



Field Safety Notice

Action Required



Date Issued MARCH 2025

Product

Product Description	List Number	Lot Number	GTIN
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

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 and 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.

Please complete the following actions, as applicable.

**Necessary
Actions to be
Taken by
Customer**

If....	Then...
You have impacted inventory in stock:	<ul style="list-style-type: none">• Discontinue use of and destroy any remaining inventory of the impacted lots according to your procedures.• 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,	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• All product lots not identified in Appendix I can continue to be used.

**Contact
Information**

If you have questions regarding this information, please contact my.techsupport@abbott.com.

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
193000	000M892269	2026 05 27	01008118770113781726052710000M892269
193000	000M914106	2026 07 30	01008118770113781726073010000M914106
ID NOW™ Influenza A&B 2 24T			
Part #	Lot #	Expiry Date	UDI
427000	000M931527	2026 07 21	01108118770104221726072110000M931527
427000	000M931825	2026 07 21	01108118770104221726072110000M931825



Customer Reply

Field Safety Notice – Acknowledgement form

Appendix II Field Safety Notice

ID NOW™ COVID-19 2.0 and ID NOW™ Influenza A&B 2 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**

<input type="checkbox"/>	I confirm that we, the Customer, have received, read, and understood this Field Safety Notice for ID NOW™ COVID-19 2.0 and ID NOW™ Influenza A&B 2.
<input type="checkbox"/>	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 1	
<input type="checkbox"/>	I do not have affected product. Please explain:
<input type="checkbox"/>	I have affected product. <i>Please complete Request for Replacement Product.</i>



Customer Reply

Field Safety Notice – Request for Replacement Product

Request for Replacement Product

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

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 BOXES replacement Qty
ID NOW™ COVID-19 2.0 24T OUS	193000	000M892269	_____ kits or <input type="checkbox"/> N/A
		000M914106	_____ kits or <input type="checkbox"/> N/A
ID NOW™ Influenza A&B 2 24T	427000	000M931527	_____ kits or <input type="checkbox"/> N/A
		000M931825	_____ kits or <input type="checkbox"/> N/A
Printed Name		Signature / Date	

3. Return acknowledgement to sender.

Email	my.techsupport@abbott.com
Deadline for returning the customer reply form	Please complete and return this form within 10 business days of receipt.