August 28, 2020

Dr. Jennifer Laffin
Sr. Laboratory Medical Director
Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711

Re: EUA200367/S001 (submitted as A001)
Trade/Device Name: SARS-CoV-2 (N gene detection) Test
Dated: June 10, 2020
Received: June 10, 2020

Dear Dr. Laffin:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 (N gene detection) Test to; (1) include the Exact Sciences Home Collection Kit for Nasal swab Collection, (2) include a nasal swab home collection kit IFU, and (3) add minor related revisions in the standard operating procedures, is granted. Upon review, we concur that the data and information submitted in EUA200367/S001 support the requested updates for use with the SARS-CoV-2 (N gene detection) Test. 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 SARS-CoV-2 (N gene detection) Test issued on May 22, 2020 and re-issued on August 3, 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