U.S. FOOD & DRUG ADMINISTRATION

May 4, 2022

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

Re: EUA210614/S001
Trade/Device Name: Assure-100 COVID-19 Test
Dated: March 31, 2022
Received: March 31, 2022

Dear Dr. Suiter:

This is to notify you that your request for the addition of an alternate swab and alternate diluent solution vial to facilitate an increase in manufacturing and a more robust supply chain, is granted. Upon review, we concur that comparative performance summary data, line data, and information submitted in EUA210614/S001 supports the requested updates to the *Instructions for Use* and *Quick Reference Instructions* to add an alternate swab and alternate diluent solution vial to the Assure-100 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 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 and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health