

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Date Issued: 05 Mar 2024

Complaint Reference: REC731

Action Type: Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product(s):

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Calibration Serum Level 3	CAL2351	05055273200966	1260UE	28 Nov 2024	29 Nov 2022
			1262UE	28 Jan 2025	16 Nov 2022
			1295UE	28 Sep 2025	25 Oct 2023
			1297UE	28 Jun 2025	29 Jun 2021
			1298UE	28 Jan 2025	29 Jan 2021
			1315UE	28 May 2025	24 Feb 2023
			1325UE	28 Sep 2025	8 Nov 2023
			1326UE	28 Sep 2025	28 Nov 2023

Reason for Action:

Randox Laboratories has identified that Inorganic Phosphate in Calibration Serum Level 3, CAL2351, is running with a negative bias on **RX Series** instruments compared to other methods. We have reassigned the target values in the above lot numbers in line with our internal master calibrator lot. Please refer to the table below for the updated calibrator targets. You may experience a shift in Quality Control and patient sample recovery up to 7%. Please discard all copies of the calibrator IFU and download the updated IFUs from www.randox.com. Quality Control targets are also being updated in line with the restandardisation and updated IFUs can be accessed via www.randox.com. If further information is required, please contact technical.services@randox.com.

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		Phosphate Inorganic – Phosphomolybdate UV				
Catalogue Number	Lot Number	Old Value mmol/L	New Value mmol/L	Old Value mg/dL	New Value mg/dL	% Difference
CAL2351	1260UE	2.13	2.27	6.60	7.04	7%
	1262UE	2.12	2.19	6.57	6.79	3%
	1295UE	2.13	2.22	6.60	6.88	4%
	1297UE	2.23	2.30	6.91	7.13	3%
	1298UE	2.08	2.19	6.45	6.79	5%
	1315UE	2.19	2.26	6.79	7.00	3%
	1325UE	2.13	2.22	6.60	6.88	4%
	1326UE	2.13	2.22	6.60	6.88	4%

Risk to Health:

Inorganic Phosphorous is required for energy production and in bone development. Phosphate is obtained through the diet and levels are maintained by the body through absorption via the intestines and excretion via the kidneys. Abnormalities in the serum inorganic phosphorous concentrations may be indicative of kidney damage and or gastrointestinal/malnutrition – related conditions. The measurement of Inorganic phosphorous should be interpreted in line with other measurements and the clinical presentation of the patient. Please review data generated using the aforementioned calibrator lots if you have used the Rx Series targets.

Action to be taken:

- Discuss the contents of this notice with your Medical Director if you have used the RX Series targets for Inorganic Phosphorous in the aforementioned lots.
- Complete and return the response form, 12187-QA to technical.services@randox.com within five working days.
- Please discard all copies of the IFUs and download the latest versions from www.randox.com.

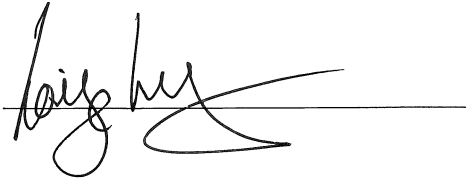
Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

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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

A handwritten signature in black ink, appearing to read 'L. Hughes', is written over a horizontal line. The signature is stylized and cursive.

