July 20, 2020

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

Re: EUA200572/A002
Trade/Device Name: Alinity m SARS-CoV-2 assay
Dated: June 19, 2020
Received: June 19, 2020

Dear Ms. Snyder:

This is to notify you that your request to update the Alinity m SARS-CoV-2 assay to; (1) update the Alinity m software to improve resolution at low target concentrations, and (2) update the device labelling for clarity, is granted. Upon review, we concur that the data and information submitted in EUA200572/A002 supports the requested updates for use with the Alinity m SARS-CoV-2 assay. 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 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