February 3, 2021

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

Re: EUA200028/S006
Trade/Device Name: Accula SARS-CoV-2 Test
Dated: January 25, 2021
Received: January 25, 2021

Dear Ms. Stevens:

This is to notify you that your request to update the Instructions for Use (IFU) of the Accula SARS-CoV-2 Test to; (1) include results of FDA Reference Panel testing, and (2) provide additional sample stability data to fulfill Condition P in the January 7, 2021 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA200028/S006 supports the requested updates for use with the Accula SARS-CoV-2 Test. 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 reissued on January 7, 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