



March 06, 2024

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

Re: EUA220484/S004
Trade/Device Name: The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector
Dated: February 15, 2024
Received: February 15, 2024

Dear Mr. Patterson:

This is to notify you that your request to extend the shelf-life expiration date of The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector to 5 months when stored at 15-25°C, based on the results of ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220484/S004 supports the requested updates for use with The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 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