April 21, 2023

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

Re: EUA202097/S016
Trade/Device Name: SalivaDirect
Dated: December 21, 2022
Received: December 21, 2022

Dear Dr. Wyllie:

This is to notify you that your request is granted to update the SalivaDirect to; (1) add use of the XDive Superfast Real-Time PCR System (OnsiteGene), Mic qPCR/Q (Biomolecular Systems), Quantabio (Avantor)), and the CFX Opus Real-Time PCR Detection System (BioRad) as authorized thermocyclers, (2) add use of the Myra Liquid Handling System (Bio Molecular Systems) for automated sample preparation, and (3) add Resolution Biomedical, Inc. and SimpliChek, Inc. as suppliers of the SalivaDirect Unsupervised Collection Kit. Upon review, we concur that the data and information submitted in EUA202097/S016 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 14, 2022.

REVOKED

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health