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: 05 July 2019
Complaint Reference: REC395

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
Calibration Serum Level3	CAL2351	05055273200966	961UE 995UE 997UE 1024UE 1055UE	28 Jan 2020 28 July 2020 28 July 2020 28 Dec 2020 28 May 2021	Jan 2018 May/June 2018 July 2018 March 2019 Dec/ Feb 2019
Bovine Chemistry Assayed	AE1032 AL1027 AN1026	05055273200119 05055273200140 05055273200294	-	-	-
Liquid Assayed Chemistry Control Premium	LAN4216 LAE4217	05055273208993 05055273209020	-	-	-
Assayed Chemistry Control Premium Plus	HN1530 HE1532	05055273203783 05055273203608	-	-	-

Reason for Action:

Randox have realigned the RX Analyser Series calibration targets by 10% for AST and 9% for ALT in line with the Mean of All Instrument method target from calibrator lot 961UE onwards. With this change a decrease in patient running means may be observed on the RX Series instruments. No other instruments are affected.
The target and range for the associated Quality Control Material has been revised to align with this change. Updated RX control targets are available at randox.com.

Risk to Health:

ALT measurements are used in the diagnosis and treatment of certain liver diseases (e.g. viral hepatitis and cirrhosis) and heart diseases. Critical changes in values are approximately x 3 higher than the upper limit of the normal range.

Elevated levels of AST is a non-specific indicator of tissue damage. Typical intraindividual variation is 16%. Critical changes in values are approximately x 20 higher than the upper limit of the normal range.

Form No. 6307-TS
REVISION (9)
24th October 2018

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The risk to patient health is negligible as the impact of a 10% change in recovery is minimal in the context of observed concentrations of ALT and AST in liver disease.

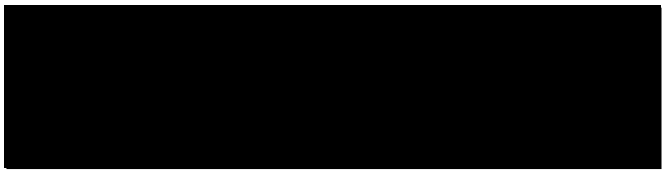
Action to be taken:

- Replace all Quality Control value sheets with the revised sheets available on www.randox.com .
- 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



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Response Form

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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 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:

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

Customer Details

Company Name	
Address	

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Response Form

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Total Quantity

Received	
Distributed	

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.