RANDOX

Urgent Field Safety Notice

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Date Issued: 27 Feb 2019 (first issued 30 November 2018)
Complaint Reference: REC359 **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
Calcium	CA3871 CA8309 CA8021	05055273200904 05055273208368 05055273208351

Reason for Recall:

Randox have released an update to the carryover avoidance technical bulletin to introduce additional steps for reagent carryover avoidance with the Calcium assay on RX instruments. The instrument testing order should be reviewed in line with the updated technical bulletin. Additional pipette washes can also be implemented as described in the technical bulletin.

Risk to Health:

Carryover to the Calcium reagent would be observed as inconsistencies in Quality control recovery which may lead to a delay in running patient samples or erroneous elevated / depressed test results.

Action to be taken:

- Review your instrument testing order in line with the carryover avoidance technical bulletin. Enable additional pipette washes.
- Update the RX user manual with the updated carryover avoidance document 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 to technical.services@randox.com within five working days.

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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