



BinaxNOW™ COVID-19 Ag Home Test Product Expiry Update

April 13, 2023

Dear Valued Customer:

Since the launch of the BinaxNOW™ COVID-19 Ag Card Home 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 Ag Card Home Test, part numbers 195-200 and 195-100, in your possession may now have a longer than labeled product expiry date.**

A listing of BinaxNOW™ COVID-19 Ag Card Home Test lots which qualify for this expiry extension, can be found in Attachment 1. 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 is in progress 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 Ag Home 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 Home Test lots with extended expiry

Lot Number	Original Expiry	New Expiry
134260	9/6/2021	10/6/2022
134260A	9/6/2021	10/6/2022
134260B	9/6/2021	10/6/2022
134260C	9/6/2021	10/6/2022
134260D	9/6/2021	10/6/2022
134260E	9/6/2021	10/6/2022
134260F	9/6/2021	10/6/2022
134260G	9/6/2021	10/6/2022
134260H	9/6/2021	10/6/2022
134260I	9/6/2021	10/6/2022
134260J	9/6/2021	10/6/2022
136102	9/1/2021	10/1/2022
136102A	9/1/2021	10/1/2022
136102B	9/1/2021	10/1/2022
136102C	9/1/2021	10/1/2022
136102D	9/1/2021	10/1/2022
136102E	9/1/2021	10/1/2022
136102F	9/1/2021	10/1/2022
136102G	9/1/2021	10/1/2022
136102H	9/1/2021	10/1/2022
136102I	9/1/2021	10/1/2022
136102J	9/1/2021	10/1/2022
136103	9/1/2021	10/1/2022
136103A	9/1/2021	10/1/2022
136103B	9/1/2021	10/1/2022
136103C	9/1/2021	10/1/2022
136103D	9/1/2021	10/1/2022
136103E	9/1/2021	10/1/2022
136103F	9/1/2021	10/1/2022
136103G	9/1/2021	10/1/2022
136103H	9/1/2021	10/1/2022
136103I	9/1/2021	10/1/2022
136103J	9/1/2021	10/1/2022
136103K	9/1/2021	10/1/2022
136903A	9/6/2021	10/6/2022
136903B	9/6/2021	10/6/2022
136903C	9/6/2021	10/6/2022
136903D	9/6/2021	10/6/2022
136903E	9/6/2021	10/6/2022
136903F	9/6/2021	10/6/2022
136903G	9/6/2021	10/6/2022
136903H	9/6/2021	10/6/2022

Lot Number	Original Expiry	New Expiry
136903J	9/6/2021	10/6/2022
136903K	9/6/2021	10/6/2022
137133A	9/6/2021	10/6/2022
137133B	9/6/2021	10/6/2022
137133C	9/6/2021	10/6/2022
137133D	9/6/2021	10/6/2022
137133E	9/6/2021	10/6/2022
137426	9/8/2021	10/8/2022
137426A	9/8/2021	10/8/2022
137426B	9/8/2021	10/8/2022
137426C	9/8/2021	10/8/2022
137426D	9/8/2021	10/8/2022
137426E	9/8/2021	10/8/2022
137426F	9/8/2021	10/8/2022
137426G	9/8/2021	10/8/2022
137426H	9/8/2021	10/8/2022
137426I	9/8/2021	10/8/2022
137426J	9/8/2021	10/8/2022
137428A	9/8/2021	10/8/2022
137428B	9/8/2021	10/8/2022
137428C	9/8/2021	10/8/2022
137428D	9/8/2021	10/8/2022
137428E	9/8/2021	10/8/2022
137525	9/10/2021	10/10/2022
137748A	9/10/2021	10/10/2022
137748B	9/10/2021	10/10/2022
137748C	9/10/2021	10/10/2022
137748D	9/10/2021	10/10/2022
137748E	9/10/2021	10/10/2022
137748F	9/10/2021	10/10/2022
138684	9/12/2021	10/12/2022
138684A	9/12/2021	10/12/2022
138684B	9/12/2021	10/12/2022
138684C	9/12/2021	10/12/2022
138684D	9/12/2021	10/12/2022
138684E	9/12/2021	10/12/2022
138684F	9/12/2021	10/12/2022
138684G	9/12/2021	10/12/2022
138684H	9/12/2021	10/12/2022
138684I	9/12/2021	10/12/2022
139051	9/18/2021	10/18/2022
139051A	9/18/2021	10/18/2022
139051B	9/18/2021	10/18/2022
139051C	9/18/2021	10/18/2022

Lot Number	Original Expiry	New Expiry
139051D	9/18/2021	10/18/2022
139051E	9/18/2021	10/18/2022
139051F	9/18/2021	10/18/2022
139051G	9/18/2021	10/18/2022
139051H	9/18/2021	10/18/2022
139051I	9/18/2021	10/18/2022
139051J	9/18/2021	10/18/2022
139216A	9/17/2021	10/17/2022
139216B	9/17/2021	10/17/2022
139216C	9/17/2021	10/17/2022
139216D	9/17/2021	10/17/2022
139380	9/18/2021	10/18/2022
139380A	9/18/2021	10/18/2022
139380B	9/18/2021	10/18/2022
139380C	9/18/2021	10/18/2022
139380D	9/18/2021	10/18/2022
139380E	9/18/2021	10/18/2022
139380F	9/18/2021	10/18/2022
139380G	9/18/2021	10/18/2022
139380I	9/18/2021	10/18/2022
139380K	9/18/2021	10/18/2022
139520A	9/21/2021	10/21/2022
139520B	9/21/2021	10/21/2022
139520C	9/21/2021	10/21/2022
139520D	9/21/2021	10/21/2022
139811	9/19/2021	10/19/2022
139811A	9/19/2021	10/19/2022
139811B	9/19/2021	10/19/2022
139811C	9/19/2021	10/19/2022
139811D	9/19/2021	10/19/2022
139811E	9/19/2021	10/19/2022
139811F	9/19/2021	10/19/2022
139811G	9/19/2021	10/19/2022
139811H	9/19/2021	10/19/2022
139811I	9/19/2021	10/19/2022
139811J	9/19/2021	10/19/2022
140591A	9/22/2021	10/22/2022
140591X	9/22/2021	10/22/2022
140591Y	9/22/2021	10/22/2022
140591Z	9/22/2021	10/22/2022
140709	9/28/2021	10/28/2022
140709B	9/28/2021	10/28/2022
140709C	9/28/2021	10/28/2022
140709D	9/28/2021	10/28/2022

Lot Number	Original Expiry	New Expiry
140709E	9/28/2021	10/28/2022
140709H	9/28/2021	10/28/2022
140869	9/22/2021	10/22/2022
140869A	9/22/2021	10/22/2022
140869B	9/22/2021	10/22/2022
140869C	9/22/2021	10/22/2022
140869D	9/22/2021	10/22/2022
140869E	9/22/2021	10/22/2022
140869F	9/22/2021	10/22/2022
140869G	9/22/2021	10/22/2022
140869H	9/22/2021	10/22/2022
140869I	9/22/2021	10/22/2022
140869J	9/22/2021	10/22/2022
141320A	9/28/2021	10/28/2022
141320B	9/28/2021	10/28/2022
141320C	9/28/2021	10/28/2022
141320D	9/28/2021	10/28/2022
141320E	9/28/2021	10/28/2022
141476W	9/27/2021	10/27/2022
141476X	9/27/2021	10/27/2022
141476Y	9/27/2021	10/27/2022
141476Z	9/27/2021	10/27/2022
141579A	9/29/2021	10/29/2022
141579B	9/29/2021	10/29/2022
141579C	9/29/2021	10/29/2022
141579D	9/29/2021	10/29/2022
141804A	10/5/2021	11/5/2022
141804B	10/5/2021	11/5/2022
141804C	10/5/2021	11/5/2022
141804D	10/5/2021	11/5/2022
141804E	10/5/2021	11/5/2022
142400	10/3/2021	11/3/2022
142400A	10/3/2021	11/3/2022
142400B	10/3/2021	11/3/2022
142400C	10/3/2021	11/3/2022
142400D	10/3/2021	11/3/2022
142400E	10/3/2021	11/3/2022
142425	10/4/2021	11/4/2022
142802	10/5/2021	11/5/2022
142802A	10/5/2021	11/5/2022
142802B	10/5/2021	11/5/2022
143543A	10/5/2021	11/5/2022
143543B	10/5/2021	11/5/2022
143543C	10/5/2021	11/5/2022

Lot Number	Original Expiry	New Expiry
143929	10/15/2021	11/15/2022
143929A	10/15/2021	11/15/2022
143929B	10/15/2021	11/15/2022
143929C	10/15/2021	11/15/2022
143929D	10/15/2021	11/15/2022
147164A	11/5/2021	12/5/2022
147164B	11/5/2021	12/5/2022
147164C	11/5/2021	12/5/2022
147164D	11/5/2021	12/5/2022
147164E	11/5/2021	12/5/2022
147647A	11/5/2021	12/5/2022
147647B	11/5/2021	12/5/2022
147647C	11/5/2021	12/5/2022
148338A	11/8/2021	12/8/2022
148338B	11/8/2021	12/8/2022
148357	11/8/2021	12/8/2022
148357A	11/8/2021	12/8/2022
148357B	11/8/2021	12/8/2022
148357C	11/8/2021	12/8/2022
148357D	11/8/2021	12/8/2022
148357E	11/8/2021	12/8/2022
148392A	11/5/2021	12/5/2022
148392B	11/5/2021	12/5/2022
148392C	11/5/2021	12/5/2022
148660	11/5/2021	12/5/2022
148660A	11/5/2021	12/5/2022
148660B	11/5/2021	12/5/2022
148660C	11/5/2021	12/5/2022
148660D	11/5/2021	12/5/2022
148660E	11/5/2021	12/5/2022
148660F	11/5/2021	12/5/2022
148660G	11/5/2021	12/5/2022
148660H	11/5/2021	12/5/2022
148660I	11/5/2021	12/5/2022
148660J	11/5/2021	12/5/2022
148756	11/13/2021	12/13/2022
148756A	11/13/2021	12/13/2022
148756B	11/13/2021	12/13/2022
148756C	11/13/2021	12/13/2022
148756D	11/13/2021	12/13/2022
148756E	11/13/2021	12/13/2022
148756F	11/13/2021	12/13/2022
148984	11/13/2021	12/13/2022
148984A	11/13/2021	12/13/2022

Lot Number	Original Expiry	New Expiry
148985	11/13/2021	12/13/2022
148985A	11/13/2021	12/13/2022
148985B	11/13/2021	12/13/2022
148985C	11/13/2021	12/13/2022
148985D	11/13/2021	12/13/2022
148985E	11/13/2021	12/13/2022
149037	11/13/2021	12/13/2022
149037A	11/13/2021	12/13/2022
149037B	11/13/2021	12/13/2022
149037C	11/13/2021	12/13/2022
149037D	11/13/2021	12/13/2022
149037E	11/13/2021	12/13/2022
149037F	11/13/2021	12/13/2022
149956	11/19/2021	12/19/2022
149956A	11/19/2021	12/19/2022
149956B	11/19/2021	12/19/2022
149956C	11/19/2021	12/19/2022
149956D	11/19/2021	12/19/2022
150087	11/21/2021	12/21/2022
150087A	11/21/2021	12/21/2022
150087B	11/21/2021	12/21/2022
150358	11/19/2021	12/19/2022
150358A	11/19/2021	12/19/2022
150358B	11/19/2021	12/19/2022
173422A	11/15/2022	9/15/2023
173422B	11/15/2022	9/15/2023
173422C	11/15/2022	9/15/2023
173998A	10/13/2022	8/13/2023
173998B	10/13/2022	8/13/2023
174087A	11/20/2022	9/20/2023
174105A	10/13/2022	8/13/2023
174110A	10/13/2022	8/13/2023
174110B	10/13/2022	8/13/2023
174292A	11/6/2022	9/6/2023
174292B	11/6/2022	9/6/2023
174365A	11/21/2022	9/21/2023
174681A	11/21/2022	9/21/2023
174681B	11/21/2022	9/21/2023
175124A	11/21/2022	9/21/2023
175124B	11/21/2022	9/21/2023
175438A	11/21/2022	9/21/2023
175438B	11/21/2022	9/21/2023
175450A	11/21/2022	9/21/2023
175450B	11/21/2022	9/21/2023

Lot Number	Original Expiry	New Expiry
175450C	11/21/2022	9/21/2023
175620A	11/21/2022	9/21/2023
175620B	11/21/2022	9/21/2023
175824A	11/19/2022	9/19/2023
175824B	11/19/2022	9/19/2023
175883A	11/21/2022	9/21/2023
175933A	12/2/2022	10/2/2023
176321A	11/21/2022	9/21/2023
176321B	11/21/2022	9/21/2023
176339A	11/21/2022	9/21/2023
176339B	11/21/2022	9/21/2023
176339C	11/21/2022	9/21/2023
176791A	12/9/2022	10/9/2023
176791B	12/9/2022	10/9/2023
177523A	11/21/2022	9/21/2023
177523B	11/21/2022	9/21/2023
178674	12/21/2022	10/21/2023
179069A	1/12/2023	10/14/2023
179069B	1/12/2023	10/14/2023
180105	1/1/2023	11/1/2023
180107	1/2/2023	11/2/2023
180109	1/1/2023	11/1/2023
180167	1/2/2023	11/2/2023
180377	1/4/2023	11/4/2023
180440	12/28/2022	10/28/2023
180685	1/1/2023	11/1/2023
180858	1/6/2023	11/6/2023
180870	1/7/2023	11/7/2023
180891A	1/28/2023	11/6/2023
180891B	1/28/2023	11/6/2023
181008A	1/28/2023	11/10/2023
181008B	1/28/2023	11/10/2023
181008C	1/28/2023	11/10/2023
181139	1/8/2023	11/8/2023
181163	1/7/2023	11/7/2023
181455A	2/4/2023	11/12/2023
181455B	2/4/2023	11/12/2023
181455C	2/4/2023	11/12/2023
182315	1/6/2023	11/6/2023
182861	1/28/2023	11/18/2023
185760A	4/30/2023	11/30/2023
185760B	4/30/2023	11/30/2023
185958A	5/2/2023	12/2/2023
185958B	5/2/2023	12/2/2023

Lot Number	Original Expiry	New Expiry
185958C	5/2/2023	12/2/2023
186702	5/6/2023	12/6/2023
186704B	5/7/2023	12/7/2023
186994A	5/7/2023	12/7/2023
186994B	5/7/2023	12/7/2023
187030A	4/6/2023	11/6/2023
187030B	4/6/2023	11/6/2023
187030C	4/6/2023	11/6/2023
187032A	4/13/2023	11/13/2023
187032B	4/13/2023	11/13/2023
187297	4/15/2023	11/15/2023
187298	5/8/2023	12/8/2023
187302A	5/2/2023	12/2/2023
187302B	5/2/2023	12/2/2023
187435A	5/9/2023	12/9/2023
187435B	5/9/2023	12/9/2023
187495	4/28/2023	11/28/2023
187636A	5/11/2023	12/11/2023
187636B	5/11/2023	12/11/2023
188045A	5/12/2023	12/12/2023