



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 225 dated 23/10/2023 Regarding NCMDR  
FSCA of Immunoassay Speciality I Level 1 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





Circular No. 225 / 2023

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23 -10-2023

نتقدم بثقة  
Moving Forward  
with Confidence



Field Safety Corrective Action of Immunoassay Speciality I Level 1 from Randox Laboratories Ltd.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19720">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19720</a>
Product	Immunoassay Speciality I Level 1.
Description	Multiple clinical chemistry constituent IVDs.
Manufacturer	Randox Laboratories Ltd.
Local Agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue number: IAS3113 GTIN: 05055273207293 Batch/Lot number: 2190EC Expiry Date: 28 Nov 23 & Manufacturing Date: 13 Jan 22
Reason	The 25-OH Vitamin D in the above device with mentioned lot number was assigned for Roche using the Roche 2nd generation Elecsys Vitamin D Total II. Roche have since released Vitamin D Total II (3rd Generation) reagent and 2190EC recovers close to the bottom of the assay range for this reagent. Randox cannot therefore provide target and ranges for use with the 3rd Generation reagent.
Action	1. Customers are requested to download provided Product Information from Randox and is available on the Instructions For Use (IFU) available on <a href="http://www.randox.com">www.randox.com</a> , please inform all relevant staff members. 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 Rubaia  
Director General

