

RANDOX
Urgent Field Safety Notice

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Date Issued: 15 May 24

Complaint Reference: REC745

Action Type: Device Modification

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
HbA1c II Calibrator	HA8124	05055273215540	637478 2454HA-2458HA	28 th Oct 2024	5 th Sep 2023
			623672 2425HA-2429HA	28 th May 2024	23 rd Feb 2023

Reason for Action:

Randox Laboratories has identified that the HbA1c II Calibrator Series HA8124 is running with a negative bias on QC's and Patient samples. We have realigned the target values in the above lot numbers to the NGSP standardisation and provided instrument specific targets for the RX Imola and RX Modena. You may experience a positive shift in Quality Control and patient sample recovery by approximately +7%. Please refer to the table below for the updated calibrator targets. 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.

- **RX Imola targets Batch 623672 lots 2425HA-2429HA**

Level	Lot Number	Previous NGSP assigned Value (%)	Updated NGSP assigned Value (%)
1	2425HA	0.0000	0.0000
2	2426HA	0.0454	0.0481

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3	2427HA	0.0801	0.0857
4	2428HA	0.1164	0.1211
5	2429HA	0.1467	0.1467

- **RX Modena targets Batch 623672 lots 2425HA-2429HA**

Level	Lot Number	Previous NGSP assigned Value (%)	Updated NGSP assigned Value (%)
1	2425HA	0.0000	0.0000
2	2426HA	0.0454	0.0458
3	2427HA	0.0801	0.0826
4	2428HA	0.1164	0.1130
5	2429HA	0.1467	0.1412

- **RX Imola targets Batch 637478 lots 2454HA – 2458HA**

Level	Lot Number	Previous NGSP assigned Value (%)	Updated NGSP assigned Value (%)
1	2454HA	0.0000	0.0000
2	2455HA	0.0414	0.0474
3	2456HA	0.0783	0.0855
4	2457HA	0.1127	0.1162
5	2458HA	0.1464	0.1462

- **RX Modena targets Batch 637478 lots 2454HA – 2458HA**

Level	Lot Number	Previous NGSP assigned Value (%)	Updated NGSP assigned Value (%)
1	2454HA	0.0000	0.0000
2	2455HA	0.0414	0.0428

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3	2456HA	0.0783	0.0821
4	2457HA	0.1127	0.1096
5	2458HA	0.1464	0.1337

Risk to Health:

HbA1c is a diabetic monitoring test run using whole blood samples. The test measures the amount of glucose bound to haemoglobin (glycated haemoglobin) inside the red blood cells. The amount of glycated haemoglobin present is an indicator of blood glucose control over the previous 2-3 months. The negative bias of the HbA1c II Calibrator Series HA8124 to the NGSP standardisation does not significantly change the clinical profile of the patient.

Action to be taken:

- Review results generated in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@radox.com within five working days.

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 Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency


