



December 2, 2022

Tarah Suiter, Ph.D.
Senior Engineer
Oceanit Foundry LLC
828 Fort Street Mall, Suite 600
Honolulu, HI 96813

Re: EUA210614/S002 & S005
Trade/Device Name: ASSURE-100 Rapid COVID-19 Test
Dated: June 7, 2022 and November 14, 2022
Received: June 7, 2022 and November 14, 2022

Dear Dr. Suiter:

This is to notify you that your request to update the ASSURE-100 Rapid COVID-19 Test EUA; (1) with results of studies performed to further evaluate the performance of the ASSURE-100 Rapid COVID-19 Test for the detection of the SARS-CoV-2 omicron variant, and (2) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the data and information submitted in EUA210614/S002 & S005 supports the requested updates for use with the ASSURE-100 Rapid COVID-19 Test and fulfills Condition of Authorization S. from the February 28, 2022, letter of authorization and Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients has been updated by FDA consistent with this revision and are included along with this letter.

By submitting these supplemental requests for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Oceanit Foundry, LLC Assure-100 COVID-19 Test issued on February 28, 2022.

Sincerely yours,

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