January 2023

Dear Valued Customer:

Since the launch of the BinaxNOW™ COVID-19 Antigen Self Test, Abbott has continued testing for product stability to extend the expiration date and have shared these results with the FDA. Testing has been completed to support a shelf-life (expiration date) of up to 22 months. **This letter is to notify you the BinaxNOW™ COVID-19 Antigen Self Test, part number 195-160 or 195-180, in your possession may now have a longer than labeled product expiry date.** All BinaxNOW COVID-19 Antigen Self Test kits currently have a twenty-two-month expiry date.

A listing of BinaxNOW™ COVID-19 Antigen Self Test kit lot numbers, which qualify for this expiry extension, can be found in Attachment 1. The attachment lists the kit lot number, currently labeled kit expiry and new kit expiry date.

The device housing has a 2D barcode for use with NAVICA. For customers using the NAVICA app, an update to the NAVICA app will be implemented to recognize the extended expiry date.

Please be aware that the product Unique Device Identifier (UDI) barcode on the kit box will display the original expiry date when scanned. This barcode is not used in conjunction with NAVICA.

We are pleased to offer our customers this additional dating in support of their COVID-19 testing efforts. Future extensions may be communicated, as more data becomes available.

If you have further questions, please contact Abbott Technical Services at:

- Telephone: 1 800 257 9525
- Email: ts.scr@abbott.com

Sincerely,

Emily Deane
Divisional Vice President, Quality Assurance

The BinaxNOW™ COVID-19 Antigen Self Test has not been FDA cleared or approved; has been authorized by the FDA under an emergency use authorization. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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### Attachment 1 - BinaxNOW™ COVID-19 Ag Self Test lots with extended expiry

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