



August 9, 2023

Dr. Ho-Jun Suk
Chief Executive Officer
DxLab Inc.
444 Somerville Ave.
Somerville, MA 02143

Re: EUA220227/S003
Trade/Device Name: DxLab COVID-19 Test
Dated: July 18, 2023
Received: July 18, 2023

Dear Dr. Suk:

This is to notify you that your request to extend the shelf-life expiration date of the DxLab COVID-19 Test to 12 months when stored at 15-30°C, based on the results of ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220227/S003 supports the requested updates for use with the DxLab COVID-19 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 DxLab COVID-19 Test issued on June 1, 2022.

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