

# RANDOX

## Urgent Field Safety Notice

Radox Laboratories Ltd  
55 Diamond Road Crumlin  
United Kingdom BT29 4QY  
[technical.services@radox.com](mailto:technical.services@radox.com)  
Tel: +44 (0) 28 9445 1070

Date Issued: 05<sup>th</sup> 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	28 <sup>th</sup> Feb 2024	20 <sup>th</sup> July 2022
			Batch 621809, 621815 Lot 1403CY – 1407CY	28 <sup>th</sup> Aug 2024	30 <sup>th</sup> Jan 2023 31 <sup>st</sup> Jan 2023
			Batch 650533 Lot 1414CY – 1418CY	28 <sup>th</sup> Nov 2024	18 <sup>th</sup> July 2023

#### Reason for Action:

Radox 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.radox.com](http://www.radox.com). If further information is required, please contact [technical.services@radox.com](mailto:technical.services@radox.com).

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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	28 <sup>th</sup> June 2024	22 <sup>nd</sup> July 2022
			1394CY	28 <sup>th</sup> Sep 2024	27 <sup>th</sup> Oct 2022
			1408CY	28 <sup>th</sup> Dec 2024	26 <sup>th</sup> Jan 2023
			1419CY	28 <sup>th</sup> March 2025	3 <sup>rd</sup> Aug 2023
Cystatin C Control Level 3	CYS 5020	05055273207422	1377CY	28 <sup>th</sup> June 2024	23 <sup>rd</sup> July 2022
			1395CY	28 <sup>th</sup> Sep 2024	27 <sup>th</sup> Oct 2022
			1409CY	28 <sup>th</sup> Dec 2024	26 <sup>th</sup> Jan 2023
			1420CY	28 <sup>th</sup> March 2025	3 <sup>rd</sup> 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](http://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.

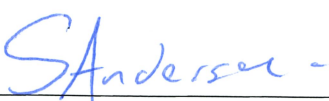
### Action to be taken:

- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form, 12187-QA to [technical.services@randox.com](mailto:technical.services@randox.com) within five working days.
- Please discard all copies of the IFUs and download the latest versions from [www.randox.com](http://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**

  
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