July 24, 2020

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

Re: EUA200734/A001
Trade/Device Name: Aptima SARS-CoV-2 assay
Dated: June 8, 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 Aptima Specimen Transfer Tube workflow for use with the assay and supporting analytical and clinical validation, (2) add the Aptima Unisex Swab Specimen Collection Kit, (3) update specimen stability claims and acceptable media based on the provided bridging study to directly compare sensitivity of Aptima and Panther Fusion SARS-CoV-2 assays, and (4) revise minor errors identified in the current IFU, is granted. Upon review, we concur that the data and information submitted in EUA200734/A001 supports the requested updates for use with the Aptima SARS-CoV-2 assay. We have reviewed and concur with the stability study protocol submitted to fulfill Condition of Authorization T. 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 Aptima SARS-CoV-2 assay issued on May 14, 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