July 30, 2020

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

Re: EUA200023/S002
Trade/Device Name: Abbott RealTi*m*e SARS-CoV-2 assay
Dated: June 29, 2020
Received: June 29, 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 Universal Collection Kit as appropriate for collection of patient samples for use with the test, (2) add bronchoalveolar lavage fluid (BAL) as an acceptable specimen type to the intended use, (3) update the *in silico* inclusivity analysis in the performance section, (4) update the clinical evaluation section with clinical testing results for nasopharyngeal specimens, and (5) make some minor edits and clarifications, including updating the Interpretation of Results table and clarifying the volume of the internal control added to the lysis buffer, has been granted. Upon review, we concur that the information submitted in EUA200023/A002 supports the requested updates to the Abbott RealTi*m*e SARS-CoV-2 assay. Updates to the Healthcare Provider and Patient Fact sheets were also made to reflect more recent EUAs. 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,

_____
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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov