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 12 **dated** 30/1/24 **Regarding NCMDR Field Safety Corrective Action of Human Assayed Multi-Sera Level 3 from (mfr: from 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
ISO 9001:2015 CERTIFIED

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

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Circular No. 12 **/ 2024**

18 -07-1445 H

30 -01-2024

Field Safety Corrective Action of Human Assayed Multi-Sera 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=19888
Product	Human Assayed Multi-Sera Level 3.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue: HE1532, GTIN: 05055273203608 Batch/Lot date: 1294UE Expiry Date: 28 Oct 26 Manufacturing Date: 15 May 23
Reason	A transcription error has occurred on the Additional value sheet for Siemens Saudi for Human Assayed Multi-Sera Level 3, HE1532, lot 1294UE for Siemens Dimension EXL for Lipase. The method was incorrectly listed as "Colorimetric Siemens Dimension (LIPL kit) 37°C." The correct method is "Colorimetric Siemens Dimension (LIP kit) 37°C."
Action	1. The additional value sheet has been updated and is available on www.randox.com, please discard the incorrect version and download the correct version. 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

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