RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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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

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