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 233 **dated** 20/12/2022 **Regarding NCMDR Field Safety Corrective Action of LinkSeq HLA Typing Kits from (mfr: One Lambda Inc).**

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

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Circular No. 233 / 2022

26 -05-1444 H

20 -12-2022

Field Safety Corrective Action of LinkSeq HLA Typing Kits from One Lambda Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18363
Product	LinkSeq HLA Typing Kits.
Description	Multiple human leukocyte antigens (HLA) typing IVDs.
Manufacturer	One Lambda Inc.
The affected products	Product Reference Codes: 1575C and 1580C Lot numbers: K4224-AC, K4227-AC, K4216-AC and K4231-AC.
Reason	May generate incorrect results without software warnings. False reactions without software warnings would result in a heterozygous DQB1*04 and DQB1*05 assignment instead of a homozygous DQB1*05 assignment. Moreover, they may generate incorrect results with software warnings encompassing rare / no call / haplocheck.
Action	Thermo fisher is advising customers that as a corrective action, the primer for LSDQB-008.1 and LSDQB-009.1 assays were updated to prevent a false positive reaction with DQB1*05:04. These assays will be added to the next lot. Once available, the Sponsor will be replacing any existing stock in the market via a recall action.In the interim Thermo Fisher ask customers to: 1. Confirmatory testing with a secondary method is required to resolve a heterozygous DQB1*04 DQB1*05 result. 2. Review past test results that were assigned DQB1*04 DQB1*05 typing results. 3. If software flagged the results to check for warnings/alerts related to typing results, test results might need to be further investigated by HLA Laboratory Director. 4. If there are no software flagged results, samples that are assigned DQB1*04 DQB1*05 typing results should be re-tested with a secondary method to confirm the typing results as required. 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

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