April 1, 2020

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

Re: EUA200023/A001
Trade/Device Name: Abbott RealTi*m*e SARS-CoV-2 assay
Dated: March 25, 2020
Received: March 26, 2020

Dear Ms. Snyder:

This is to notify you that your request to update the Instructions for Use (IFU) of the Abbott RealTi*m*e SARS-CoV-2 assay to; (1) add use of the Abbott multi-Collect Specimen Collection Kit, (2) add "*nasal swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare worker*" as specimens in the intended use, and (3) make minor edits the Instructions for Use, has been granted. Upon review, we concur that the information submitted in EUA200023/A001 supports the requested updates to the Abbott RealTi*m*e SARS-CoV-2 assay. We also concur with the related changes to the Instructions for Use for the Abbott RealTi*m*e SARS-CoV-2 assay that reflect the requested updates. 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 Abbott RealTi*m*e SARS-CoV-2 assay issued on March 18, 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