April 28, 2023

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

Re: EUA220227/S002
Trade/Device Name: DxLab COVID-19 Test
Dated: January 04, 2023
Received: January 04, 2023

Dear Dr. Suk:

This is to notify you that your request to update the authorized labeling of the DxLab COVID-19 Test to; (1) provide asymptomatic clinical performance data in the Instructions for Use (IFU) to support the serial screening claim and to fulfill Condition Q of the June 1, 2022 letter, (2) add results from newly collected prospective specimens and update the corresponding symptomatic clinical performance results to the IFU, (3) remove the limitation related to lack of performance evaluation in asymptomatic subjects from the IFU, (4) add a warning related to user confirmation of Time and Date settings for correct lot expirations to the DxHub User Manual, (5) add back information that was erroneously removed from the originally authorized version of the DxHub User Manual, and (6) provide minor clarifying edits and corrections to the IFU and DxHub User Manual, is granted. Upon review, we concur that the data and information submitted in EUA220227/S002 supports the requested updates for use with the DxLab COVID-19 Test. 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 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