April 30, 2020

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

Re: EUA200028/A001
Trade/Device Name: Accula SARS-Cov-2 Test
Dated: April 22, 2020
Received: April 22, 2020

Dear Ms. Stevens:

This is to notify you that your request to update the intended use for the Accula SARS-Cov-2 Test to change the specimen type from throat swab and nasal swab combined to nasal swab alone and the associated updates to the the Instructions for Use (IFU) labeling, is granted. We have updated the Healthcare Provider Fact Sheet accordingly to reflect the update in specimen type. By submitting this amendment 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