



March 21, 2023

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

Re: EUA210015/S008
Trade/Device Name: Status COVID-19/Flu A&B
Dated: January 11, 2023
Received: January 11, 2023

Dear Dr. Kim:

This is to notify you that your request is granted to update the Status COVID-19/Flu A&B to; (1) extend the shelf-life expiration date to 24 months, when stored at 2 °C – 30 °C, based on the results of your completed stability studies, and (2) provide data from your ongoing study to further evaluate the clinical performance of the Status COVID-19/Flu A&B in anterior nasal swab specimens for influenza A and B, performed to address Condition of Authorization P. in the October 27, 2021 Letter of Authorization. Upon review, we concur that the data and information submitted in EUA210015/S008 support the requested shelf-life extension for the Status COVID-19/Flu A&B. Upon review, we concur that the data and information submitted in EUA210015/S008 partially fulfills Condition of Authorization P. in the October 27, 2021, letter, with respect to influenza A, but that additional data for influenza B is required to completely fulfill the condition for the Status COVID-19/Flu A&B. 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/Flu A&B re-issued on October 27, 2021.

Sincerely yours,

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health