August 24, 2020

Barbara Stevens,
Regulatory Affairs
Mesa Biotech Inc.
6190 Cornerstone Court, Suite 220,
San Diego, CA 92121

Re: EUA200028/S002
Trade/Device Name: Accula SARS-Cov-2 Test
Dated: July 2, 2020
Received: July 2, 2020

Dear Ms. Stevens:

This is to notify you that your request to update the instructions for use (IFU) for the Accula SARS-Cov-2 Test to; (1) include mid-turbinate swab specimens as an authorized specimen, (2) update the intended use to reflect more recent authorizations (as requested by FDA), (3) update the acceptable swab types that may be included in or used with the Accula SARS-CoV-2 Test kit and the associated Technical Bulletin to inform customers, and (4) added new clinical data to the performance section, is granted. Upon review, we concur that the data and information submitted in EUA200028/S001 supports the requested updates for use with the Accula SARS-Cov-2 Test. We have also updated the Healthcare Provider and Patient Fact Sheets 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 Accula SARS-Cov-2 Test issued on March 23, 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



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