



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: EUA210506/S006
Trade/Device Name: SalivaDirect for use with DTC Kits
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 for use with DTC Kits to; (1) add use of the XDive Superfast Real-Time PCR System (OnsiteGene), Mic qPCR/QX200 Molecular Systems/Quantabio (Avantor)), and the CFX Opus Real-Time PCR Detection System (BioRad) as authorized thermocyclers, and (2) add use of the Myra Liquid Handling System (Bio Molecular Systems) for automated sample preparation. Upon review, we concur that the data and information submitted in EUA210506/S006 supports the requested updates for use with the SalivaDirect for use with DTC Kits. By submitting this FDA 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health