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: 26 Apr 23

Complaint Reference: REC656

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
Immunoassay Premium Level 3	IA2640	05055273203868	2031EC	28th Nov 23	14th May 21
Immunoassay Premium Control Tri Level	IA2633	05055273203837	583135	28th April 23	19th Oct 21

Reason for Action:

Randox Laboratories can confirm that the quoted target value and range for ACTH in Immunoassay Premium Level 3, IA2640, lot 2031EC and Immunoassay Premium Control Tri Level kit batch 583135 lot 2031EC has been reassigned on the Roche Cobas e801 due to high recovery outside range. The following instrument targets for ACTH have been removed from the value sheets: Siemens Immulite 2000/2500, Roche Cobas 4000/E411, Roche Cobas e601/602, CIS IRMA and Diasorin Liaison XL, it is expected these will also require reassignment by up to +30%.

Lot Number	Analyser	Old Value		Old Range		New Value		New Range	
2031EC	Roche e801	pmol/l	pg/ml	pmol/l	pg/ml	pmol/l	pg/ml	pmol/l	pg/ml
		23.0	105	17.3-28.8	78.6-131	29.7	135	22.3-37.1	101-169

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

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Risk to Health:

No Risk to patient, delay in reporting results due to Quality Controls running high outside of range.

Action to be taken:

- Discontinue use of and discard the current IFU and download the updated IFU from 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

Form No. 6307-TS
REVISION (10)
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Response Form

Randox Laboratories Ltd
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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
- ❑ downloaded updated IFU

Customer Details

Company Name	
Address	

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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.

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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: _____