Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Date: 28 November 2023

To Whom It May Concern

RE: Revised Field Safety Notice (FSN) for ID Now Instrument FSCA (Identifier 2023 09)

This notice is to inform you of a correction made to the original Field Safety Notice (FSN), FSCA Identifier 2023 09 that was provided on 19 October 2023.

We identified an inadvertent omission of an additional part number (NAT-000S) for the refurbished ID NOW Instrument and the Alere I from the original FSN. While this part number was omitted from the original FSN, it was however included as part of the impacted part numbers within the original FSCA Report filed.
This oversight was only on the original FSN and has been resolved in the attached revised FSN.

In addition, please note that any subsequent data that may have been provided after the initial FSCA communication, does contain the correct data i.e., it included both part numbers (NAT-000 and NAT-000S) of the ID NOW instrument and were therefore not impacted by this error.

Please do not hesitate to contact us at ARDX.AR@abbott.com if you have any queries or require further information.

Yours Sincerely,

Jeanette Johnson
Director, QA Post Market Surveillance
Abbott Diagnostics Scarborough, Inc

Urgent Field Safety Notice

ID NOW™ Instrument

FSCA-identifier: 2023 09
Device Modification : Software upgrade

October 2023

Product Name:	Part Number:	Serial Numbers
ID NOW™ Instrument	NAT-000 (GTIN 00811877010593 / 00811877010821)	All
	NAT-000S (GTIN 00811877010838)	

Dear Valued Customer,

Abbott Diagnostics Scarborough, Inc. is bringing to your immediate attention a product correction via software upgrade for the ID NOW™ Instrument, part number NAT-000, NAT-000S.

Reason for Correction:
Our records show that you have received ID NOW Instrument, which is used in conjunction with the ID NOW COVID-19 2.0 and ID NOW Influenza A&B 2 tests. When using the current version of ID NOW software, version 7.0, users have the ability to run the ID NOW COVID-19 2.0 and ID NOW Influenza A&B 2 test sequentially, from one patient sample. Some customers have reported an increase in Influenza B false positive test results when using the device in this manner.

In house testing has confirmed ID NOW Influenza A & B 2 Influenza B Specificity remains within label claims (97.1% with a 95% confidence interval of 95.9%-98.1%) when using sequential workflow, but due to an increase in customer complaints, a software modification has been implemented in software version 7.1 to mitigate the potential occurrence of false positive Influenza B test results.

Per a Health Hazard Evaluation conducted, the anticipated risk to patients due to Influenza B false positive test results is low. A patient receiving a false positive Influenza B test result is unlikely to experience serious harm or result in unnecessary medical intervention.

Action to be taken:

- Please upgrade your ID NOW Instrument software using the included ID NOW Software Upgrade kit NAT-300 to software version 7.1.
- Please complete and return the attached Return Response Form within 10 days of receipt of this letter.

Transmission of this Urgent Field Notice:
Please communicate this Field Notice to all those who need to be aware of it within the organization. Additionally, please communicate this notice to any organization where the affected product has been transferred or transfer this notice to other organizations where this action has an impact.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

The undersigned confirms that the relevant Competent Authorities have been advised of this Field Safety Notice, as applicable.

We regret any inconvenience that this may cause your facility. We appreciate your attention and cooperation in this matter. If you have additional questions relating to the product, please contact your local Abbott Representative.

Sincerely,

Abbott Rapid Diagnostics Quality Assurance

It is important that your organization takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice.

Your organization's reply is the evidence Abbott needs to monitor the progress of the corrective actions.

Field safety notice – Acknowledgement form

Product Name:	Part Number:	Serial Numbers
ID NOW™ Instrument	NAT-000 (GTIN 00811877010593 / 00811877010821)	All
	NAT-000S (GTIN 00811877010838)	

1. Customer details

Account/Customer Number	
Healthcare Organization Name*	
Street*	
City*	
State*	
Zip code*	
Contact name*	
Department/Unit	
Title or function	
Telephone number*	
E-mail*	
Shipping address if different than above*	
SN	

2. Customer action taken on behalf of Healthcare Organization. Please check ALL appropriate boxes.

☐	I have read and understand the instructions provided in the letter dated October 2023 **and will update the software of the ID NOW instrument.**
☐	I confirm that my facility has affected product(s) at site. Current software version used: _____
☐	I do not have affected product. Please explain: _____

Print Name	Date/signature

3. Return acknowledgement to sender

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