U.S. FOOD & DRUG ADMINISTRATION

January 22, 2021

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

Re: EUA200734/S005
Trade/Device Name: Aptima SARS-CoV-2 assay
Dated: December 11, 2020
Received: December 11, 2020

Dear Dr. Capkova:

This is to notify you that your request to update the Panther and Panther Fusion System Software Version 7.2 authorized for use with the Aptima SARS-CoV-2 assay to include pooling features, is granted. 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 re-issued 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