February 5, 2021

Nathan Grubaugh, Ph.D.
Yale School of Public Health
Department of Epidemiology of Microbial Diseases
60 College Street
New Haven, CT 06510

Re: EUA202097/S005
Trade/Device Name: SalivaDirect
Dated: November 3, 2020
Received: November 3, 2020

Dear Dr. Grubaugh:

This is to notify you that your request to update the EUA Summary and Instructions for Use of the SalivaDirect to; (1) add the Quantstudio 6 and Quantstudio 7 thermocyclers to the SalivaDirect workflow, (2) add an RUO qualification protocol per a Condition in the letter of authorization, and (3) update the cutoff for the ABI 7500 Fast Dx, is granted. Upon review, we concur that the data and information submitted in EUA202097/S005 supports the requested updates for use with the SalivaDirect. 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 SalivaDirect reissued 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