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: 13 Nov 23

Complaint Reference: REC701 **Action Type:** Device Modification

Please note, there are three sections within this notice. Review the document in full prior to completing the response form.

Part 1

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
Calibration Serum Level 3	CAL2351	05055273200966	1214UE	28 Nov 2023	28 Mar 2022
			1249UE	28 Jul 2024	30 May 2022
			1260UE	28 Nov 2024	29 Nov 2022
			1262UE	28 Jan 2025	16 Nov 2022
			1268UE	28 Jul 2024	2 Jun 2022
			1297UE	28 Jun 2025	29 Jun 2021
			1298UE	28 Jan 2025	29 Jan 2021
			1315UE	28 May 2025	24 Feb 2023

Reason for Action:

Randox Laboratories has identified that CK Total in Calibration Serum Level 3, CAL2351, is running with a positive bias on **RX Series** instruments compared to other methods. We have reassigned the target values in the above lot numbers in line with both the IFCC and DGKC reference materials. Please refer to the table below for the updated calibrator targets. You may experience a shift in Quality Control and patient sample recovery of up to 13%. Please discard all copies of the calibrator IFU and download the updated sheets 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.

		CK-NAC (IFCC) 37°C			CK-NAC substrate start (DGKC) 37°C		
Catalogue Number	Lot Number	Old Value U/L	New Value U/L	% Difference	Old Value U/L	New Value U/L	% Difference
CAL2351	1214UE	635	560	11.81%	627	548	12.60%
	1249UE	594	522	12.12%	600	515	14.17%
	1260UE	571	522	8.58%	574	520	9.41%
	1262UE	587	521	11.24%	582	516	11.34%
	1297UE	577	507	12.13%	564	503	10.82%
	1298UE	573	497	13.26%	555	494	10.99%
	1315UE	584	524	10.27%	572	521	8.92%

Risk to Health:

Creatine Kinase (CK) is an enzyme found mainly in cardiac and skeletal muscle. Total CK levels are elevated following damage to either skeletal or cardiac muscle and it is therefore measured to monitor and diagnose myopathies. Please review data generated using the aforementioned calibrator lots if you have used either of 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 CK Total 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.

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Part 2

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
Calibration Serum Level 3	CAL2351	05055273200966	1214UE	28 Nov 2023	23 Mar 2022

Reason for Action:

Randox Laboratories can confirm that the target for Alkaline Phosphatase (ALP) for the AMP optimised to IFCC 37°C method has been mis-assigned for the **RX Series** instruments in Calibration Serum Level 3, CAL2351, lot 1214UE by approximately 10%. If you are using the affected lot for this assay, please contact technical.services@randox.com.

Risk to Health:

Alkaline Phosphatase is an enzyme found at high levels in the liver and bones. Increased levels can indicate disorders of the liver and bones when measured alongside other analytes. With this lot of calibrator, you can observe a negative bias of up to 10% on Quality Control and patient samples.

Action to be taken:

- Review your calibrator inventory of this lot and assess your laboratories needs for reimbursement for discarded inventory.
- 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.

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Part 3

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
			1315UE	28 May 2025	24 Feb 2023
Human Assayed Multi-Sera Level 2	HN1530	05055273203783	1577UN	28 Jan 2026	12 Jun 2023
			1592UN	28 Jan 2026	29 Jan 2022
			1593UN	28 Jan 2026	30 May 2022
Human Assayed Multi-Sera Level 3	HE1532	05055273203608	1248UE	28 Jan 2026	2 May 2022
			1264UE	28 Jan 2026	29 Jan 2022
			1265UE	28 Jan 2026	29 Jan 2022

Reason for Action:

Randox Laboratories can confirm that there have been transcription errors on the Instructions For Use (IFU) for the Calibration Serum Level 3, CAL2351, Human Assayed Multi-Sera Level 2, HN1530 and Human Assayed Multi-Sera Level 3, HE1532, for the lots listed in the table above. Details of the errors are stipulated below. Please discard all copies of the IFUs and download the latest versions from www.randox.com.

CAL2351, lot 1262UE

The mg/dl Bilirubin Direct target value under the Roche Cobas c303/501/502/503 section for the Roche DPD JG standardised method was listed with an additional value in error. Please see the correct targets below.

Analyte	Method	Old Information	New Information
Bilirubin Direct	Roche DPD JG standardised	µmol/l 31.5 mg/dl 1.84 mg/dl 1.51	µmol/l 31.5 mg/dl 1.84

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CAL2351, lots 1260UE & 1315UE

The mg/dl Triglycerides target value under the Siemens Dimension EXL® section for the Lipase/Glycerol Dehydrogenase method was listed with an additional value in error. Please see the correct targets below.

Lot	Analyte	Method	Old Information	New Information
1260UE	Triglycerides	Lipase/Glycerol Dehydrogenase	mmol/l 2.88 mg/dl 255 mg/dl 253	mmol/l 2.88 mg/dl 255
1315UE	Triglycerides	Lipase/Glycerol Dehydrogenase	mmol/l 2.97 mg/dl 263 mg/dl 264	mmol/l 2.97 mg/dl 263

HN1530, lots 1577UN, 1592UN & 1593UN

Under the Method section, there was a target for TIBC that was listed without an associated method. This has since been removed from the sheets.

HE1532, lots 1248UE, 1264UE & 1265UE

Under the Roche Cobas C311® and Cobas Integra® sections, there was a target for Lipase that was listed without an associated method. This has since been removed from the sheets.

Risk to Health:

Bilirubin is a waste product produced from the breakdown of haemoglobin in the red blood cells. The measurement of conjugated and unconjugated Bilirubin can be used to assess different disease states, including liver disease and bile blockage. If the incorrect Direct Bilirubin target was used to calibrate, a difference of up to +18% could be observed in Quality Control and patient results.

Triglycerides are the most abundant form of fat stored by the body. Elevated levels are associated with cardiovascular disease risk. Triglyceride measurements often form a part of a standard lipid profile assessment. If the incorrect Triglyceride target was used to calibrate, a difference of <1% would be observed in Quality Control and patient results.

The risk of using the incorrect Quality Control target for TIBC or Lipase is low as these values were not assigned to a method. Please consult the latest versions of the IFUs on www.randox.com.

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Action to be taken:

- Discuss the contents of this notice with your Medical Director if you have used the incorrect target value for either Direct Bilirubin in CAL2351 lot 1262UE or Triglycerides in lots 1260UE or 1315UE.
- 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 the 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

[redacted]

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Response Form

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

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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
- ❑ new IFUs downloaded

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.

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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.

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: _____