October 23, 2024

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

Re: EUA220131/S002
Trade/Device Name: ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test
Dated: December 6, 2023
Received: December 6, 2023

Dear Dr. Kim:

This is to notify you that your request is granted to update the ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test; (1) to include the results of testing with the WHO International Standard in the authorized labeling, in accordance with Condition of Authorization (CoA) P. in the September 8, 2023 Letter of Authorization (Letter), (2) with results of additional analytical performance studies performed to fulfill CoA R. in the Letter, (3) with results of additional flex studies performed to fulfill CoA S. in the Letter and the associated update to the authorized labeling, and (4) other minor updates to the authorized labeling that were typographical or clarifying in nature. Upon review, we concur that the data and information submitted in EUA220131/S002 supports the requested updates for use with the ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test and fulfills CoA R. and S. of the September 8, 2023, Letter. 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 ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test issued on September 8, 2023.

Sincerely yours,

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