January 7, 2022

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

Re: EUA210264/S003
Trade/Device Name: BinaxNOW COVID-19 Antigen Self Test
Dated: December 27, 2021
Received: December 27, 2021

Dear Ms. Drysdale:

This is to notify you that your request to; (1) update the shelf-life expiration date of the BinaxNOW COVID-19 Ag Card to 15 months at room temperature (28–30°C) based on the results of your ongoing stability studies, and (2) add use of an additional nitrocellulose membrane option for manufacturing, is granted. Upon review, we concur that the data and information submitted in EUA210264/S003 supports the requested updates for use with the BinaxNOW COVID-19 Antigen Self Test. FDA made some minor updates to the Healthcare Provider and Individual Fact Sheets 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 Antigen Self Test re-issued on November 8, 2021.

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