



December 21, 2022

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

Re: EUA210264/S006/A001
Trade/Device Name: BinaxNOW COVID-19 Antigen Self Test
Dated: November 23, 2022
Received: November 23, 2022

Dear Angela Drysdale:

This is to notify you that your request to update the BinaxNOW COVID-19 Antigen Self Test to extend the shelf-life expiration date to 22 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210264/S006/A001 support the requested update for the BinaxNOW COVID-19 Antigen Self Test. 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 April 4, 2022.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health