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. 264 **dated** 21/12/23 **Regarding NCMDR Field Safety Corrective action of Serology ToRCH IgM Positive Control 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

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. 264 / 2023

08 -05-1445 H
21 -12-2023

Field Safety Corrective Action of Serology ToRCH IgM Positive Control 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=19809
Product	Serology ToRCH IgM Positive Control.
Description	Multiple infectious organism IVDs.
Manufacturer	Randox Laboratories Ltd..
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Catalogue number: SR10349 Lot number: 157SR (Manufacturing Date:9th December 2022 ,Expiray Date: : 28th May 2024) Lot number: 216SR (Manufacturing Date:25th July 2023 ,Expiray Date: : 28th Feb 2025)
Reason	There has been a decrease in the reactivity of HSV Type 1/2 IgM in the Serology ToRCH IgM Positive Control, SR10349, lot 157SR when tested on the DiaSorin Liaison XL. There has been a Transcription error on the instructions of use (IFU) for SR10349 lot 216SR.
Action	1. Please discard all copies of the IFU that are mentioned in the attachment and download the latest version of them from www.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: 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: 6 Nov 23

Complaint Reference: REC699 **Action Type:** Device Modification

Please note, there are two sections within this notice. Review the document in full prior to completing the response form.

Part 1

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
SEROLOGY ToRCH IgM POSITIVE CONTROL	SR10349	05055273216424	157SR	28th May 2024	9th December 2022

Reason for Action:

Randox Laboratories can confirm there has been a decrease in the reactivity of HSV Type 1/2 IgM in the Serology ToRCH IgM Positive Control, SR10349, lot 157SR when tested on the DiaSorin Liaison XL. While still testing positive for HSV Type 1/2 IgM, we advise that all customers cease the usage of the control for this marker as a precaution. The other markers within this lot are not affected. Please discard all copies of the IFU and download the latest version from www.randox.com.

Risk to Health:

As the control material is still testing positive for HSV Type 1/2 IgM, there is no risk to health. If the control did test negative for this analyte, the affected run should be discarded, and the samples re-analysed.

Action to be taken:

- 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.
- Please discard all copies of the IFU and download the latest version from www.randox.com.

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

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

- For any additional questions, please contact technical.services@randox.com

Part 2

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
SEROLOGY ToRCH IgM POSITIVE CONTROL	SR10349	05055273216424	216SR	28th February 2025	25th July 2023

Reason for Action:

Randox Laboratories can confirm there has been a transcription error in the Instructions For Use (IFU) for the Serology ToRCH IgM Positive Control, SR10349, lot 216SR. For Toxo IgM, the method listed was "Reactive", which has been updated to "Biomerieux Vidas". For HSV Type 1/2 IgM, the method listed was "Biomerieux Vidas", which has been updated to "DiaSorin Liaison XL". The IFU has been updated with the correct reactivity table and is available on www.randox.com, please discard the incorrect IFU. The updated reactivity table can be seen below.

Marker	Method	Reactivity
CMV IgM	Biomerieux Vidas	Reactive
Rubella IgM	Biomerieux Vidas	Reactive
Toxo IgM	Biomerieux Vidas	Reactive
HSV Type 1/2 IgM	DiaSorin Liaison XL	Reactive

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

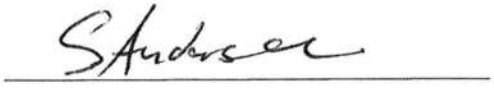
Action to be taken:

- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.
- Please discard all copies of the IFU and download the latest version from www.randox.com.
- For any additional questions, please contact technical.services@randox.com

Transmission of the 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