April 21, 2020

Angela Drysdale,
Vice President, RA
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road,
Scarborough, ME 04074

Re: EUA200074/A001
Trade/Device Name: ID NOW COVID-19
Dated: April 15, 2020
Received: April 15, 2020

Dear Ms. Drysdale:

This is to notify you that your request to update the Instructions for Use (IFU) and the Quick Reference Instructions (QRI) of the ID NOW COVID-19 to remove nasal, nasopharyngeal or throat swabs eluted in viral transport media swabs in VTM as a specimen type, due to concerns that the dilution will result in decreased detection of low positive samples that are near the limit of detection of the ID NOW COVID-19, has been granted. Upon review, we concur that the data and information submitted in EUA200074/A001 supports the requested updates to the ID NOW COVID-19 test. We also concur with the associated updates to the Healthcare Provider Fact Sheet and the limitation included in the ID NOW COVID-19 test IFU, and other minor updates to improve clarity. By submitting this amendment 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 issued on March 27, 2020.

Sincerely yours,

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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