January 25, 2024

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

Re: EUA210666/S011
Trade/Device Name: UOL COVID-19 Test
Dated: September 20, 2023
Received: September 20, 2023

Dear Dr. Ball:

This is to notify you that your request to update the Instructions for Use of the UOL COVID-19 Test to; (1) update the buffer formulation in the squeeze vial component, (2) include data from a Limit of Detection study using the reformulated buffer reagent, and (3) provide minor updates, is granted. Upon review, we concur that the data and information submitted in EUA210666/S011 supports the requested updates for use with the UOL 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 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,

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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