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: 11 December 2019

Complaint Reference: REC430

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 Clinical Chemistry Control	LAE4217	05055273208993	1021UE	30 Jun 2020	21 Oct 2018

Reason for Action:

A transcription error has occurred for the Randox Lipase colorimetric value in Liquid Clinical Chemistry Control lot 1021UE. The target and range are listed as 50 U/L (40 – 60) and should be 72U/L (58 – 86).

Risk to Health:

Control falling out of range could lead to a delay in reporting patient results. See attached HHE.

Action to be taken:

- Update the affected kits with the correct target values provided.
- 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.

Last printed: 11 December 2019

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

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

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

Last printed: 11 December 2019

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

RANDOX

Response Form

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

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

Date Issued: 11 December 2019

Complaint Reference: REC430 **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 Clinical Chemistry Control	LAE4217	05055273208993	1021UE	30 Jun 2020	21 Oct 2018

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	

RANDOX

Response Form

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

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.

RANDOX
Response Form

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

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: _____