



April 6, 2021

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

Re: EUA202537/S002
Trade/Device Name: BinaxNOW COVID-19 Ag Card
Dated: March 23, 2021
Received: March 24, 2021

Dear Ms. Drysdale:

This is to notify you that your request to update the shelf-life expiration date of the BinaxNOW COVID-19 Ag Card to 12 months at room temperature (28–30°C) based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA202537/S002 supports the requested updates for use with the BinaxNOW COVID-19 Ag Card. FDA have updated the Healthcare Provider and Patient 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 Ag Card re-issued on December 16, 2020.

Sincerely yours,

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