

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 10th May 2021

Complaint Reference: REC 527

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
NEFA	FA115	05055273203066	544642	28 th Nov 2022	23 rd Nov 2020

Reason for Action:

Randox can confirm the NEFA standard **522FA** packed within NEFA kit Catalogue Number FA115 Batch 544642 has been assigned incorrectly. Calibrating with the incorrect value will cause a positive shift of up to +8% with both quality controls and patient samples.

522FA	Incorrect Value: 1.04 mmol/l	Updated Value: 0.96 mmol/l
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Risk to Health:

Delay in reporting patient results due to controls running with a constant positive bias. 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. NEFA is not a stand-alone test for diagnosis purposes.

Action to be taken:

- Please discard previous value sheets and ensure standard value is updated.
- 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.

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- Complete and return the response form 12187-QA to technical.services@radox.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 Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

A handwritten signature in black ink, appearing to read 'Louise Hur', is written over a horizontal line. The signature is stylized and includes a large loop at the end.