May 6, 2021

Amy Hummel
Associate Director for IND/IDE Management
Yale School of Public Health
Yale Center for Clinical Investigation
2 Church Street South, Suite 112
New Haven, CT 06519

Re: EUA210243/S001
Trade/Device Name: SalivaDirect At-Home Collection Kit
Dated: May 5, 2021
Received: May 5, 2021

Dear Ms. Hummel:

This is to notify you that your request to update the authorized labeling for the SalivaDirect At-Home Collection Kit to include use of UPS as an authorized shipping carrier, is granted. Upon review, we concur that the information submitted in EUA210243/S001 supports the requested update for use with the SalivaDirect At-Home Collection. 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 At-Home Collection Kit issued on April 9, 2021.

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