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: 30th July 2020

Complaint Reference: REC483

Action Type: Device Recall

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
Ammonia	AM1015	05022273200256	517541	March 2022	June 2020
	AM1054	05055273200263	512103	January 2022	February 2020

Reason for Action:

Randox Ammonia reagents, AM1015, batch 517541 and AM1054, batch 512103 are being recalled from the field due to a positive bias of up to 140µmol/l being observed on patient samples. It should be noted that the recommended quality control will not reflect this positive bias due to the aqueous nature of the material.

These batches of material do not meet performance claims and should not be used in any further testing with immediate effect.

Risk to Health:

Since a positive bias will not be seen with Randox Quality Control materials, incorrect patient results may have been reported. Ammonia is not a single conclusive diagnostic test and is used in combination with other clinical diagnostic tests such as kidney and liver function markers.

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Action to be taken:

- Discontinue use of, quarantine and discard any stock of AM1015, batch 517541 and AM1054, batch 512103 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 laboratory needs for reimbursement for discarded inventory.
- 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

Paul Armstrong

Last printed: 30 July 2020

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

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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
- ❑ destroyed (*specify quantity, date and method*);
    - ❑ I have provided proof of scrappage (batch labels removed from kits)

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Customer Details

Company Name	
Address	

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.

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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.

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: _____