Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

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 113 **dated** 10/6/2025 **Regarding SFDA Recall of Alinity m Resp-4-Plex AMP Kit from (mfr: Abbott Molecular Division Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 113 **/ 2025**

14 -12-1446 H
10 -06-2025

Recall of Alinity m Resp-4-Plex AMP Kit from Abbott Molecular Division Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/382
Product	Alinity m Resp-4-Plex AMP Kit.
Manufacturer	Abbott Molecular Division Inc.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	List Number: 09N79-090 Lot Numbers: 409383, 410627, 411921 UDI: Refer to the attachment.
Reason	Increase in reactive negative controls and false positive results.
Action	1. Discard inventory of the affected lots. 2. Contact the local agent for the replacement of any unused kit(s).
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: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Molecular Diagnostics at Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m Resp-4-Plex AMP Kit
List Number: 09N79-090
Lot Numbers: 409383, 410627, 411921
Unique Device Identifiers (UDIs): See table below

April 24, 2025

Dear Abbott Customer,

This letter contains important information regarding the Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090 Lot Numbers 409383, 410627, and 411921, utilized with the Alinity m System. Please review this information carefully.

LIST NUMBER	LOT NUMBER	UDI
09N79-090	409383	(01)00884999049338(10)409383(17)251030(240)09N79-090
09N79-090	410627	(01)00884999049338(10)410627(17)260103(240)09N79-090
09N79-090	411921	(01)00884999049338(10)411921(17)260103(240)09N79-090

Background:
Abbott has received reports of an increase in reactive negative controls and false positive results, with Alinity m Resp-4-Plex AMP Kit, List Number 09N79-090 Lot Numbers 409383, 410627, and 411921, on the Alinity m System. Specifically, an increase in the amount of reactive negative controls and false positive results have been reported for the Respiratory Syncytial Virus (RSV) and Influenza B virus (flu B) and targets. Based on internal evaluation, false positive results and reactive negative controls manifest as a weak signal with a late cycle number for these targets. Internal evaluation has not shown impact to Influenza A virus (flu A) and SARS targets.

To date, there have been 13 customer complaints associated with these lots, and no reported injuries.

Potential Impact:
There is a potential for delayed results and false positive results for RSV and flu B when using these lots. All subsequent lots of Alinity m Resp-4-Plex AMP kits are not impacted.

Necessary Actions:
- Discard inventory of the lots listed in the above table. Contact Abbott Customer Support for replacement any unused kit(s).
- If you have forwarded any kits of these lots to other laboratories, please inform them of this Urgent Field Safety Notice and provide a copy of this letter.
- Return the associated Customer Reply form.

Abbott

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Pamela Yip 4.24.2025

Pamela Yip
Divisional Vice President, Quality Assurance
Molecular Diagnostics at Abbott