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 120 **dated** 10/6/2025 **Regarding SFDA Recall of ID NOW™ COVID-19 2.0, ID NOW™ RSV & ID NOW™ Influenza A & B 2 from (mfr: Abbott Diagnostics Scarborough, Inc. - Alere Scarborough 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

ISO 9001:2015 CERTIFIED

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
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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 120 **/ 2025**

14 -12-1446 H
10 -06-2025

Recall of ID NOW™ COVID-19 2.0, ID NOW™ RSV & ID NOW™ Influenza A & B 2 from Abbott Diagnostics Scarborough, Inc. - Alere Scarborough Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/378
Product	ID NOW™ COVID-19 2.0, ID NOW™ RSV & ID NOW™ Influenza A & B 2.
Manufacturer	Abbott Diagnostics Scarborough, Inc. - Alere Scarborough Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ID NOW™ COVID-19 2.0 24T, List Number: 192000, GTIN: 00811877011354 ID NOW™ COVID-19 2.0 24T OUS, List Number: 193000, GTIN: 00811877011378 ID NOW™ Influenza A&B 2 24T, List Number: 427000, GTIN: 10811877010422 ID NOW™ RSV 24T, List Number: 435000, GTIN: 10811877010521 Refer to the attachment for the affected lot Numbers
Reason	The affected lots have a higher occurrence of invalid rates when compared to the product Instructions for Use.
Action	1. Discontinue use of and destroy any remaining inventory of the impacted lots according to your procedures. 2. Contact your Abbott Distributor if assistance is needed to fulfill these directions.
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

Abbott

Field Safety Notice

Action Required

Date Issued MARCH 2025

Product

Product Description	List Number	Lot Number	GTIN
ID NOW™ COVID-19 2.0 24T	192000	Various – Reference Appendix I	00811877011354
ID NOW™ COVID-19 2.0 24T OUS	193000	Various – Reference Appendix I	00811877011378
ID NOW™ Influenza A&B 2 24T	427000	Various – Reference Appendix I	10811877010422
ID NOW™ RSV 24T	435000	Various – Reference Appendix I	10811877010521

Explanation

Dear Valued Customer,

The purpose of this letter is to inform you that Abbott Diagnostics Scarborough, Inc. is performing a Product Correction impacting select lots of ID NOW™ COVID-19 2.0, ID NOW™ RSV & ID NOW™ Influenza A & B 2. Abbott has confirmed that the impacted lots identified in Appendix I of this document have a higher occurrence of invalid rates when compared to the product Instructions for Use. The issue has been isolated to specific sample receiver devices, which have been assembled into the kit lots outlined in Appendix I.

Please review the steps below which provide details on the actions required by you. We sincerely apologize for any inconvenience this action may cause you and those you serve.

Abbott has worked diligently to determine the root cause of this event, and the necessary actions have been taken to prevent recurrence. We remain committed to providing you with the highest quality diagnostic products and support services to meet your needs.

Impact on Patient Results

- There is a potential for delay of patient results due to inability to generate a valid result.
- Any test result (positive or negative) generated should be considered as valid.

Necessary Actions to be Taken by Customer

Please complete the following actions, as applicable.

If....	Then...
You have impacted inventory in stock:	• Discontinue use of and destroy any remaining inventory of the impacted lots according to your procedures. Contact your Abbott Representative if assistance is needed to fulfill these directions. • Complete and return the Customer Reply Form (Form must be completed, signed and returned to receive a replacement lot). • Please retain this letter for your records.
You have forwarded the product listed above to others in the network,	• Inform them of this Field Safety Notice and provide to them a copy of this notice and request they take the necessary action.
You do not have impacted inventory in stock	• All product lots not identified in Appendix I can continue to be used.

Contact Information

If you have questions regarding this information, please contact Sedgwick at one of the numbers below between the hours of 8am – 5pm, Monday - Friday.

Country	*Toll-Free*
Belgium	0800 75 577
France	0 805 98 79 73
Germany	800-92952266
Italy	0800-796824
Japan	800-8050681
Netherlands	800-0221129
UK	0800 102 6530
International	+44 20 8834 9591

If you have experienced any patient or user injury associated with this Field Safety Notice, please immediately report the event to your local area Customer Service.
Adverse reactions or quality problems experienced with the use of this product may be reported to your local health authority.

Appendix I

ID NOW™ COVID-19 2.0 24T			
Part #	**Lot #**	**Expiry Date**	**UDI**
192000	000M914119	2026 07 30	01008118770113541726073010000M914119
192000	000M915352	2026 08 03	01008118770113541726080310000M915352
192000	000M934978	2026 09 27	01008118770113541726092710000M934978
ID NOW™ COVID-19 2.0 24T OUS			
Part #	**Lot #**	**Expiry Date**	**UDI**
193000	000M892269	2026 05 27	01008118770113781726052710000M892269
193000	000M908401	2026 07 13	01008118770113781726071310000M908401
193000	000M908703	2026 07 14	01008118770113781726071410000M908703
193000	000M908726	2026 07 14	01008118770113781726071410000M908726
193000	000M908830	2026 07 15	01008118770113781726071510000M908830
193000	000M913824	2026 07 29	01008118770113781726072910000M913824
193000	000M914106	2026 07 30	01008118770113781726073010000M914106
193000	000M924752	2026 08 28	01008118770113781726082810000M924752
ID NOW™ Influenza A & B 2 24T			
Part #	**Lot #**	**Expiry Date**	**UDI**
427000	000M919592	2026 06 14	01108118770104221726061410000M919592
427000	000M920324	2026 06 14	01108118770104221726061410000M920324
427000	000M931527	2026 07 21	01108118770104221726072110000M931527
427000	000M931825	2026 07 21	01108118770104221726072110000M931825
ID NOW™ RSV 24T			
Part #	**Lot #**	**Expiry Date**	**UDI**
435000	000M907281	2025 11 07	01108118770105211725110710000M907281
435000	000M934610	2026 01 28	01108118770105211726012810000M934610

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Customer Reply

Field Safety Notice – Acknowledgement form

Appendix II

ID NOW™ COVID-19 2.0, ID NOW™ Influenza A & B 2 and ID NOW™ RSV Products

Identifier: **2025 02**

This response form is to confirm receipt of this notification and to request replacement product, if eligible.

1. Customer Details

Account / Customer Number	
Healthcare Organization Name*	
Distributor/ Vendor, if applicable	
Street*	
City*	
Country*	
Contact Name*	
Department/Unit	
Title or function	
Telephone number*	
E-mail*	
Shipping Address if different than above	

2. Customer action undertaken

☐	I confirm that we, the Customer, have received, read, and understood this Field Safety Notice for ID NOW™ COVID-19 2.0, ID NOW™ Influenza A & B 2 and ID NOW™ RSV products.
☐	We have taken the necessary actions as directed by this Field Safety Notice and have destroyed the quantity of affected product that we have outlined in the table below.
Please select one:	
☐	I do not have affected product. Please explain:
☐	I have affected product. *Please complete Request for Replacement Product.*

Abbott

Customer Reply

Field Safety Notice – Request for Replacement Product

Request for Replacement Product

ID NOW™ COVID-19 2.0, ID NOW™ Influenza A & B 2 and ID NOW™ RSV Products

Identifier: **2025 02**

This response form is to confirm receipt of this notification and to request replacement product, if eligible.

Kit Name	Part number	Lot number(s)	Requested KIT BOX replacement Qty
ID NOW™ COVID-19 2.0 24T	192000	000M914119	_____ kits or □ N/A
		000M915352	_____ kits or □ N/A
		000M934978	_____ kits or □ N/A
ID NOW™ COVID-19 2.0 24T OUS	193000	000M892269	_____ kits or □ N/A
		000M908401	_____ kits or □ N/A
		000M908703	_____ kits or □ N/A
		000M908726	_____ kits or □ N/A
		000M908830	_____ kits or □ N/A
		000M913824	_____ kits or □ N/A
		000M914106	_____ kits or □ N/A
		000M924752	_____ kits or □ N/A
ID NOW™ Influenza A & B 2 24T	427000	000M919592	_____ kits or □ N/A
		000M920324	_____ kits or □ N/A
		000M931527	_____ kits or □ N/A
		000M931825	_____ kits or □ N/A
ID NOW™ RSV 24T	435000	000M907281	_____ kits or □ N/A
		000M934610	_____ kits or □ N/A
Printed Name		Signature / Date	

3. **Return acknowledgement to sender.**

Email	AbbottIDNOW@sedgwick.com
Deadline for returning the customer reply form	Please complete and return this form within **10 business days** of receipt.