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: 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	28th Nov 2022	23rd 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**

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.

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

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- 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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Response Form

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

Date Issued: 10th May 2021
Complaint Reference: REC527 **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	28th Nov 2022	23rd Nov 2020

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
- ❑ quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

Form No. 12187-QA
REVISION (2)
17 Jul 2019

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Response Form

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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: _____

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