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: 05th Feb 2024

Complaint Reference: REC718 **Action Type:** Device Modification

Please note, there are two 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
Cystatin C Calibrator	CYS 2699	050552732 07439	Batch 600957 Lot 1378CY – 1382CY	28th Feb 2024	20th July 2022
			Batch 621809, 621815 Lot 1403CY – 1407CY	28th Aug 2024	30th Jan 2023 31st Jan 2023
			Batch 650533 Lot 1414CY – 1418CY	28th Nov 2024	18th July 2023

Reason for Action:

Randox Laboratories has identified that the Cystatin C Calibrator Series CYS 2699, is running with a negative bias compared to other methods. We have realigned the target values in the above lot numbers to the IFCC Reference Standard. Please refer to the table below for the updated calibrator targets. You may experience a positive shift in Quality Control and patient sample recovery. If you are using CYS 2699 batch 600957 lots 1378CY – 1382CY please provide proof of scrappage and a replacement calibrator lot will be provided. Please discard all copies of the calibrator Instructions For Use (IFU)s and download the updated IFUs from www.randox.com. If further information is required, please contact technical.services@randox.com.

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

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Catalogue Number	Batch Number	Lot Number	Previous Value mg/l	Updated Value mg/l
CYS 2699	600957	1378CY	0.44	Contact technical support for replacements
		1379CY	1.26	
		1380CY	2.53	
		1381CY	4.88	
		1382CY	8.35	
CYS 2699	621809, 621815	1403CY	0.46	0.60
		1404CY	1.28	1.61
		1405CY	2.52	2.92
		1406CY	4.82	5.64
		1407CY	8.28	9.75
CYS 2699	650533	1414CY	0.47	0.61
		1415CY	1.29	1.62
		1416CY	2.58	2.98
		1417CY	5.00	5.84
		1418CY	8.80	10.00

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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
Cystatin C Control Level 2	CYS 5019	05055273207415	1376CY	28th June 2024	22nd July 2022
			1394CY	28th Sep 2024	27th Oct 2022
			1408CY	28th Dec 2024	26th Jan 2023
			1419CY	28th March 2025	3rd Aug 2023
Cystatin C Control Level 3	CYS 5020	05055273207422	1377CY	28th June 2024	23rd July 2022
			1395CY	28th Sep2024	27th Oct 2022
			1409CY	28th Dec 2024	26th Jan 2023
			1420CY	28th March 2025	3rd Aug 2023

Reason for Action:

In line with the realignment to the Cystatin C Calibrator Series, we are updating the target and range for the Cystatin C controls, CYS5019 and CYS5020. The updated target and range can be found in the table below. Please discard any copies of the IFU and download the updated version from www.randox.com.

Cat Number	Batch / Lot number	Previous Value mg/l	Previous Range mg/l	Updated Value mg/l	Updated Range mg/l
CYS 5019	1376CY	0.68	0.58-0.78	0.96	0.82-1.10
	1394CY	0.69	0.59-0.79	0.96	0.82-1.10
	1408CY	0.68	0.58-0.78	0.95	0.81-1.09

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	1419CY	0.70	0.59-0.80	0.96	0.82-1.10
CYS 5020	1377CY	3.18	2.86-3.50	3.69	3.32-4.06
	1395CY	3.17	2.85-3.49	3.67	3.30-4.04
	1409CY	3.23	2.91-3.55	3.64	3.28-4.00
	1420CY	3.45	3.11-3.80	3.79	3.41-4.17

Risk to Health:

Cystatin C is a marker of kidney function ran alongside Creatinine test for reduced Glomerular Filtration Rate. Cystatin C is a protein that is produced by the majority of cells in the body. If blood levels rise this indicates impaired kidney function. Please review data generated using the aforementioned calibrator lots and review your QC target values in line with the updated targets and ranges provided.

Action to be taken:

- 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.
- 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
- ❑ downloaded updated IFU(s)

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: _____