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.96**..... dated .**22/5/22**.. Regarding GHC recall of Magellan Diagnostics from (mrf: Magellan Diagnostics).**

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. 96 / 2022

23 -10-1443 H

22 -05-2022

Recall of LeadCare from Magellan Diagnostics.

Source	GHC- Gulf Health Council.
Product	LeadCare.
Description	LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests
Manufacturer	Magellan Diagnostics.
The Affected Products	Attached.
Reason	Due to a significant risk of falsely low results.
Action	1. Kindly take the necessary action to recall the above-mentioned Jots of the medical device if available in your facility. 2. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

MOHAP/O/22/002829

التاريخ: 2022/04/06
المرجع : MOHAP/O/22/002829

تقارير السلامة للوسائل الطبية
Safety Alerts for Medical Device

To : All Healthcare Facilities All Healthcare Professionals		إلى: جميع المنشآت الصحية جميع ممارسي الرعاية الصحية
Subject: Safety Alerts for Medical Device		**الموضوع: تقارير السلامة للوسائل الطبية**
Name of product:	**LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests**	**اسم المنتج:**
Company Name:	**Magellan Diagnostics**	**الشركة المصنعة:**
Source of Recall: USA FDA	https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk?utm_medium=email&utm_source=govdelivery	**مصدر السحب:** إدارة الغذاء والدواء الامريكية

Name of product اسم المنتج	Lot No. التشغيلات المتأثرة	تاريخ انتهاء الصلاحية Expiration date
LeadCare II	2013M	22APR22
	2014M	29APR22
	2015M	12MAY22
	2016M	19MAY22
	2017M	10JUN22
	2101M	28JUL22
	2103M	18AUG22
	2105M	11SEP22
	2106M	21JAN22
	2107M	30SEP22
	2012M Sublots: -08, -09, -10, -11, -12, -13, -14	08APR22
	2018M	06JUN22
	2102M	30SEP21
	2109M	15OCT22
	2110M	29OCT22
	2111M	31MAY22
	2112M	13NOV22
	2113M	30JUN22
	2114M	17DEC22
	2115M	29DEC22
	7114M	17DEC22
LeadCare Plus LeadCare Ultra	2011MU	25MAR22
	2104MU	25AUG22
	2108MU	31MAR22

Product Status in MOHAP:	For professional use	لاستخدام ممارسي الرعاية الصحية	**الوضع القانوني للمنتج في الوزارة:**
Indication:	To test blood lead level.	لفحص مستوى الرصاص في الدم	**دواعي الاستخدام:**
Reason for Recall: Due to a significant risk of falsely low results.			**سبب السحب:** بسبب وجود احتمال كبير للحصول على نتائج منخفضة بشكل خاطئ
Recommendation: Kindly take the necessary action to recall the above-mentioned lots of the medical device if available in your facility.			**التوصيات:** يرجى اتخاذ إجراءاتكم اللازمة حيال سحب التشغيلات المذكورة أعلاه للوسائل الطبية، في حال توفرها لديكم.
Report adverse reaction	http://www.mohap.gov.ae/ar/services/Pages/406.aspx UAE RADR Smart Application		**للإبلاغ عن الآثار الجانبية للدواء**
For All Enquiries	pv@moh.gov.ae		**لجميع الاستفسارات**

This circular is for regulatory procedures & should not be used for media publication

هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي

لمزيد من التنسيق والمتابعة نرجو منكم الايعاز لمن يلزم للتواصل على الارقام التالية
هاتف: 042301667/042301443/042301523 - البريد الالكتروني: pv@mohap.gov.ae

مع تحيات قطاع التنظيم الصحي
بوزارة الصحة ووقاية المجتمع