March 26, 2021

Katerina Capkova
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Re: EUA200734/S006
Trade/Device Name: Aptima SARS-CoV-2 Assay
Dated: February 26, 2021
Received: February 28, 2021

Dear Dr. Capkova:

This is to notify you that your request to update the Instructions for Use (IFU) of the Aptima SARS-CoV-2 Assay to; (1) include the Hologic Direct Load Capture Cap (DLC) Collection Kit – CLASSIQSwab and the Hologic Direct Load Tube (DLT) Collection Kit as authorized collection kits and (2) change the formulation of the Enzyme Reagent, is granted. Upon review, we concur that the data and information submitted in EUA200734/S006 supports the requested updates for use with the Aptima SARS-CoV-2. In addition, FDA has added a statement in the IFU regarding clinical performance with circulating variants as well as updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations. 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 Aptima SARS-CoV-2 Assay reissued on October 5, 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