RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 02 December 2019

Complaint Reference: REC422

Action Type: Recall – Product Withdrawal

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
NEFA	FA115	05055273203066	485343	28 Mar 2021	31 May 2019

Reason for Action:

Non-Esterified Fatty Acids (NEFA) FA115 batch 485343 shows a positive shift in recovery for patient samples of approximately 10% at the medical decision limit. The recovery at lower concentrations increases as the concentration decreases. Low abnormal samples are unlikely to be detected.

This lot of material is not meeting the performance claims and should not be used in any further testing.

Risk to Health:

NEFA may be elevated in subjects with central obesity, insulin resistance and type II diabetes. It is measured as part of a profile of blood tests to investigate metabolic disorders. Although patient results will appear elevated with this batch the results may not match the patient profile. Quality Control material may be elevated however may still recover in range.

Action to be taken:

- Discontinue use of and discard any of the product detailed above immediately.
- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Review your reagent inventory of these products and assess your laboratories needs for reimbursement for discarded inventory.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Form No. 6307-TS
REVISION (10)

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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

CC: Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities.