

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

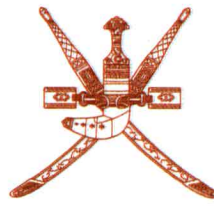
After Compliments,

Please find attached our Circular No 144 dated 18/7/23 Regarding NCMDR Recall of Liquid Urine Controls Level 2 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





Circular No. 144 / 2023

نتقدم
Moving Forward
With Confidence

رؤية عُمان
2040
Oman
Vision

30-12-1444 H

18-07-2023

Recall of Liquid Urine Controls Level 2 from Randox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19617
Product	Liquid Urine Controls Level 2.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue number: UC5074; Batch/ Lot number: 1209UC; Expiry Date: 28 Mar 24; Manufacturing: 28 Apr 22
Reason	There is vial to vial variation resulting in some vials recovering positive for hCG, which should be negative and high and outside range for cortisol. There has been a transcription error for Creatinine in the Instructions For Use (IFU) The target and ranges for Creatinine for the Roche Creatinine Plus method have been listed incorrectly.
Action	1. Discontinue use of and discard any of the above product immediately (see the attachment). Review previous results for this controls and ensure patients result were not reported if control result were not within range. 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

