



سنقدم بثقة
Moving Forward
with Confidence



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 106 dated 19/5/2025 Regarding SFDA Field Safety Corrective Action of Liquid Assayed Specific Protein Control Level 1/2/3 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. 106 / 2025

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21 -11-1446 H
19 -05-2025

FSCA of Liquid Assayed Specific Protein Control Level 1/2/3 from Randox Laboratories Ltd.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/359
Product	Liquid Assayed Specific Protein Control Level 1/2/3.
Manufacturer	Randox Laboratories Ltd.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to the attachment for more information.
Reason	The Rheumatoid Factor (RF) concentrations in Liquid Assayed Specific Protein Controls Level 1 Lots 647LPC and 686LPC are low below the measurement range of nephelometric methods on Siemens instruments.
Action	1. Randox have updated the IFU's and removed the associated targets and ranges of the affected Liquid Assayed Specific Protein Controls Level 1. 2. Anti Streptolysin O (ASO) target and range values have been reassigned by Randox Laboratories in lot no's 706LPC, 707LPC, 708LPC, 709LPC and 710LPC. Please refer to the table in the attachment for updated target values. 3. Download corrected IFU from Smartdocs.com and discard of previous copies 4. 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: 9th April 2025

Complaint Reference: REC778

Action Type: Device Modification

Detail on Affected Devices:

Device Name	Catalogue Number	UDI	Batch / Lot number	Expiry Date	Manufacturing Date
Liquid Assayed Specific Protein Control Level 1	PS2682	05055273204896	647LPC	28 th June 2025	09 th Nov 2022
	PS10221		686LPC	28 th Dec 2025	03 rd Jan 2024
			708LPC	28 th Jan 2026	14 th Aug 2024
Liquid Assayed Specific Protein Control Level 2	PS2683	05055273204902	706LPC	28 th Jan 2026	03 rd Sep 2024
	PS10222		709LPC	28 th Jan 2026	19 th Nov 2024
Liquid Assayed Specific Protein Control Level 3	PS2684	05055273204919	707LPC	28 th Jan 2026	08 th Aug 2024
	PS10223		710LPC	28 th Jan 2026	10 th Oct 2024

Reason for Notification:

Randox Laboratories can confirm that the Rheumatoid Factor (RF) concentrations in Liquid Assayed Specific Protein Controls Level 1 Lots 647LPC and 686LPC are low below the measurement range of nephelometric methods on Siemens instruments. Randox have since updated the IFU's and removed the associated targets and ranges.

Randox Laboratories can also confirm that Anti Streptolysin O (ASO) target and range values have been reassigned in lot no's 706LPC, 707LPC, 708LPC, 709LPC and 710LPC. Please see table below for updated target values.

Table 1:

Lot Numbers	Method	Units	Previous Target	Previous Range	Updated Target	Updated Range
706LPC	Turbidimetric (Non IFCC)	IU/ml	193	154-232	160	128-192

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707LPC	Turbidimetric (Non IFCC)	IU/ml	293	234-352	257	206-308
708LPC	Turbidimetric (Non IFCC)	IU/ml	97.7	78.2-117	80.6	64.5-96.7
709LPC	Turbidimetric (Non IFCC)	IU/ml	197	158-236	163	130-196
710LPC	Turbidimetric (Non IFCC)	IU/ml	296	237-355	262	210-314

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.

Download corrected IFU from Smartdocs.com and discard of previous copies.

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.