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. 93 **dated** 8/5/22 **Regarding NCMDR FSCA of Alinity m SARS-CoV-2 AMP Kit, Alinity m Resp-4-Plex AMP Kit, Alinity m SARS-CoV-2 Application Specification File, and Alinity m Resp-4-Plex Applcation Specification File from (mrf: Abbott Molecular 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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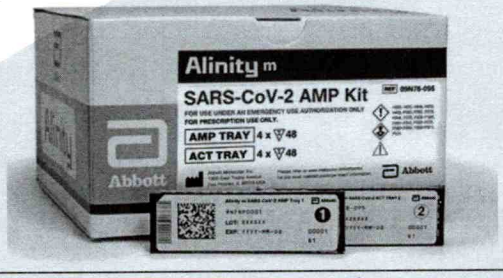
Circular No. 83 / 2022

07 -10-1443 H

08 -05-2022

Field Safety Corrective Action of Alinity m SARS-CoV-2 AMP Kit, Alinity m Resp-4-Plex AMP Kit, Alinity m SARS-Co Application Specification File, and Alinity m Resp-4-Plex Application Specification File. from Abbott Molecular Inc.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16116
Product	Alinity m SARS-CoV-2 AMP Kit, Alinity m Resp-4-Plex AMP Kit, Alinity m SARS-CoV-2 Application Specification File, and Alinity m Resp-4-Plex Application Specification File.
Description	IVD.
Manufacturer	Abbott Molecular Inc.
Local Agent	Waleed Pharmacy & Stores LLC.
The affected products	List Numbers: 09N78-090, 09N78-091, 09N79-090, 09N78-01E, and 09N79-01D Not Lot Specific. Unique Device Identifiers (UDIs): 00884999049215, 00884999049963, 00884999049338, (01)00884999050228(240)09N78-01E(8012)5.00, and (01)00884999050235(240)09N79-01D(8012)4.00
Reason	Reports of Alinity m SARS-CoV-2 false positive results.
Action	1. Abbott has updated the existing Application Specification files for Alinity m SARS-CoV-2 and Resp-4-Plex to further reduce the potential for carryover. 2. A Molecular Diagnostics Abbott Representative will be contacting you once the updated Application Specification files are available. 3. 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

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