Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 107 **dated** 29/5/23 **Regarding NCMDR Field Safety Corrective Action of Assayed Urine Control Level 2, Assayed Urine Control Level 3 from (mfr: Randox Laboratories Ltd).**

Copy to:

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 107 / 2023

09 -11-1444 H

29 -05-2023

FSCA of Assayed Urine Control Level 2, Assayed Urine Control Level 3 from Randox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19543
Product	Assayed Urine Control Level 2, Assayed Urine Control Level 3.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Refer to "Detail on Affected Devices" in the attachment.
Reason	In line with the Requirements and Implementation of the In Vitro Diagnostic Devices Regulations (IVDR) and the continuous monitoring of the performance and stability claims of Quality Control (QC) products, the manufacturer aims to provide the most accurate and up-to-date information on the Instructions for Use (IFUs). For this reason, the manufacturer have updated the reconstituted 2 - 8 ºC stability claim for Catecholamines, Vanillylmandelic Acid (VMA), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA) in Assayed Urine Controls Levels 2 & 3.
Action	1. Refer to "Action to be taken" in the attachment. 2. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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ISO 9001:2015 CERTIFIED

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

RANDOX

Customer Notification

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 15 Mar 23

Complaint Reference: REC646

Action Type: Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Assayed Urine Control Level 2	AU2352	05055273200539	1072UC	28th Oct 23	21st Apr 20
			1101UC	28th Mar 24	12th Aug 20
			1122UC	28th Sep 24	9th Aug 21
Assayed Urine Control Level 3	AU2353	05055273200546	1077UC	28th Oct 23	12th Feb 20
			1106UC	28th Mar 24	10th Aug 20
			1127UC	28th Sep 24	9th Aug 21

Reason for Notification:

In line with the Requirements and Implementation of the *In Vitro* Diagnostic Devices Regulations (IVDR) and the continuous monitoring of the performance and stability claims of our Quality Control (QC) products, we aim to provide the most accurate and up-to-date information on our Instructions for Use (IFUs). For this reason, we have updated the reconstituted 2 - 8 °C stability claim for Catecholamines, Vanillylmandelic Acid (VMA), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA) in Assayed Urine Controls Levels 2 & 3.

- There are no stability claims made for Catecholamines, Vanillylmandelic Acid (VMA), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA) as these analytes are unstable in urine samples. The samples should be prepared according to the standard procedure within each laboratory.

The full storage and stability claim for each product can be found in the lot-specific sheets, accessed through www.randox.com.

These changes apply to the lots listed above.

RANDOX

Customer Notification

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Action to be taken:

Transmission of Customer Notification: Send a copy of the notification to all affected customers and to those who need to be aware within the organisation.

Complete and return the response form (12187-QA) to technical.services@randox.com within five working days.

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.