

RANDOX

Urgent Field Safety Notice

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Date Issued: 12th February 2020

Complaint Reference: Recall 439

Action Type: Field Correction

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Chemistry QC Premium Plus (Liq)	LAL4213	05055273209006	306UL	28/12/2020	10/04/2019

Reason for Action:

Randox can confirm the control target and range value for Sodium using the ISE indirect method has been assigned incorrectly. The sections for Roche Cobas series and mean of all instruments have now been updated.

Updated value sheets are now available on www.randox.com and attached to this contact.

Risk to Health:

Quality control results which are not within range can lead to a delay in reporting results.

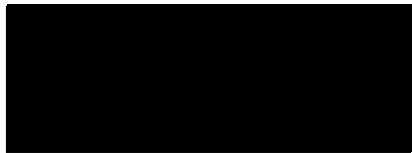
Action to be taken:

- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency



Please complete this form even if you do not have any affected stock.

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Please check ALL appropriate boxes.

- ☐ I have read and understand the instructions provided in the Field Safety Notice.
- ☐ I have checked my stock and identified the affected kits.
- ☐ I have notified all those who need to be aware of this notice within the organisation.
- ☐ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ☐ no affected stock
- ☐ returned (*specify quantity, date and method*)/held for return;
- ☐ destroyed (*specify quantity, date and method*);
- ☐ relabelled (*specify quantity and date*);
- ☐ quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ☐ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

OR

- ☐ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Have your customers notified you of any adverse events associated with recalled product?

☐ YES

☐ NO

If yes, please explain: _____