



BinaxNOW™ COVID-19 Ag Card Product Expiry Update

May 2021

Dear Valued Customer:

Since the launch of the BinaxNOW™ COVID-19 Ag Card, 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 12 months. **This letter is to notify you the BinaxNOW™ COVID-19 Ag Card, part number 195-000, in your possession may now have a longer than labeled product expiry date.** All BinaxNOW COVID-19 Ag Cards currently have a twelve-month expiry date. This letter has been revised since the version dated March 2021 with additional lots and revised expiry dates.

A listing of BinaxNOW™ COVID-19 Ag Card lots, part number 195-000, which qualify for this expiry extension, can be found in Attachment 1. These lots were originally dated with an expiry of 6 or 9 months. The attachment lists the 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 in May 2021.

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 Ag Test Card 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.

Lot Number	Original Expiry	12 Month Expiry
129345	9-Apr-21	9-Oct-21
129358	12-Apr-21	12-Oct-21
129360	11-Apr-21	11-Oct-21
129364	10-Apr-21	10-Oct-21
129365	8-Apr-21	8-Oct-21
129380	14-Apr-21	14-Oct-21
129381	14-Apr-21	14-Oct-21
129382	13-Apr-21	13-Oct-21
129383	13-Apr-21	13-Oct-21
129427	12-Apr-21	12-Oct-21
129436	31-Mar-21	30-Sep-21
129564	12-Apr-21	12-Oct-21
129705	14-Apr-21	14-Oct-21
129711	14-Apr-21	14-Oct-21
129723	14-Apr-21	14-Oct-21
129724	13-Apr-21	13-Oct-21
129736	14-Apr-21	14-Oct-21
129737	14-Apr-21	14-Oct-21
129880	12-Apr-21	12-Oct-21
129917	2-Apr-21	2-Oct-21
129929	17-Apr-21	17-Oct-21
129957	27-Mar-21	27-Sep-21
129963	14-Apr-21	14-Oct-21
130017	15-Apr-21	15-Oct-21
130053	17-Apr-21	17-Oct-21
130090	19-Apr-21	19-Oct-21
130102	17-Apr-21	17-Oct-21
130107	17-Apr-21	17-Oct-21
130108	19-Apr-21	19-Oct-21
130109	19-Apr-21	19-Oct-21
130110	15-Apr-21	15-Oct-21
130111	19-Apr-21	19-Oct-21
130112	16-Apr-21	16-Oct-21
130113	15-Apr-21	15-Oct-21
130194	15-Apr-21	15-Oct-21
130207	13-Apr-21	13-Oct-21
130257	16-Apr-21	16-Oct-21
130300	16-Apr-21	16-Oct-21
130302	31-Mar-21	30-Sep-21
130321	16-Apr-21	16-Oct-21
130322	20-Apr-21	20-Oct-21
130323	20-Apr-21	20-Oct-21
130330	20-Apr-21	20-Oct-21