



May 24, 2023

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

Re: EUA210517/S003
Trade/Device Name: ID NOW COVID-19 2.0
Dated: May 16, 2023
Received: May 16, 2023

Dear Ms. Drysdale:

This is to notify you that your request to extend the shelf-life expiration date for the ID NOW COVID-19 2.0 and for the ID NOW COVID-19 2.0 Positive Control Swab to 24 months when stored at the recommended conditions outlined in the Instructions for Use, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210517/S003 supports the requested updates for use with the ID NOW COVID-19 2.0. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 ID NOW COVID-19 2.0 issued on May 6, 2022

Sincerely yours,

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health