



Circular No. 17 / 2025

نتقدم بثقة
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29 -07-1446 H
29 -01-2025

Field Safety Corrective Action of HbA1c II Calibrator from Randox Laboratories.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/243
Product	HbA1c II Calibrator.
Manufacturer	Randox Laboratories.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Number: HA8124 Please refer to the attachment for more details.
Reason	It has been identified by Randox Laboratories that the HbA1c II Calibrator Series HA8124 is running with a negative bias on QC's and Patient samples.
Action	<ol style="list-style-type: none">1. Please refer to the table in the attachment for the updated calibrator targets.2. Please discard all copies of the calibrator Instructions for use (IFU)s and download the updated IFUs from www.randox.com.3. Review results generated in line with the clinical profile of the patient.4. Discuss the contents of the attachment with your Medical Director5. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





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To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 17/2025 dated 29/1/2025 Regarding SFDA Field Safety Corrective Action of HbA1c II Calibrator from (mfr: Randox Laboratories).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information

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: 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	28 th Oct 2024	5 th Sep 2023
			2454HA-2458HA		
			623672	28 th May 2024	23 rd Feb 2023
			2425HA-2429HA		

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


