RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Date Issued: 17 December 2019

Complaint Reference: REC427

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
RX Daytona + with ISE	RX4040	05055273207774
RX Daytona +	RX4041	05055273207781

Reason for Action:

Randox have now released software version UI2550642107 for the RX Daytona + instrument.

See Randox Technical Bulletin RXTB-0113

- Correction: The Run/Results screen now displays Normal sample results in numerical order according to sample ID (SID).
- Correction: Colour flagging of IQC data points on the QC Graph screen.
- Enabling: Volume checking of detergent following filling of cuvette function.
- Enabling: On board stability information to be retained after parameter settings have been edited.
- Enabling: Delete All button is activated when using the copy/delete function on the Run/Test selection screen.

Risk to Health:

Randox software update version UI2550642107 represents no risk to health.

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Action to be taken:

- 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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