January 31, 2023

Angela Drysdale
DVP, Regulatory Affairs
Infectious Disease
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: Revocation of EUA210275

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc., received via email on January 20, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card issued on March 31, 2021, amended on September 23, 2021, January 7, 2022, and November 1, 2022, and reissued on February 4, 2022. Abbott Diagnostics Scarborough, Inc., indicated that they no longer required the authorization of the BinaxNOW COVID-19 Ag 2 Card and requested that the EUA be revoked. FDA understands that no products associated with this EUA were released to the United States market.

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 Diagnostics Scarborough, Inc. has requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag 2 Card, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210275 for the BinaxNOW COVID-19 Ag 2 Card, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag 2 Card 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration