

RANDOX
Urgent Field Safety Notice

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Date Issued: 12th February 2020

Complaint Reference: Recall 439

Action Type: Field Correction

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
Chemistry QC Premium Plus (Liq)	LAL4213	05055273209006	306UL	28/12/2020	10/04/2019

Reason for Action:

Radox can confirm the control target and range value for Sodium using the ISE indirect method has been assigned incorrectly. The sections for Roche Cobas series and mean of all instruments have now been updated.

Updated value sheets are now available on www.radox.com and attached to this contact.

Risk to Health:

Quality control results which are not within range can lead to a delay in reporting results.

Action to be taken:

- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@radox.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 Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency


