



نتقدم بثقة  
Moving Forward  
with Confidence



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 234 dated 29/10/2023 Regarding NCMDR Recall of Glucose-6-Phosphate Dehydrogenase (G-6-PDH) 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



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Circular No. 234/2023

13 -04-1445 H

29 -10-2023

Recall of Glucose-6-Phosphate Dehydrogenase (G-6-PDH) from Radox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19735">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19735</a>
Product	Glucose-6-Phosphate Dehydrogenase (G-6-PDH).
Description	Clinical chemistry enzyme IVDs.
Manufacturer	Radox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue number: PD410 GTIN: 05055273204797 Batch/ Lot number: 629055 Expiry Date: 28th Feb 2026 Manufacturing Date: 25th April 2023
Reason	The R2 (NADP) and R3 (Substrate) are showing low rate of absorption change, resulting in cases of low or no reaction taking place, leading to low QC recovery to target and patient results reported below the normal range in erythrocytes 245-299 mU/109 & 6.97 -20.5 U/g Hb (+37°C).
Action	1. Customers are advised to discontinue use of and discard all stock of the above product immediately. Review results generated with the affected batches in line with the clinical profile of the patient. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General

