U.S. FOOD & DRUG ADMINISTRATION

February 4, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: EUA202537/S003
Trade/Device Name: BinaxNOW COVID-19 Ag Card
Dated: December 23, 2021
Received: January 3, 2022

Dear Ms. Drysdale:

This is to notify you that your request to; (1) add use of an additional nitrocellulose membrane option for manufacturing, and (2) minor updates to the BinaxNOW COVID-19 Ag CARD Instructions for Use and the BinaxNOW COVID-19 Ag CARD Procedure Card, is granted. Upon review, we concur that the data and information submitted in EUA202537/S003 supports the requested updates for use with the BinaxNOW COVID-19 Ag Card. FDA made some minor updates to the Fact Sheet for Healthcare Provider and Fact Sheet for Patients to reflect more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the BinaxNOW COVID-19 Ag Card re-issued on December 16, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health