



April 18, 2023

Nelson Patterson
President and Chief Executive Officer
ADL Diagnostics, Inc., dba Anavasi Diagnostics
15305 NE 95th Street
Redmond, WA 98052

Re: EUA220484/S002
Trade/Device Name: The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector
Dated: March 8, 2023
Received: March 8, 2023

Dear Mr. Patterson:

This is to notify you that your request to update the authorized labeling of the The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector to; (1) support a shelf-life claim of up to 4 months when stored at 15–30°C, based on the results of your ongoing real-time stability studies, and (2) provide shipping stability data for the unopened kit, is granted. Upon review, we concur that the data and information submitted in EUA220484/S002 supports the requested updates for use with the The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector. 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 The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector issued on February 8, 2023

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health