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: 26th Oct 2022

Complaint Reference: REC624

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
IgA Immunoturbidimetric Assay	IA3832	05055273203882	Not Batch Specific
IgM Immunoturbidimetric Assay	IM3834	05055273204001	Not Batch Specific

Reason for Action:

Randox have released an update to the carryover avoidance technical bulletin to detail that IgA and IgM assays should not be run immediately after Fructosamine Catalogue Number FR3133 or FR4030 on the RX instruments testing order.

Risk to Health:

Interference to the IgA and IgM assays can lead to an elevation in Quality Control and Patient results of up to +13% for IgA and +51% for IgM respectively, which may lead to a delay in running patient samples or erroneous elevated test results.

Action to be taken:

- Review your instrument testing order in line with the Carryover Avoidance Technical Bulletin (RXTB-0136)
- Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0136) and ensure all operators are aware of the recommendations.

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

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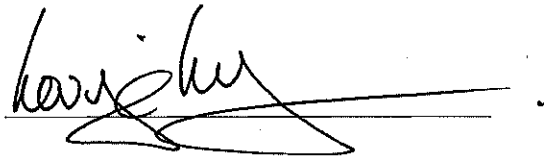
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

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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Response Form

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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 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.

- ❑ I have downloaded updated Carryover Avoidance Technical Bulletin (RXTB-0136)
- ❑ I have updated the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0136) and ensured all operators are aware of the recommendations.

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Response Form

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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.

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: _____