



April 10, 2023

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

Re: EUA203107/S006/A001  
Trade/Device Name: BinaxNOW COVID-19 Ag Card Home Test  
Dated: April 4, 2023  
Received: April 4, 2023

Dear Angela Drysdale:

This is to notify you that your request to update the BinaxNOW COVID-19 Ag Card Home 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 EUA203107/S006/A001 support the requested update for the BinaxNOW COVID-19 Ag Card Home 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 Ag Card Home Test reissued on January 30, 2023.

Sincerely yours,

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