

FIELD SAFETY NOTICE

March 4th, 2022

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	20-0816	2022-06-30
		20-1073	2022-06-30
		20-1192	2022-10-31
	MGXB-0600	20-0817	2022-06-30
		20-1056	2022-06-30
		20-1194	2022-06-30
		20-1193	2022-06-30

Table 1: Product list

The purpose of this notification is to inform 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 claim of MAGNESIUM XB (ref. MGXB-0250, MGXB-0600) may not be met.

Internal tests demonstrated a risk of underestimation up to 11.5% for serum sample at 3.65 mg/dl (1.50 mmol/L); and up to 13.8 % for urine sample at 17.1 mg/dl (7.0 mmol/L).

Internal investigations are underway to identify the origin of the problem.

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.
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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,

Valerie LAMBERT

Regulatory Affairs Manager



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REPLY FORM ACKNOWLEDGING RECEIPT Safety Notice

COMPANY NAME :

ADDRESS:

PHONE NUMBER : Email :

<input checked="" type="radio"/>	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="radio"/>	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="radio"/>	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: Valerie LAMBERT
Email: v.lambert@elitechgroup.com

