of clinical symptoms and additional laboratory tests, such as Calcium and Potassium.

ELITech Clinical Systems SAS is not aware of any reports of risk to patient health as a result of this finding.

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Actions to be taken by laboratory/user	*Serum samples having concentration*: - **from 3.5 to 17.5 mg/dL** (1.44 to 7.20 mmol/L) should be **diluted manually 1:5** in 9 g/L NaCl solution and reassayed. - **> 17.5 mg/dL** (7.20 mmol/L) should be **diluted manually 1:10** in 9 g/L NaCl solution and reassayed. *Urine samples having concentration* - **from 16 to 80 mg/dL** (6.6 to 32.9 mmol/L) should be **diluted manually 1:5** in 9 g/L NaCl solution and reassayed. - **> 80 mg/dL** (32.9 mmol/L) should be **diluted manually 1:10** in 9 g/L NaCl solution and reassayed.
Actions to be taken by Distributor	1. Provide a copy of this FSN to all customers who have received ELITech Clinical Systems SAS MAGNESIUM XB reagent. 2. Ensure that this information is distributed to all relevant personal in your organisation and keep a copy on file. 3. Complete and return to ELITechGroup the acknowledgement of receipt attached within 8 days.

The French Competent Authority (ANSM) has been notified of the distribution of this FSN.

Conscious of the disturbances that this situation may cause in your laboratories, we remain at your disposal should you require any further information or clarification.

Sincerely yours,

Valérie LAMBERT

Regulatory Affairs Manager

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REPLY FORM ACKNOWLEDGING RECEIPT
Safety Notice
Only for the lots below

Designation	*Reference Code*	*Lot #*	*Expiry date*
MAGNESIUM XB	MGXB-0250	21-0121 21-0320 21-0484 21-0749 21-1164	2023-01-31 2023-03-31 2023-04-30 2023-07-31 2023-10-31
	MGXB-0600	21-0413 21-0483 21-0505 21-0750 21-0753 21-0902 21-1165	2023-03-31 2023-03-31 2023-04-30 2023-05-31 2023-07-31 2023-07-31 2023-10-31
	MGXB-M430	21-0321	2023-03-31

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REPLY FORM ACKNOWLEDGING RECEIPT
Safety Notice
Only for the lots indicated in the previous page 4.

COMPANY NAME : .....

ADDRESS : .....
.
PHONE NUMBER : ..... Email : .....

☑	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Name and signature distributor Date to complete
☐	I have checked my stock and quarantined inventory	
☑	I have identified customers that received or may have received this device	Name and signature distributor Date to complete
☐	I have attached customer list	
☑	I have informed the identified customers of this FSN	Name and signature distributor Date to complete
☑	I have received confirmation of reply from all identified customers	Name and signature distributor Date to complete
☐	I have returned affected devices - enter number of devices returned and date complete.	
☐	I have destroyed affected devices – enter number destroyed and date complete.	
☐	Neither I nor any of my customers has any affected devices in inventory	

By signing above, I acknowledge that I have read the Field Safety Notice regarding ELITechGroup MAGNESIUM XB (Ref. MGXB-XXXX) and will fully implement the recommended actions.

Document to return by email to: Valérie LAMBERT
Email : v.lambert@elitechgroup.com