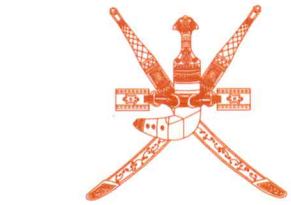
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط



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 222 **dated** 23/10/2023 **Regarding NCMDR FSCA of Randox Liquid Protein Calibrators 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**

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

ISO 9001:2015 CERTIFIED

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

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 222/ **2023**

08 -04-1445 H

23 -10-2023

Field Safety Corrective Action of Randox Liquid Protein Calibrators from Randox Laboratories Ltd.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19715
Product	Randox Liquid Protein Calibrators.
Description	IVD; In vitro diagnostic devices.
Manufacturer	Randox Laboratories Ltd.
Local Agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	GTIN: 05055273204032 Batch/Lot number (Expiry Date, Manufacturing Date): 590858 (28 Aug 23, 16 Dec 21);590859 (28 Aug 23, 29 Aug 21);627222 (28 Jul 24, 29 Jul 22);627224 (28 Jul 24, 20 Jan 23); 634886 (28 Jul 24, 29 Jul 22); 634887 (28 Jul 24, 27 Mar 23)
Reason	Ferritin in Liquid Protein Calibrators have been restandardized, IT2691, to reference material NISBC 19/118. The calibrators lots 2112IT-2116IT, packed into batches mentioned above have been reassigned as part of the restandardization. Following this restandardization, Ferritin results for Quality Control material and patient samples recovered erroneously higher than the targeted calibrator values by approximately +10% across the assay range following this restandardization.
Action	1. Updated calibrator targets for the batches have been listed in Table1 in the attachment. 2. The updated Instructions For Use (IFU) is available on www.randox.com. 3. Please discard any previous versions of the IFU and download the latest version. 4. Review results generated with the affected batches in line with the clinical profile of the patient. 5. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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

RANDOX

Urgent Field Safety Notice

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

Date Issued: 19 Jul 23

Complaint Reference: REC684

Action Type: Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Liquid Protein Calibrators	IT2691	05055273204032	590858	28 Aug 23	16 Dec 21
			590859	28 Aug 23	29 Aug 21
			627222	28 Jul 24	29 Jul 22
			627224	28 Jul 24	20 Jan 23
			634886	28 Jul 24	29 Jul 22
			634887	28 Jul 24	27 Mar 23

Reason for Action:

As part of our ongoing quality monitoring, Randox Laboratories have restandardised Ferritin in Liquid Protein Calibrators, IT2691, to reference material NISBC 19/118. Current calibrators lots 2112IT-2116IT, packed into batches 627222, 627224, 634886 and 634887 have been reassigned as part of the restandardisation.

Ferritin results for Quality Control material and patient samples is expected to recover higher by approximately +10% across the assay range following this restandardisation. Updated calibrator targets for the batches have been listed in Table1 below. The updated Instructions For Use (IFU) is available on www.randox.com, please discard the previous version of the IFU and download the latest version.

Table 1

Lot Number	Previous Target (ng/ml)	Updated Target (ng/ml)
2112IT	23.4	23.9
2113IT	47.2	54.2
2114IT	96.9	102.6
2115IT	190.5	216.4
2116IT	423.5	483.6

Form No. 6307-TS
REVISION (10)
4th Feb 2019

RANDOX

Urgent Field Safety Notice

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

Any customers using batches 590858 and 590859 for Ferritin, please contact technical.services@randox.com

Risk to Health:
Ferritin is an iron storage protein, and a test may be ordered along with other iron status test in a patient suffering from symptoms suggestive of iron deficiency anaemia.
Potential to misclassify patient results due to an incorrectly reported result, however, Ferritin results are likely to be reviewed along with other iron status tests.

Action to be taken:

- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

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.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Form No. 6307-TS
REVISION (10)
4th Feb 2019