



November 21, 2022

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

Re: EUA202537/S004/A001  
Trade/Device Name: BinaxNOW COVID-19 Ag Card  
Dated: October 10, 2022  
Received: October 10, 2022

Dear Angela Drysdale:

This is to notify you that your request to update the BinaxNOW COVID-19 Ag Card 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 EUA202537/S004 support the requested update for the BinaxNOW COVID-19 Ag Card. 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  
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health