RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 7 March 2019
Complaint Reference: REC371

Action Type: Device Modification

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
Liquid Cardiac Control	CQ5051	05055273207446	4243CK	28 Nov 2019	5 Feb 2018
	CQ5052	05055273207453	4244CK		
	CQ5053	05055273207460	4245CK		

Reason for Action:

Randox has confirmed a change in recovery with regards to NTproBNP in the the Liquid Cardiac Control lots detailed in the table above, on Siemens Dimension EXL LOCI. Customers may observe a decrease in recovered concentration compared to the quoted target value in the value sheet, for this analyser only.

Risk to Health:

Quality control results which are not within range can lead to a delay in reporting results however NTproBNP is used in conjunction with other results and indicators to diagnose and monitor heart failure in patients. This therefore should not pose a serious risk to health.

Action to be taken:

- Inspect your stock and quarantine affected stock.
- Replace the value sheet in the kit with the revised value sheet provided.
- Randox is not recommending a review of previous results as changes in quality control recovery would be reviewed at the time of occurrence.
- Discuss the contents of this notice with your Medical Director.
- Complete the response form even if you no longer have the affected product. Return the response form to technical.services@randox.com within five working days.

Last printed: 07 March 2019

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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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 Randox Technical Services.

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

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Response Form

Randox Laboratories Ltd
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Please check ALL appropriate boxes.

- ❑ I have read and understand the recall instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and have quarantined the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.

Indicate disposition of recalled product:

- ❑ no affected stock
- ❑ returned (*specify quantity, date and method*)/held for return;
- ❑ replaced the value sheet (*specify quantity and date*);
- ❑ quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

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Area of Distribution (To be completed by Distributors and Randox Offices)

- ❑ 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)

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

- ❑ YES
- ❑ NO

If yes, please explain: _____

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

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.