



August 25, 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/S001
Trade/Device Name: SalivaDirect
Dated: August 19, 2020
Received: August 19, 2020

Dear Dr. Grubaugh:

This is to notify you that your request to update the Instructions for Use (IFU) of the SalivaDirect to; (1) add the Integrated DNA Technologies CDC-qualified lot of ATTO647-labeled RFLP probe, and (2) some minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA202097/S001 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 issued on August 15, 2020.

Sincerely yours,

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