August 24, 2020

Kim Snyder
Director Regulatory Affairs
Abbott Molecular Inc.
1300 E. Touhy Ave.,
Des Plaines, IL 60018

Re: EUA200572/S003
Trade/Device Name: Alinity m SARS-CoV-2 assay
Dated: August 1, 2020
Received: August 1, 2020

Dear Ms. Snyder:

This is to notify you that your request to update the Alinity m SARS-CoV-2 assay to; (1) change the formulation of the SARS-CoV-2 AMP kit, (2) increase the on-board storage time of the SARS-CoV-2 AMP kit, (3) remove the limitation "*Phosphate-containing buffers may interfere with sample extraction for the Alinity m SARS-CoV-2 assay and therefore are not recommended for use with this assay*", (4) update the maximum fill volumes for associated Alinity m tubes, and (4) make the associated labeling changes in the instructions for use, is granted. Upon review, we concur that the data and information submitted in EUA200572/S003 supports the requested updates for use with the Alinity m SARS-CoV-2 assay. 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 Alinity m SARS-CoV-2 assay issued on May 11, 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