Urgent Field Notice

Incorrect patient swabs contained in ID NOW COVID-19 Test Kits

FSCA-identifier: 2021 10
Device Correction

October 27, 2021

Product Name:	Part Number:	Lots
ID NOW COVID-19 24T Kit	191-000	1036275, 1036281, 1036134, 1036165, 1036244, 1036304, 1036250, 1036365

Dear Valued Customer,

Abbott Diagnostics Scarborough, Inc. is bringing to your immediate attention the product correction (Part Number 191-000) listed above. This Notice is not related to patient safety and there is no impact to patient test results.

Reason for Correction:
Our records show that you have received ID NOW COVID-19 24 T Kit Lot(s) mentioned above, which contains foam Patient Swabs that are not registered for use in your country. No other components in the above Lots are affected. All other ID NOW Lots are unaffected by this recall.

Actions to be Taken:

- Please cease usage of the Patient Swabs in your kits for the above identified Lots. Dispose of the patient swabs as per your local disposal requirements. Note, only the patient swabs are to be disposed. Do not dispose of the other components within the Kit.
- Please complete and return the attached Return Response Form within 10 days of receipt of this letter. Abbott will provide replacement patient swabs for the affected kits based on quantities indicated on the Return Response Form.
- Upon receipt of the replacement swabs, continue using the identified Lots and all other kit components along with the replacement patient swabs.

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 and maintain records of these notices.

The undersigned confirms that the relevant Competent Authorities have been advised of this Field Correction Notice.

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 performance, please contact your local Technical Services using the contact information in the Product Insert.

Sincerely,
Director, Quality Assurance

Abbott

October 27, 2021

PRODUCT CORRECTION RETURN RESPONSE FORM

Product Name:	Part Number:	Lots
ID NOW COVID-19 24T Kit	191-000	1036275, 1036281, 1036134, 1036165, 1036244, 1036304, 1036250, 1036365

Please check the appropriate box.

☐ I have read and followed the instructions in the letter; I have the following Lots in my possession:

ID NOW COVID-19 Kit Lot(s)	Quantity

☐ I have checked our stock and do not have this product.

Response Form Completed By:

Name:	
Title:	
Telephone Number:	
Email Address:	
Organization Name:	
Account Number:	
Street:	
City:	
State:	
Zip Code:	
Country:	

EMAIL COMPLETED RESPONSE FORM TO: field.safety.notifications@abbott.com