



March 17, 2021

To Users of the Abbott BinaxNOW™ COVID-19 Ag Card,

The Abbott BinaxNOW™ COVID-19 Ag Card has been authorized by the FDA under an emergency use authorization (EUA). Since the launch of the BinaxNOW™ COVID-19 Ag Card, Abbott has continued testing for product stability to extend the expiration date and has shared these results with the FDA. Testing has been completed to support a shelf-life (expiration date) of up to 9 months. **This letter is to notify you the BinaxNOW™ COVID-19 Ag Card product in your possession may now have a longer than labeled product expiration date.** The product was originally dated with an expiration date of 6 months. All BinaxNOW COVID-19 Ag Cards currently have a nine-month expiration date.

The device housing has a 2D barcode for use with the NAVICA app. For customers using the NAVICA app, an update to the NAVICA app was implemented to recognize the extended expiration date. Please be aware that the product Unique Device Identifier (UDI) barcode on the kit box will display the original expiration date when scanned. This barcode is not used in conjunction with the NAVICA app.

In light of the urgent need for COVID-19 testing during the public health emergency, FDA does not intend to object to users of the BinaxNOW™ COVID-19 Ag Card to continue testing with specific kit lots past their original expiration dates as long as it is not longer than 3 months past the original 6 month expiration dating labeled on the kit (see attached Abbott Customer letter with specific lots that qualify). Abbott is continuing their stability testing and if the expiration dating can be further extended, Abbott will notify customers at that time.

We note that there may be additional considerations regarding your obligations under CLIA as typically waived and moderate complexity laboratories are not permitted to deviate from the manufacturer's instructions for use. We suggest you discuss any potential need for enforcement discretion from those requirements with CLIA/CMS.

In closing, let me reiterate my thanks for your participation in COVID-19 testing efforts and your attention to this letter.

Sincerely,

Timothy T. Stenzel, M.D., Ph.D.

Director

OHT7: Office of In Vitro Diagnostics and Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health