



نتقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

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 101 dated 24/5/23 Regarding NCMDR Field Safety Corrective Action of Immunoassay Premium Level 3, Immunoassay Premium Control Tri Level 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



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



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



Circular No. 101 / 2023

نتقدم بتقديم  
Leading Forward  
with Confidence



04 -11-1444 H

24 -05-2023

**FSCA of Immunoassay Premium Level 3, Immunoassay Premium Control Tri Level from Randox 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=19526">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=19526</a>
Product	Immunoassay Premium Level 3, Immunoassay Premium Control Tri Level.
Description	IVD.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Number: IA2640, IA2633 GTIN: 05055273203868, 05055273203837 Batch / Lot number: 2031EC, 583135 Expiry date: 28th Nov 23, 28th April 23 Manufacturing date: 14th May 21, 19th Oct 21
Reason	The quoted target value and range has been reassigned on the Roche Cobas e801due to high recovery outside range.
Action	1. Discontinue use of and discard the current IFU and download the updated IFU from randox.com. 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 Rubate

Director General

