



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,

---

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