September 1, 2020

Christina Kang
Senior Advisor
Kord Partners, LLC on behalf of Seasun Biomaterials
500 W. 190th St., Suite 200
Gardena, CA 90248

Re: EUA200451/S001
Trade/Device Name: U-TOP COVID-19 Detection Kit
Dated: July 10, 2020
Received: July 10, 2020

Dear Ms. Kang:

This is to notify you that your request to update the Instructions for Use (IFU) of the U-TOP COVID-19 Detection Kit to include; (1) use of the TOP Virus Collection Kit, (2) use of the TOP Viral DNA/RNA Extraction Kit, (3) use of the PANAMAX Viral DNA/RNA Extraction Kit performed on the PANAMAX 48 Nucleic Acid Extraction System, and (4) additional clinical study data in which clinical specimens were evaluated with the U-TOP COVID-19 Detection Kit and another FDA-authorized real-time RT-PCR assay, is granted. Upon review, we concur that the data and information submitted in EUA200451/S001 supports the requested updates for use with the U-TOP COVID-19 Detection Kit. The Healthcare Provider, Patient Fact Sheets and Intended Use have been updated by FDA to reflect more recent authorizations and policies. 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 U-TOP COVID-19 Detection Kit issued on April 27, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
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

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