July 16, 2021

Tammy Moncur
VP, Quality & Regulatory Affairs
Ambry Genetics Laboratory
7 Argonaut
Aliso Viejo, CA 92656

Re: EUA202196/S003
Trade/Device Name: Ambry COVID-19 RT-PCR Test
Dated: June 11, 2021
Received: June 14, 2021

Dear Ms. Moncur:

This is to notify you that your request to update the Ambry COVID-19 RT-PCR Test Saliva Collection Kit Accessioning Instructions, is granted. Upon review, we concur that information submitted in EUA202196/S003 supports the requested updates for use with the Ambry COVID-19 RT-PCR. In addition, FDA has updated the webpage links provided in the HCP Fact Sheet. 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 Ambry COVID-19 RT-PCR Test re-issued on April 29, 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