RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 9 Jun 2023

Complaint Reference: REC673

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
Urea Enzymatic Kinetic Assay	UR3825	05055273206906	Not Batch Specific
	UR3873	05055273206913	Not Batch Specific
	UR8334	05055273209600	Not Batch Specific
	UR8070	05055273209594	Not Batch Specific

Reason for Action:

Randox have released an update to the carryover avoidance technical bulletin to detail that Urea should not be run immediately after Direct LDL-Cholesterol, catalogue numbers CH3841, CH8312 or CH8032 on the RX instruments testing order.

Risk to Health:

Interference to the Urea assay can lead to a decrease in Quality Control and patient results of up to -11%, which may lead to a delay in running patient samples or erroneous decreased test results.

Action to be taken:

- Review your instrument testing order in line with the Carryover Avoidance Technical Bulletin (RXTB-0148)
- Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0148) 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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