September 24, 2020

Connie Chao-Shern Ph.D.,
Chief Laboratory Officer
Avellino Lab USA, Inc.
1505 Adams Drive Suite B2,
Menlo Park, CA 94025 US

Re: EUA200006/S001
Trade/Device Name: AvellinoCoV2 Test
Dated: June 8, 2020
Received: June 8, 2020

Dear Dr. Chao-Shern:

This is to notify you that your request to update the EUA Summary of the AvellinoCoV2 Test to include; (1) description and data of the new limit of detection study and (2) additional clinical validation studies to support FDA recommendations, is granted. Upon review, we concur that the data and information submitted in EUA200006/S001 supports the requested updates for use with the AvellinoCoV2 Test. FDA has updated the Intended Use statement to reflect more recent authorizations and policy. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you will comply with the Conditions of Authorization stated in the letter authorizing the emergency use of the AvellinoCoV2 Test issued on March 15, 2020.

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