March 12, 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/S007
Trade/Device Name: SalivaDirect
Dated: January 26, 2021
Received: January 26, 2021

Dear Dr. Grubaugh:

This is to notify you that your request to update the authorized labeling of the SalivaDirect to; (1) add six thermocyclers [CFX384 Touch (384-well), ABI QuantStudio 5, 6, 7 Pro, 7 Flex, and 12K Flex (384-well)], (2) add a more concentrated RT-PCR reaction mix for use with the 384-well thermocyclers, and (3) add an alternative work flow for the SalivaDirect protocol, is granted. Upon review, we concur that the data and information submitted in EUA202097/S007 supports the requested updates for use with the SalivaDirect. In addition, FDA has updated the Fact Sheet for Healthcare Providers to reflect more recent authorizations and policy. 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 reissued letter authorizing the emergency use of the SalivaDirect issued 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