



February 24, 2023

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

Re: EUA210614/S004
Trade/Device Name: ASSURE-100 Rapid COVID-19 Test
Dated: August 24, 2022
Received: August 24, 2022

Dear Tarah Suiter:

This is to notify you that your request to update the ASSURE-100 Rapid COVID-19 Test to extend the shelf-life expiration date to 12 months when stored at 15°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210614/S004 support the requested update for the ASSURE-100 Rapid 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 ASSURE-100 Rapid COVID-19 Test issued on February 28, 2022.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health