

September 9, 2022

Cameron Ball, PhD Chief Executive Officer Uh-Oh Labs Inc. 3485 Victor St Santa Clara, CA 95054

Re: EUA210666/S004

Trade/Device Name: UOL COVID-19 Test

Dated: August 11, 2022 Received: August 11, 2022

Dear Dr. Ball:

This is to notify you that your request to update the result interpretation algorithm for the Dx Pro mobile software application used with your device, is granted. Upon review, we concur that the data and information submitted in EUA210666/S004 supports the requested updates for use with the UOL 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 UOL COVID-19 Test issued on February 8, 2022.

Sincerely yours,

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health