Urgent Field Safety Notice

ID NOW Instrument

FSCA-identifier: 2023 09
Device Modification : Software upgrade

September 2023

Product Name:	Part Number:	Serial Numbers
ID NOW Instrument	NAT-000	All

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.

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	All

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*	

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 September 2023 **and will update the software of the ID NOW instrument(s)**
☐	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	ardx.swupdatecanada@abbott.com
Deadline for returning this form	Please complete and return this form within **10 business days** of receipt