ELITech Clinical Systems SAS
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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 21-0939 22-0087	2023-06-30 2023-09-30 2024-01-31
	MGXB-0600	21-0661 21-0938 22-0088	2023-06-30 2023-09-30 2024-01-31
	MGXB-M430	21-0940 21-0086	2023-09-30 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.

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	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,

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Regulatory Affairs Manager

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REPLY FORM ACKNOWLEDGING RECEIPT
Safety Notice

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	
☐	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: …