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: 23 May 19
Complaint Reference: REC 398

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
Human Assayed Control Level 2	HN1530	05055273203783	1306UN	28 June 2022	13 Nov 2018
			1308UN	28 June 2022	13 Nov 2018
			1309UN	28 June 2022	01 Nov 2018

Reason for Action:
Randox can confirm the RX series control target and range value for ALT (Tris buffer without P5P 37C), Bicarbonate and gamma-GT has been incorrectly assigned for lot numbers 1306UN, 1308UN and 1309UN in the Human Assayed Multi-Sera Controls.

Randox has identified a labelling error in the value sheet for Human Assayed Controls Level 2 lots 1306UN, 1308UN and 1309UN. The method listed for Transferrin in the Mean of all section of the value sheet is Roche Cobas E411, however it should be Immunoturbidimetric. Values are not affected.

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

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

Transferrin: There is negligible risk to health as the Roche Cobas E411 is an immunoturbidimetric assay and therefore these are the correct values for controls for this system.

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

Last printed: 23 May 2019

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Action to be taken:

- Review your reagent inventory of these products. Remove all previous versions of the Value Sheets in use and replace with the revised version.
- 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 Randox Technical Services.

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

M Kelly

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Response Form

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Date Issued: 23 May 2019
Complaint Reference: REC 398 **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
Human Assayed Multi-Sera-Level 2	HN1530	05055273203783	1306UN 1308UN 1309UN	28 June 2022 28 June 2022 28 June 2022	13 Nov 2018 13 Nov 2018 01 Nov 2018

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
- ❑ quarantined pending correction (*specify quantity*);
- ❑ relabelled (*specify quantity and date*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

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Response Form

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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.