Single Registration Number (SRN): N/A

Field Correction Notice

Action Required

Date Issued JUNE 2025

Product

Product Description	List Number	Lot Number	GTIN
ID NOW™ COVID-19 2.0 24T OUS	193000	00M924752L	00811877011378

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 previously identified 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 lot listed above and Appendix I**.**

NOTE: As of June 2025, an additional lot has been identified. This notice pertains solely to the newly added lot. If you have not received this notice previously, you are only impacted by the lot number mentioned above in this letter. Please take the actions outlined herein and below.

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 of the **ADDITIONAL LOT** highlighted on page 1 of this notice:	• Discontinue use of and destroy any remaining inventory of the impacted lot according to your procedures. Contact your Abbott Representative if assistance is needed to fulfill these directions. • Count how many kit boxes (24 tests / kit box) require replacement. • Complete and return the Customer Reply Form (Customer Reply Form must be completed, signed and returned **within 10 business days of receipt** to receive replacement product). • 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 and RETURN THE FORM TO YOU to coordinate product replacement on their behalf
You do not have impacted inventory in stock of the **ADDITIONAL LOT** highlighted on page 1 of this notice:	• All product lots not identified on page 1 can continue to be used. • Complete and return the Customer Reply Form indicating "I do not have any product".

Contact Information

If you have questions regarding this information, please contact Abbott RMDx Rapid and Molecular Diagnostics by email at Field.safety.notifications@abbott.com .

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 OUS			
Part #	**Lot #**	**Expiry Date**	**UDI**
193000	00M924752L	2026 08 28	0100811877011378172608281000M924752L

Abbott

Customer Reply

Field Correction Notice – Acknowledgement form

Appendix II

ID NOW™ COVID-19 2.0 24T OUS

Identifier: **2025 02**

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

1. **Customer Details** (**all fields are mandatory unless otherwise noted**)

Account / Customer Number (optional)	
Healthcare Organization Name	
Distributor Name (if applicable)	
Street	
City	
Zip Code / State	
Contact Name	
Department/Unit	
Title or function	
Telephone number	
E-mail	
Shipping Address (if different than above)	

2. **Customer action undertaken. Please read below. Confirm and complete the actions taken**.

3.

Please read below. Select the checkbox to confirm the actions taken.	
☐	I confirm that we, the Customer, have received, read, and understood this Field Safety Notice for ID NOW COVID-19 2.0 product.
☐	We have taken the necessary actions as directed by this Field Correction Notice and have destroyed the quantity of affected product that we have outlined in the table below.
Please Select one (1) of the options below:	
☐	I have affected product. *Please complete Request for Replacement Product (next page)* **Print and sign below**.
☐	I do not have affected product. *(Request for Replacement Product is not required*) **Print and sign below**.
Printed Name	**Signature / Date**

Customer Reply

Field Correction Notice – Request for Replacement Product

Request for Replacement Product

ID NOW™ COVID-19 2.0 24T OUS

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 (24 tests / kit box)	193000	00M924752L	_____ kits or ☐ N/A

Before submitting, please ensure that section 2 "Customer Actions Undertaken" is fully completed, signed and dated. Otherwise, the request for replacement product cannot be processed.

4. Return acknowledgement to sender.

Email	Field.safety.notifications@abbott.com
Deadline for returning the customer reply form	Please complete and return this form within **10 business days** of receipt.