U.S. FOOD & DRUG ADMINISTRATION

April 24, 2020

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

Re: EUA200014/A001
Trade/Device Name: Panther Fusion SARS-CoV-2 Assay
Dated: April 13, 2020
Received: April 13, 2020

Dear Ms. Capkova:

This is to notify you that your request to update the Instructions for Use (IFU) labeling for the Hologic Panther Fusion SARS-CoV-2 assay to; (1) add the Aptima MultiTest Collection Kit, (2) add nasal swab and lower respiratory tract (LRT) specimens and the associated limitation, (3) add UTM, Saline, Liquid Amies, and Hologic specimen transport media as acceptable media for NP, nasal, and oropharyngeal specimens, and (4) minor edits to the Instructions For Use, is granted. Upon review, we concur that the data and information submitted in EUA200014/A001 supports the requested updates for use with the Panther Fusion SARS-CoV-2 assay. We also concur with the associated updates made to the Healthcare Provider and Patient Fact Sheets. 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 Panther Fusion SARS-CoV-2 assay issued on March 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

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