RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

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
	CAL10388	N/A	1295UE	28 Sep 2025	14 Feb 2024
			1325UE	28 Sep 2025	16 Oct 2023

Reason for Action:

Randox Laboratories has identified that Inorganic Phosphate in Calibration Serum Level 3, CAL2351 & CAL10388, 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

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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restandardisation and updated IFUs can be accessed via www.randox.com. If further information is required, please contact technical.services@randox.com.

		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%
CAL10388	1295UE	2.13	2.22	6.60	6.88	4%
	1325UE	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.

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- 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.

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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Response Form

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Please complete this form *even if you do not have any affected stock*.

Date Issued: 05 Mar 24
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Detail on Affected Devices:

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			1325UE	28 Sep 2025	16 Oct 2023

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ no affected stock
- ❑ downloaded the updated IFU(s)

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Response Form

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Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Have your customers notified you of any adverse events associated with recalled product?

❑ YES

❑ NO

If yes, please explain: _____