



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