RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 05 August 2020

Complaint Reference: REC459 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
Lactate Dehydrogenase L-P (LDH) (NAD)	LD3842 LD8052 LD8323	05055273204124 05055273215434 05055273209068
Lactate Dehydrognease P-L (UV)	LD3818 LD8051 LD8322	05055273204117 05055273209037 05055273209051

Reason for Action:

Randox have released an update to the carryover avoidance technical bulletin to introduce additional steps for reagent carryover avoidance with the Lactate Dehydrogenase assay on RX Instruments. Additional pipette washes can be implemented as described in the technical bulletin.

Risk to Health:

Interference to the Lactate Dehydrogenase (LDH) reagent would be observed as inconsistencies in Quality Control recovery, which may lead to a delay in running patient samples, or erroneous elevated test results. LDH will be used in conjunction with other test results and patient history.

Action to be taken:

- Review your instrument testing order in line with the updated Carryover Avoidance Technical Bulletin (RXTB-0121) and enable additional pipette washes.
- Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0121) 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.

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REVISION (10)
4th Feb 2019

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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