



BinaxNOW™ COVID-19 Ag Card Product Expiry Update

March 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 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 expiry date.** All BinaxNOW COVID-19 Ag Cards currently have a nine-month expiry date.

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 months, and data supports a three-month extension (9 months total). 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 the NAVICA™ App. For customers using the NAVICA app, an update to the app will be implemented to recognize the extended expiry date by March 12, 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.

Attachment 1 - BinaxNOW™ COVID-19 Ag Card lots with extended expiry

Lot Number	Original Expiry	New Expiry
124008	07-Feb-21	07-May-21
124073	08-Feb-21	08-May-21
124199	10-Feb-21	10-May-21
124380	11-Feb-21	11-May-21
124410	12-Feb-21	12-May-21
124462	14-Feb-21	14-May-21
124557	16-Feb-21	16-May-21
124569	18-Feb-21	18-May-21
124743	21-Feb-21	21-May-21
124858	21-Feb-21	21-May-21
124865	23-Feb-21	23-May-21
125049	24-Feb-21	24-May-21
125052	25-Feb-21	25-May-21
125406	28-Feb-21	28-May-21
125419	28-Feb-21	28-May-21
125425	01-Mar-21	01-Jun-21
125523	02-Mar-21	02-Jun-21
125525	02-Mar-21	02-Jun-21
125528	27-Feb-21	27-May-21
125605	04-Mar-21	04-Jun-21
125781	07-Mar-21	07-Jun-21
125849	05-Mar-21	05-Jun-21
125851	28-Feb-21	28-May-21
125957	06-Mar-21	06-Jun-21
126028	09-Mar-21	09-Jun-21
126029	27-Feb-21	27-May-21
126072	08-Mar-21	08-Jun-21
126138	10-Mar-21	10-Jun-21
126140	11-Mar-21	11-Jun-21
126149	12-Mar-21	12-Jun-21
126265	07-Mar-21	07-Jun-21
126370	11-Mar-21	11-Jun-21
126383	14-Mar-21	14-Jun-21
126397	12-Mar-21	12-Jun-21
126404	05-Mar-21	05-Jun-21
126563	05-Feb-21	05-May-21
126628	12-Mar-21	12-Jun-21
126639	12-Mar-21	12-Jun-21
126640	16-Mar-21	16-Jun-21
126647	09-Mar-21	09-Jun-21
126658	08-Mar-21	08-Jun-21
126692	13-Mar-21	13-Jun-21
126703	15-Mar-21	15-Jun-21
126706	01-Mar-21	01-Jun-21

Lot Number	Original Expiry	New Expiry
126750	17-Mar-21	17-Jun-21
126791	09-Mar-21	09-Jun-21
126828	18-Mar-21	18-Jun-21
126833	16-Mar-21	16-Jun-21
126842	17-Mar-21	17-Jun-21
126869	21-Mar-21	21-Jun-21
126873	21-Mar-21	21-Jun-21
126929	16-Mar-21	16-Jun-21
126930	20-Mar-21	20-Jun-21
126978	22-Mar-21	22-Jun-21
127092	18-Mar-21	18-Jun-21
127094	23-Mar-21	23-Jun-21
127099	23-Mar-21	23-Jun-21
127115	15-Mar-21	15-Jun-21
127128	19-Mar-21	19-Jun-21
127136	24-Mar-21	24-Jun-21
127137	19-Mar-21	19-Jun-21
127139	22-Mar-21	22-Jun-21
127165	22-Mar-21	22-Jun-21
127208	26-Mar-21	26-Jun-21
127220	26-Mar-21	26-Jun-21
127254	18-Mar-21	18-Jun-21
127358	28-Mar-21	28-Jun-21
127397	25-Mar-21	25-Jun-21
127426	28-Mar-21	28-Jun-21
127435	29-Mar-21	29-Jun-21
127497	21-Mar-21	21-Jun-21
127566	30-Mar-21	30-Jun-21
127578	24-Mar-21	24-Jun-21
127634	30-Mar-21	30-Jun-21
127672	25-Mar-21	25-Jun-21
127676	01-Apr-21	01-Jul-21
127677	27-Mar-21	27-Jun-21
127752	27-Mar-21	27-Jun-21
127762	01-Apr-21	01-Jul-21
127763	25-Mar-21	25-Jun-21
127778	26-Mar-21	26-Jun-21
127854	29-Mar-21	29-Jun-21
127857	01-Apr-21	01-Jul-21
127880	29-Mar-21	29-Jun-21
128003	27-Mar-21	27-Jun-21
128004	03-Apr-21	03-Jul-21
128005	04-Apr-21	04-Jul-21
128023	01-Apr-21	01-Jul-21
128024	30-Mar-21	30-Jun-21
128146	29-Mar-21	29-Jun-21

Lot Number	Original Expiry	New Expiry
128166	03-Apr-21	03-Jul-21
128167	03-Apr-21	03-Jul-21
128226	03-Apr-21	03-Jul-21
128266	04-Apr-21	04-Jul-21
128345	04-Apr-21	04-Jul-21
128385	03-Apr-21	03-Jul-21
128397	05-Apr-21	05-Jul-21
128417	06-Apr-21	06-Jul-21
128420	06-Apr-21	06-Jul-21
128427	06-Apr-21	06-Jul-21
128428	06-Apr-21	06-Jul-21
128429	03-Apr-21	03-Jul-21
128430	03-Apr-21	03-Jul-21
128503	04-Apr-21	04-Jul-21
128515	04-Apr-21	04-Jul-21
128520	04-Apr-21	04-Jul-21
128524	27-Mar-21	27-Jun-21
128545	03-Apr-21	03-Jul-21
128548	04-Apr-21	04-Jul-21
128563	07-Apr-21	07-Jul-21
128566	08-Apr-21	08-Jul-21
128585	05-Apr-21	05-Jul-21
128694	09-Apr-21	09-Jul-21
128758	06-Apr-21	06-Jul-21
128770	09-Apr-21	09-Jul-21
128857	10-Apr-21	10-Jul-21
128874	09-Apr-21	09-Jul-21
128910	11-Apr-21	11-Jul-21
128917	11-Apr-21	11-Jul-21
128931	07-Apr-21	07-Jul-21
128938	07-Apr-21	07-Jul-21
128940	08-Apr-21	08-Jul-21
129100	11-Apr-21	11-Jul-21
129106	14-Apr-21	14-Jul-21
129111	06-Apr-21	06-Jul-21
129112	10-Apr-21	10-Jul-21
129113	10-Apr-21	10-Jul-21
129345	09-Apr-21	09-Jul-21
129358	12-Apr-21	12-Jul-21
129360	11-Apr-21	11-Jul-21
129364	10-Apr-21	10-Jul-21
129365	08-Apr-21	08-Jul-21
129380	14-Apr-21	14-Jul-21
129381	14-Apr-21	14-Jul-21
129382	13-Apr-21	13-Jul-21
129383	13-Apr-21	13-Jul-21

Lot Number	Original Expiry	New Expiry
129427	12-Apr-21	12-Jul-21
129436	31-Mar-21	30-Jun-21
129564	12-Apr-21	12-Jul-21
129705	14-Apr-21	14-Jul-21
129711	14-Apr-21	14-Jul-21
129723	14-Apr-21	14-Jul-21
129724	13-Apr-21	13-Jul-21
129736	14-Apr-21	14-Jul-21
129737	14-Apr-21	14-Jul-21
129880	12-Apr-21	12-Jul-21
129917	02-Apr-21	02-Jul-21
129929	17-Apr-21	17-Jul-21
129957	27-Mar-21	27-Jun-21
129963	14-Apr-21	14-Jul-21
130017	15-Apr-21	15-Jul-21
130053	17-Apr-21	17-Jul-21
130090	19-Apr-21	19-Jul-21
130102	17-Apr-21	17-Jul-21
130107	17-Apr-21	17-Jul-21
130108	19-Apr-21	19-Jul-21
130109	19-Apr-21	19-Jul-21
130110	15-Apr-21	15-Jul-21
130111	19-Apr-21	19-Jul-21
130112	16-Apr-21	16-Jul-21
130113	15-Apr-21	15-Jul-21
130194	15-Apr-21	15-Jul-21
130207	13-Apr-21	13-Jul-21
130257	16-Apr-21	16-Jul-21
130300	16-Apr-21	16-Jul-21
130302	31-Mar-21	30-Jun-21
130321	16-Apr-21	16-Jul-21
130322	20-Apr-21	20-Jul-21
130323	20-Apr-21	20-Jul-21
130331	21-Apr-21	21-Jul-21
130332	18-Apr-21	18-Jul-21
130333	17-Apr-21	17-Jul-21
130345	18-Apr-21	18-Jul-21
130346	18-Apr-21	18-Jul-21
130360	08-Apr-21	08-Jul-21
130361	18-Apr-21	18-Jul-21
130388	21-Apr-21	21-Jul-21
130397	18-Apr-21	18-Jul-21
130445	21-Apr-21	21-Jul-21
130446	14-Apr-21	14-Jul-21
130447	18-Apr-21	18-Jul-21
130653	22-Apr-21	22-Jul-21

Lot Number	Original Expiry	New Expiry
130654	20-Apr-21	20-Jul-21
130662	22-Apr-21	22-Jul-21
130708	20-Apr-21	20-Jul-21
130748	21-Apr-21	21-Jul-21
130761	16-Apr-21	16-Jul-21
130823	16-Apr-21	16-Jul-21
130852	19-Apr-21	19-Jul-21
130885	20-Apr-21	20-Jul-21
131121	22-Apr-21	22-Jul-21
131155	23-Apr-21	23-Jul-21
131167	31-Mar-21	30-Jun-21
131179	22-Apr-21	22-Jul-21
131192	22-Apr-21	22-Jul-21
131235	21-Apr-21	21-Jul-21
131238	22-Apr-21	22-Jul-21
131244	24-Apr-21	24-Jul-21
131245	25-Apr-21	25-Jul-21
131246	23-Apr-21	23-Jul-21
131247	22-Apr-21	22-Jul-21
131285	24-Apr-21	24-Jul-21
131347	24-Apr-21	24-Jul-21
131349	22-Apr-21	22-Jul-21
131350	23-Apr-21	23-Jul-21
131351	24-Apr-21	24-Jul-21
131371	25-Apr-21	25-Jul-21
131405	23-Apr-21	23-Jul-21
131413	25-Apr-21	25-Jul-21
131414	24-Apr-21	24-Jul-21
131415	26-Apr-21	26-Jul-21
131428	27-Apr-21	27-Jul-21
131511	27-Apr-21	27-Jul-21
131522	26-Apr-21	26-Jul-21
131524	25-Apr-21	25-Jul-21
131534	25-Apr-21	25-Jul-21
131556	27-Apr-21	27-Jul-21
131560	26-Apr-21	26-Jul-21
131665	27-Apr-21	27-Jul-21
131673	30-Apr-21	30-Jul-21
131690	27-Apr-21	27-Jul-21
131707	21-Apr-21	21-Jul-21
131710	28-Apr-21	28-Jul-21
131711	28-Apr-21	28-Jul-21
131712	27-Apr-21	27-Jul-21
131783	17-Apr-21	17-Jul-21
131848	23-Apr-21	23-Jul-21
131849	30-Apr-21	30-Jul-21

Lot Number	Original Expiry	New Expiry
131853	29-Apr-21	29-Jul-21
131854	29-Apr-21	29-Jul-21
131855	23-Apr-21	23-Jul-21
131856	28-Apr-21	28-Jul-21
131963	30-Apr-21	30-Jul-21
131966	27-Apr-21	27-Jul-21
131991	02-May-21	02-Aug-21
132014	02-May-21	02-Aug-21
132026	29-Apr-21	29-Jul-21
132092	02-May-21	02-Aug-21
132093	30-Apr-21	30-Jul-21
132096	30-Apr-21	30-Jul-21
132097	02-May-21	02-Aug-21
132116	03-May-21	03-Aug-21
132117	03-May-21	03-Aug-21
132118	23-Apr-21	23-Jul-21
132119	23-Apr-21	23-Jul-21
132143	23-Apr-21	23-Jul-21
132144	23-Apr-21	23-Jul-21
132145	01-May-21	01-Aug-21
132148	30-Apr-21	30-Jul-21
132151	29-Apr-21	29-Jul-21
132152	23-Apr-21	23-Jul-21
132164	28-Apr-21	28-Jul-21
132172	30-Apr-21	30-Jul-21
132184	02-May-21	02-Aug-21
132185	23-Apr-21	23-Jul-21
132186	02-May-21	02-Aug-21
132282	23-Apr-21	23-Jul-21
132361	23-Apr-21	23-Jul-21
132370	23-Apr-21	23-Jul-21
132374	04-May-21	04-Aug-21
132529	05-May-21	05-Aug-21
132557	03-May-21	03-Aug-21
132602	17-Apr-21	17-Jul-21
132613	05-May-21	05-Aug-21
132617	26-Apr-21	26-Jul-21
132618	05-May-21	05-Aug-21
132619	05-May-21	05-Aug-21
132685	01-May-21	01-Aug-21
132723	04-May-21	04-Aug-21
132806	17-Apr-21	17-Jul-21
132807	02-May-21	02-Aug-21
132874	02-May-21	02-Aug-21
132883	06-May-21	06-Aug-21
132918	08-May-21	08-Aug-21

Lot Number	Original Expiry	New Expiry
132921	07-May-21	07-Aug-21
132936	05-May-21	05-Aug-21
133269	10-May-21	10-Aug-21
133292	10-May-21	10-Aug-21
133304	08-May-21	08-Aug-21
133306	07-May-21	07-Aug-21
133312	07-May-21	07-Aug-21
133328	04-May-21	04-Aug-21
133329	06-May-21	06-Aug-21
133332	07-May-21	07-Aug-21
133343	08-May-21	08-Aug-21
133344	27-Apr-21	27-Jul-21
133345	09-May-21	09-Aug-21
133346	11-May-21	11-Aug-21
133347	09-May-21	09-Aug-21
133348	10-May-21	10-Aug-21
133349	09-May-21	09-Aug-21
133350	08-May-21	08-Aug-21
133351	09-May-21	09-Aug-21
133357	09-May-21	09-Aug-21
133366	10-May-21	10-Aug-21
133367	05-May-21	05-Aug-21
133368	10-May-21	10-Aug-21
133396	10-Mar-21	10-Jun-21
133397	11-May-21	11-Aug-21
133399	07-May-21	07-Aug-21
133400	10-Mar-21	10-Jun-21
133403	11-Mar-21	11-Jun-21
133404	10-May-21	10-Aug-21
133423	11-May-21	11-Aug-21
133441	09-May-21	09-Aug-21
133514	14-May-21	14-Aug-21
133538	12-May-21	12-Aug-21
133539	12-May-21	12-Aug-21
133584	11-May-21	11-Aug-21
133608	14-May-21	14-Aug-21
133655	12-May-21	12-Aug-21
133670	02-May-21	02-Aug-21
133699	13-May-21	13-Aug-21
133756	12-May-21	12-Aug-21
133851	12-May-21	12-Aug-21
133940	16-May-21	16-Aug-21
133959	13-May-21	13-Aug-21
133971	11-May-21	11-Aug-21
133987	13-May-21	13-Aug-21
134060	15-May-21	15-Aug-21

Lot Number	Original Expiry	New Expiry
134072	16-May-21	16-Aug-21
134119	14-May-21	14-Aug-21
134125	13-May-21	13-Aug-21
134127	14-May-21	14-Aug-21
134148	17-May-21	17-Aug-21
134399	15-May-21	15-Aug-21
134436	13-May-21	13-Aug-21
134439	10-May-21	10-Aug-21
134440	15-May-21	15-Aug-21
134467	06-May-21	06-Aug-21
134468	06-May-21	06-Aug-21
134469	06-May-21	06-Aug-21
134508	17-May-21	17-Aug-21
134514	17-May-21	17-Aug-21
134525	05-May-21	05-Aug-21
134532	16-May-21	16-Aug-21
134533	16-May-21	16-Aug-21
134544	13-May-21	13-Aug-21
134545	16-May-21	16-Aug-21
134553	18-May-21	18-Aug-21
134555	18-May-21	18-Aug-21
134565	18-May-21	18-Aug-21
134575	17-May-21	17-Aug-21
134580	17-May-21	17-Aug-21
134595	17-May-21	17-Aug-21
134644	06-May-21	06-Aug-21
134690	19-May-21	19-Aug-21
134701	15-May-21	15-Aug-21
134756	19-May-21	19-Aug-21
134759	14-May-21	14-Aug-21
134764	09-May-21	09-Aug-21
134775	17-May-21	17-Aug-21
134808	17-May-21	17-Aug-21
134815	12-May-21	12-Aug-21
134818	20-May-21	20-Aug-21
134829	19-May-21	19-Aug-21
134830	19-May-21	19-Aug-21
134862	21-May-21	21-Aug-21
134864	21-May-21	21-Aug-21
134867	21-May-21	21-Aug-21
134907	20-May-21	20-Aug-21
134931	21-May-21	21-Aug-21
134955	16-May-21	16-Aug-21
134984	20-May-21	20-Aug-21
135051	25-Apr-21	25-Jul-21
135079	24-May-21	24-Aug-21

Lot Number	Original Expiry	New Expiry
135168	21-May-21	21-Aug-21
135177	22-May-21	22-Aug-21
135179	10-May-21	10-Aug-21
135180	21-May-21	21-Aug-21
135248	13-May-21	13-Aug-21
135249	20-May-21	20-Aug-21
135252	21-May-21	21-Aug-21
135266	21-May-21	21-Aug-21
135315	25-May-21	25-Aug-21
135338	28-May-21	28-Aug-21
135399	28-May-21	28-Aug-21
135406	23-May-21	23-Aug-21
135414	22-May-21	22-Aug-21
135431	10-May-21	10-Aug-21
135504	20-May-21	20-Aug-21
135507	21-May-21	21-Aug-21
135566	26-May-21	26-Aug-21
135589	26-May-21	26-Aug-21
135738	20-May-21	20-Aug-21
135741	24-May-21	24-Aug-21
135819	08-May-21	08-Aug-21
135826	22-May-21	22-Aug-21
135827	24-May-21	24-Aug-21
135872	17-May-21	17-Aug-21
135887	28-May-21	28-Aug-21