March 3, 2021

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

Re: EUA202196/S002
Trade/Device Name: Ambry COVID-19 RT-PCR Test
Dated: February 18, 2021
Received: February 20, 2021

Dear Ms. Moncur:

This is to notify you that your request to update the authorized labeling of the Ambry COVID-19 RT-PCR Test to; (1) include the results from testing of the FDA reference panel, and (2) remove the KingFisher Presto as an authorized extraction instrument, is granted. Upon review, we concur that the data and information submitted in EUA202196/S002 supports the requested updates for use with the Ambry COVID-19 RT-PCR. In addition, FDA has updated the EUA Summary to reflect more recent authorizations. 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 issued on January 22, 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