

UPDATE ON INFORMATION RELATING TO THE FIELD SAFETY NOTICE (FSN) ON MARCH 2022 ABOUT MAGNESIUM XB REAGENT

October 31st, 2022

Dear Distributor, dear valued customer,

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

Commercial Designation	References	Batch numbers	Expiration date
MAGNESIUM XB	MGXB-0250	21-0660	2023-06-30
		21-0939	2023-09-30
		22-0087	2024-01-31
	MGXB-0600	21-0661	2023-06-30
		21-0938	2023-09-30
		22-0088	2024-01-31
	MGXB-M430	21-0940	2023-09-30
		21-0086	2024-01-31

Table 1: Product list

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

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.

As a result of Internal investigations on all manufactured lots undertaken to determine the root cause, the origin of this problem is due to the manufacturing process.

In light of this, the manufacturing process has been modified and implemented from Lot 22-0178.

Based on this improvement, ELITech Clinical Systems is confident that this problem is resolved and the future batches will perform in accordance with specifications.

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.

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,

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



Valérie LAMBERT

Regulatory Affairs Manager

REPLY FORM ACKNOWLEDGING RECEIPT Safety Notice

COMPANY NAME :

ADDRESS :

PHONE NUMBER : Email :

<input checked="" type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Name and signature distributor Date to complete
<input type="checkbox"/>	I have checked my stock and quarantined inventory	
<input checked="" type="checkbox"/>	I have identified customers that received or may have received this device	Name and signature distributor Date to complete
<input type="checkbox"/>	I have attached customer list	
<input checked="" type="checkbox"/>	I have informed the identified customers of this FSN	Name and signature distributor Date to complete
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	
<input type="checkbox"/>	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