



November 23, 2022

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

Re: EUA220227/S001  
Trade/Device Name: DxLab COVID-19 Test  
Dated: October 11, 2022  
Received: October 11, 2022

Dear Dr. Suk:

This is to notify you that your request to update the DxLab COVID-19 Test to; (1) include a shelf-life claim of up to 6 months when stored at the recommended temperature ( $30\pm 2^{\circ}\text{C}$ ), (2) add a new distributor to the list of authorized distributors of the DxLab COVID-19 Test, and (3) add a Unique Device Identifier, the date of manufacture, and the label name and revision number to the labeling on the kit outer box and individual reagent pouch, is granted. Upon review, we concur that the data and information submitted in EUA220227/S001 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,

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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