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 112 **dated** 29/5/23 **Regarding NCMDR Field Safety Notice of Alinity i Anti-TPO Reagent Kit, Alinity i CMV IgM Reagent Kit from (mfr: Abbott).**

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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سلطنة عُمان
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Circular No. 112 **/ 2023**

09 -11-1444 H

29 -05-2023

Field Safety Notice of Alinity i Anti-TPO Reagent Kit, Alinity i CMV IgM Reagent Kit from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19524
Product	Alinity i Anti-TPO Reagent Kit, Alinity i CMV IgM Reagent Kit.
Description	IVD.
Manufacturer	Abbott.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	List Number (LN): 09P3522, 07P4432 Lot Number: 50321FN00, 49341FN00 UDI: (01)00380740150617 (17)240720(10)50321FN00, (01)00380740129880 (17)240117(10)49341FN00
Reason	Due to a manufacturing fill volume error, the Alinity i reagents above, contain a marginal lower fill volume than detailed in the Kit Contents section of the Instructions For Use (IFU).
Action	1. Refer to "Necessary Actions to be Taken by Customer" in the attached FSN. 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

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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CORE DIAGNOSTICS
Abbott Ireland Diagnostics Division,
Finiskin Business Park,
Sligo, Ireland

Single Registration Number (SRN):
IE-MF-000009849

Urgent Product Correction

Immediate Action Required

Date Issued April 24, 2023

Product

Product Description	List Number (LN)	Lot Number	UDI
Alinity i Anti-TPO Reagent Kit	09P3522	50321FN00	(01)00380740150617 (17)240720(10)50321FN00
Alinity i CMV IgM Reagent Kit	07P4432	49341FN00	(01)00380740129880 (17)240117(10)49341FN00

Explanation

Abbott has confirmed that due to a manufacturing fill volume error, the Alinity i reagents below, contain a marginal lower fill volume than detailed in the Kit Contents section of the Instructions For Use (IFU):

Alinity i Anti-TPO Reagent Kit, Lot 50321FN00.
Although the volume in the impacted lot is below the defined volume in the IFU, adequate reagent exists to provide the defined number of tests in the kit.

Alinity i CMV IgM Reagent Kit, Lot 49341FN00.
Due to the reduced reagent volume, there may not be adequate volume to achieve the defined number of tests in the IFU. There is the potential to generate Liquid Level Sense (LLS) message codes. For example, message code "3424 – (0) pipettor aspiration error" followed by "3048 - Maximum number of LLS errors exceeded in reagent cartridge (0) position located in reagent carousel position (1), 0 = Bottle, 1 = Reagent carousel position ".

Abbott has confirmed there is no impact to assay performance for the affected lots.

Abbott is investigating further the root cause of this event and will take the necessary actions to prevent recurrence in the future.

Impact on Patient Results There is no impact to patient results.

Necessary Actions to be Taken by Customer

We recommend that you follow the necessary actions below:

Alinity i Anti-TPO Reagent Kit (2x100T), Lot 50321FN00
No action is required. You may continue to use the lot as adequate volume exists to provide the defined number of tests in the kit.

Alinity i CMV IgM Reagent Kit (2x500T), Lot 49341FN00
You may continue to use LN 07P4432, lot 49341FN00, however these kits may not contain sufficient reagent volume to complete 500 tests. These kits will provide approximately 475 tests.

If liquid level sense message codes such as 3424 followed by 3048 are generated after approximately 475 tests, replace the reagent cartridge to continue testing. If you receive a message code before achieving 475 tests, please perform troubleshooting per the Alinity ci-series Operations Manual.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Complete and return the Customer Reply form.

Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.