



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 90 dated 28/4/2025 Regarding SFDA Field Safety Corrective Action of Human Assayed Mutli Sera Level 3 from (mfr: Randox Laboratories Ltd).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 90/2025

بنقدم بثقة
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29-10-1446 H
28-04-2025

Field Safety Corrective Action of Human Assayed Mutli Sera Level 3 from Randox Laboratories Ltd.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/353
Product	Human Assayed Mutli Sera Level 3.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Numbers: HE1532, HS2611 UDI: 05055273203608, 05055273203813 Batch/Lot number: 1248UE 1264UE 1265UE 1264UE Packed into batches 610445, 606991. Please refer to the attachment for more details.
Reason	The analyte NEFA in the above listed lots and packed into the above listed batches has increased over the shelf life of the product and requires the targets and ranges to be reassigned.
Action	1. Please see the table in the attachement for updated targets and ranges. The value sheets have been updated and are available on www.randox.com , please discard the previous version and download the updated 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: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General



RANDOX

Customer Notification

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 31st March 2025

Complaint Reference: REC781

Action Type: Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	UDI	Batch/Lot Number	Expiry Date	Manufacturing Date
Human Assayed Mutli- Sera Level 3	HE1532	05055273203608	1248UE	28 th Jan 2026	2 nd May 2022
			1264UE	28 th Jan 2026	19 th July 2022
			1265UE	28 th Jan 2026	20 th Oct 2022
			1264UE Packed into batches 610445, 606991	28 th Dec 2025	06 th July 2022
	HS2611	05055273203813			

Reason for Notification:

Randox Laboratories can confirm the analyte NEFA in the above listed lots and packed into the above listed batches has increased over the shelf life of the product and requires the targets and ranges to be reassigned. Please see below table for updated targets and ranges. The value sheets have been updated and are available on www.randox.com, please discard the previous version and download the updated version.

RANDOX

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Tel: +44 (0) 28 9445 1070

Catalogue Number	Lot Numbers	Previous Target	Previous Range	Updated Target	Updated Range
HE1532, HS2611	1248UE 1264UE 1265UE	0.43	0.34 – 0.52	0.51	0.41-0.61

Action to be taken:

Transmission of Customer Notification: Send a copy of the notification to all affected customers and to those who need to be aware within the organisation.

Complete and return the response form (12187-QA) to technical.services@randox.com within five working days.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.