February 24, 2021

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

Re: EUA202959/S002
Trade/Device Name: Aptima SARS-CoV-2/Flu Assay
Dated: February 16, 2021
Received: February 18, 2021

Dear Dr. Chen:

This is to notify you that we have reviewed the results of your Inclusivity and Specimen Stability post-authorization studies. Upon review, we concur that the data and information submitted in EUA202959/S002 is acceptable for the Aptima 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 Aptima SARS-CoV-2/Flu Assay issued on December 16, 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