



June 28, 2023

Young-A Kim, Ph.D.
Director, RA/QA
Princeton BioMeditech Corp.
4242 US Hwy 1
Monmouth Junction, NJ 08852

Re: EUA220119/S001
Trade/Device Name: Status COVID-19 Antigen Rapid Test for Home Use
Dated: May 10, 2023
Received: May 10, 2023

Dear Dr. Kim:

This is to notify you that your request to update the Status COVID-19 Antigen Rapid Test for Home Use to extend the shelf-life expiration date to 24 months when stored at 2 – 30°C, is granted. Upon review, we concur that the data and information submitted in EUA220119/S001 supports the requested updates for use with the Status COVID-19 Antigen Rapid Test for Home Use. 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 Status COVID-19 Antigen Rapid Test for Home Use issued on April 24, 2023.

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