February 14, 2023

Jingwen Chen, Ph.D.
Regulatory Affairs Specialist 2
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Re: EUA202959-S005
Trade/Device Name: Aptima SARS-CoV-2/Flu assay
Dated: February 01, 2023
Received: February 01, 2023

Dear Dr. Chen:

This is to notify you that your request to update the Instructions for Use of the Aptima SARS-CoV-2/Flu assay to; (1) extend the shelf life claim to 12 months, (2) add hazard, storage, and handling information for the assay reagents, and (3) provide minor updates, is granted. Upon review, we concur that the data and information submitted in EUA202959-S005 supports the requested updates for use with the Aptima SARS-CoV-2/Flu assay. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 reissued letter authorizing the emergency use of the Aptima SARS-CoV-2/Flu assay issued on March 23, 2022.

Sincerely yours,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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