



December 14, 2022

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

Re: EUA210506/S004
Trade/Device Name: SalivaDirect for use with DTC Kits
Dated: May 31, 2022
Received: May 31, 2022

Dear Dr. Wyllie:

This is to notify you that your request to update the authorized labeling of the SalivaDirect for use with DTC Kits to include use of four additional real-time PCR thermocyclers for use with the SalivaDirect for use with DTC Kits: the Applied Biosystems ViiA 7 Real-Time PCR System (using QuantStudio Real-Time PCR Software v1.3), ABI QuantStudio 3 Real-Time PCR system (using QuantStudio Design and Analysis Software v2.4.3), Liberty16 Pro (using Liberty16 App Version 1.8 (iOS)) and the Mic (using mic pro version 2.10.5), is granted. Upon review, we concur that the data and information submitted in EUA210506/S004 supports the requested updates for use with the SalivaDirect for use with DTC Kits. We also acknowledge your current list of designated authorized laboratories. FDA have updated the Fact Sheet for Healthcare Providers and Fact Sheet for Individuals to be consistent with 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 letter authorizing the emergency use of the SalivaDirect for use with DTC Kits reissued on February 23, 2022.

Sincerely yours,

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

Cc: Amy Hummel, MS, Associate Director for IND/IDE Management, Yale Center for Clinical Investigation