



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 223 dated 23/10/2023 Regarding NCMDR FSCA of Human Assayed Multi-Sera Control Level 3 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. 223/2023

بنقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

08 -04-1445 H

23 -10-2023

Field Safety Corrective Action of Human Assayed Multi-Sera Control Level 3 from Randox Laboratories Ltd.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19713
Product	Human Assayed Multi-Sera Control Level 3.
Description	IVD; In vitro diagnostic devices.
Manufacturer	Randox Laboratories Ltd.
Local Agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Number: HE1532 GTIN: 05055273203608 Batch / Lot number: 1294UE Expiry Date: 28 Oct 26 Manufacturing Date: 16 May 23.
Reason	The stability for AST (GOT) has been reduced from 7 days to 6 days when stored at 2-8°C for the affected product listed above.
Action	1. The Instructions For Use (IFU) have been updated and is now available on www.randox.com . 2. Please discard any previous versions of the IFU and download the updated IFU. 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



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



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