



نتقدم بثقة
Moving Forward
with Confidence

رؤية عُمان
2040
Vision

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 128 dated 21/6/2023 Regarding NCMDR Field Safety Corrective Action of Urea Enzymatic Kinetic Assay from (mfr: Radox 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



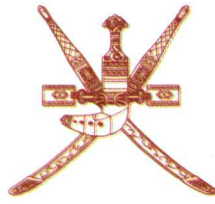
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

Twitter: [dgpa_dc](#) Email: dg-padc@moh.gov.om



Circular No. 128/2023

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03-12-1444 H

21-06-2023

Field Safety Corrective Action of Urea Enzymatic Kinetic Assay from Randox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19598
Product	Urea Enzymatic Kinetic Assay.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Number: UR3825, UR3873, UR8334, UR8070 GTIN: 05055273206906, 05055273206913, 05055273209600, 05055273209594 Batch / Lot number: Not Batch Specific.
Reason	Randox have released an update to the carryover avoidance technical bulletin to detail that Urea should not be run immediately after Direct LDL-Cholesterol, catalogue numbers CH3841, CH8312 or CH8032 on the RX instruments testing order.
Action	1. Review your instrument testing order in line with the Carryover Avoidance Technical Bulletin (RXTB-0148). 2. Update the RX user manual with the updated Carryover Avoidance Technical Bulletin (RXTB-0148) and ensure all operators are aware of the recommendations. 3. 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



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