August 17, 2022

Susan Harrington, Ph.D.
The Cleveland Clinic Foundation
9500 Euclid Ave
Cleveland, OH 44195

Re: EUA220184/S001
Trade/Device Name: SelfCheck cobas SARS-CoV-2 + Flu Assay
Dated: July 20, 2022
Received: July 20, 2022

Dear Dr. Harrington:

This is to notify you that your request to update the authorized labeling of the SelfCheck cobas SARS-CoV-2 + Flu Assay to; (1) revise the supplier of the Nylon Flocked Swab provided with the SelfCheck Nasal Swabbing Kit, (2) revise the supplier and content (replace sterile saline with UTM) of the collection tube provided with the SelfCheck Nasal Swabbing Kit, and (3) other minor updates and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA220184/S001 supports the requested updates for use with the SelfCheck cobas SARS-CoV-2 + Flu 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 SelfCheck cobas SARS-CoV-2 + Flu Assay issued on April 11, 2022.

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