October 15, 2020

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

Re: EUA202097/S003
Trade/Device Name: SalivaDirect
Dated: September 17, 2020
Received: September 17, 2020

Dear Dr. Grubaugh:

This is to notify you that your request to update the authorized labeling of the SalivaDirect to; (1) add the Applied Biosystems QuantStudio 5 Real-Time PCR System as a new real-time PCR instrument, (2) add additional commercial sources of primer/probe materials, Eurofins Genomics and LGC Biosearch Technologies, and (3) some minor updates and clarifications to the Instructions for Use, is granted. Upon review, we concur that the data and information submitted in EUA202097/S003 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 re-issued on August 28, 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