



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 121 dated 13/6/23 Regarding NCMDR Field Safety Corrective Action of Calibration Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3 from (mfr: Radox 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





Circular No. 121 / 2023

نتقدم بتميز
Moving Forward
with Confidence



24-11-1444 H

13-06-2023

FSCA of Calibration Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3 from Randox Laboratories Ltd.

| | |
|-----------------------|--|
| Source | NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19549 |
| Product | Calibration Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3. |
| Description | IVD. |
| Manufacturer | Randox Laboratories Ltd. |
| Local agent | Mustafa Sultan Science & Industry Co.LLC. |
| The affected products | - Calibration Serum Level 3 (CAL2351/CAL10338) - Human Precision Control Levels 2 & 3 (UN1557 & UE1558) - Human Assayed Multi-Sera Levels 2 & 3 (HN1530, HE1532 and HS2611) -Refer to "Table 1: Affected Devices" in the attachment for more details. |
| Reason | Updating the reconstituted 2 - 8 °C stability claim for GLDH in Calibrations Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3 and Alkaline Phosphatase in Calibration Serum Level 3. |
| Action | 1. Customers should be aware of the updated information of the above products stability in the attachment. 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



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: 17 May 23

Complaint Reference: REC662

Action Type: Device Modification

Reason for Notification:

In line with the Requirements and Implementation of the *In Vitro* Diagnostic Devices Regulations (IVDR) and the continuous monitoring of the performance and stability claims of our Quality Control (QC) products, we aim to provide the most accurate and up-to-date information on our Instructions for Use (IFUs). For this reason, we have updated the reconstituted 2 - 8 °C stability claim for GLDH in Calibrations Serum Level 3, Human Precision Control Levels 2 & 3 and Human Assayed Multi-Sera Levels 2 & 3 and Alkaline Phosphatase in Calibration Serum Level 3.

Calibration Serum Level 3 (CAL2351/CAL10338)

- GLDH reconstituted stability has been reduced from 7 days to 1 day when stored at 2-8°C.
- Alkaline Phosphatase reconstituted stability has been reduced from 7 days to 3 days when stored at 2-8°C.

Human Precision Control Levels 2 & 3 (UN1557 & UE1558) and Human Assayed Multi-Sera Levels 2 & 3 (HN1530, HE1532 and HS2611)

- GLDH reconstituted stability has been reduced from 7 days to 2 days when stored at 2-8°C.

The full storage and stability claim for each product can be found in the lot-specific sheets, accessed through www.randox.com.

The list of affected lot numbers is available in the table below.

RANDOX

Customer Notification

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 United Kingdom BT29 4QY
technical.services@randox.com
 Tel: +44 (0) 28 9445 1070

Table 1: Affected Devices

| Device Name | Catalogue Number | GTIN | Batch / Lot number | Expiry Date | Manufacturing Date |
|----------------------------------|------------------|----------------|--------------------|-------------------------|---------------------------|
| Calibration Serum Level 3 | CAL10388 | N/A | 1155UE | 28 th May 23 | 19 th Apr 21 |
| | CAL2351 | 05055273200966 | 1154UE | 28 th May 23 | 10 th Jun 21 |
| | | | 1155UE | 28 th May 23 | 15 th Apr 21 |
| | | | 1156UE | 28 th May 23 | 19 th Nov 2020 |
| | | | 1225UE | 28 th Oct 23 | 7 th Sep 21 |
| | | | 1196UE | 28 th Oct 23 | 9 th Sep 21 |
| Human Precision Control Level 2 | UN1557 | 05055273206807 | 1400UN | 28 th May 23 | 3 rd Sep 19 |
| | | | 1440UN | 28 th May 23 | 12 th Nov 19 |
| | | | 1459UN | 28 th Jan 24 | 20 th Mar 2020 |
| Human Precision Control Level 3 | UE1558 | 05055273206791 | 1088UE | 28 th Jun 23 | 9 th Aug 19 |
| | | | 1116UE | 28 th Jun 23 | 9 th Aug 19 |
| Human Assayed Multi-Sera Level 2 | HN1530 | 05055273203783 | 1416UN | 28 th Jun 23 | 4 th Mar 2020 |
| | | | 1417UN | 28 th Jun 23 | 1 st Apr 21 |
| | | | 1489UN | 28 th May 24 | 20 th Apr 21 |
| | | | 1496UN | 28 th May 24 | 27 th Apr 21 |
| | | | 1497UN | 28 th May 24 | 12 th May 21 |
| | | | 1502UN | 28 th Jun 24 | 20 th Jul 21 |

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|---|--------|----------------|--------|-------------------------|--------------------------|
| Human Assayed Multi-Sera Level 3 | HE1532 | 05055273203608 | 1102UE | 28 th Jul 23 | 4 th Mar 2020 |
| | | | 1103UE | 28 th Jul 23 | 22 nd Mar 21 |
| | | | 1104UE | 28 th Jul 23 | 8 th Jul 23 |
| | | | 1222UE | 28 th Dec 23 | 31 st May 21 |
| | | | 1173UE | 28 th Jun 24 | 3 rd Jun 21 |
| | | | 1174UE | 28 th Jun 24 | 20 th Apr 21 |
| | | | 1223UE | 28 th Apr 25 | 23 rd Sep 21 |
| | | | 1224UE | 28 th Apr 25 | 23 rd Sep 21 |
| Human Assayed Multi-Sera Levels 2 & 3 | HS2611 | 05055273203813 | 578618 | 28 th Jun 24 | 27 th Sep 21 |

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@radox.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 Radox Technical Services.