



Circular No. 19 / 2025

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29 -07-1446 H
29 -01-2025

Field Safety Corrective Action of Liquid Assayed Specific Protein Controls from Randox laboratories.

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/247
Product	Liquid Assayed Specific Protein Controls.
Manufacturer	Randox laboratories .
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue Number: PS2682, PS2683, PS2684, PS10221 , PS10222 , PS10223.
Reason	Randox have confirmed that the levels of Free Lambda Light Chains in our Liquid Assayed Specific Protein Controls will increase over the shelf life of the product. While this analyte will remain in the Liquid Assayed Specific Protein Controls, values and stability claims will no longer be quoted for this analyte for all lots. .
Action	1. The IFUs have been updated and are available on www.randox.com . Please discard the old IFUs and download the updated IFUs 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

Dr. Mohammed Hamdan Al Rubaie
Director General





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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. 19/2025 dated 29/11/2025 Regarding Field Safety Notice of Liquid Assayed Specific Protein Controls from (mfr: Randox laboratories).

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

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: 9th January 2025

Complaint Reference: REC775

Action Type: Device Modification

Detail on Affected Devices:

Assay	Catalogue Number	UDI
Liquid Assayed Specific Protein Controls	PS2682	05055273204896
	PS2683	05055273204902
	PS2684	05055273204919
	PS10221	05055273215670
	PS10222	05055273215687
	PS10223	05055273215694

Reason for Notification: Randox have confirmed that the levels of Free Lambda Light Chains in our Liquid Assayed Specific Protein Controls will increase over the shelf life of the product. While this analyte will remain in the Liquid Assayed Specific Protein Controls, values and stability claims will no longer be quoted for this analyte for all lots. The IFUs have been updated and are available on www.randox.com. Please discard the old IFUs and download the updated IFUs.

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.

If you have any questions or concerns, please contact Randox Technical Services.