January 22, 2021

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

Re: EUA200014/S004
Trade/Device Name: Panther Fusion 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 Fusion System Software Version 7.2 authorized for use with the Panther Fusion SARS-CoV-2 Assay to include pooling features, is granted. 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 Panther Fusion SARS-CoV-2 assay re-issued on September 24, 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