September 15, 2020

Katerina Capkova, Ph.D.
Regulatory Affairs Specialist
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Re: EUA200734/S001
Trade/Device Name: Aptima SARS-CoV-2 assay
Dated: July 17, 2020
Received: July 17, 2020

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) add an uncapped workflow for testing with the Aptima SARS-CoV-2 assay on the Panther and Panther Fusion systems and (2) add updated *in silico* inclusivity study results (3) add LoD study results obtained with additional commercial materials to aid in laboratory verification, and (4) revise minor errors identified in the current IFU, is granted. Upon review, we concur that the data and information submitted in EUA200734/S001 supports the requested updates for use with the Aptima SARS-CoV-2 assay. FDA also requested minor updates to the intended use to reflect more recent authorizations and reporting recommendations and updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting these EUA revisions 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 issued on May 14, 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