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: 29 Nov 23

Complaint Reference: REC704

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
Copper	CU2340	050552732019	592278	28 Feb 24	25 Mar 22
			610661	28 Aug 24	7 Oct 22
			610669	28 Aug 24	29 Aug 22
			629021	28 Feb 25	24 Mar 23
			647201	28 Sep 25	3 Oct 23
			657944	28 Aug 24	29 Aug 22

Reason for Action:
Randox Laboratories have released an update to the Carryover Avoidance Technical Bulletin to detail that Copper, should not be run directly after Total Protein, on the RX series instruments testing order. **If reagent carryover persists, avoid running Copper on analysers that run Total Protein.**

Please discard all previous version of the Carryover Avoidance Technical Bulletin and replace with the updated version.

Risk to Health:
Interference to the Copper assay can lead to an increase in Quality Control and patient results, which may lead to a delay in running patient samples or increased test results.

Action to be taken:

- Review your instrument testing order in line with the Carryover Avoidance Technical Bulletin (RXTB-0148)

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

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- Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0148) and ensure all operators are aware of the recommendations.
- 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 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
- ❑ I have downloaded updated Carryover Avoidance Technical Bulletin (RXTB-0148)
- ❑ I have updated the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0148) 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*);

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: _____