February 24, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074
Re: Revocation of EUA210272

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc. ("Abbott"), received via email on February 21, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test issued on March 31, 2021 and amended on September 23, 2021 and January 7, 2022. FDA understands no product was distributed under the EUA. Abbott indicated that authorization of the BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required, in consideration of Abbott's product available under another EUA issued to Abbott.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Abbott has notified FDA that the EUA for BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required and requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210272 for the BinaxNOW COVID-19 Ag Card 2 Home Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag Card 2 Home Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration