August 02, 2022

Corey Yackel
Sr. Regulatory Affairs Specialist
Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711

Re: EUA203022/S003
Trade/Device Name: COVID-Flu Multiplex Assay
Dated: March 2, 2022
Received: March 2, 2022

Dear Ms. Yackel:

This is to notify you that your request to update the EUA Summary and the "COVID-Flu Multiplex Assay PCR Plate Setup" SOP of the COVID-Flu Multiplex Assay to; (1) add an option for an alternate Flu B probe labeled with HEX dye, (2) include analytical bridging study data in the EUA Summary to support the equivalent performance of the HEX-labeled Flu B probe with the Yakima Yellow-labeled Flu B probe included in the original authorization, and (3) include minor revisions, is granted. Upon review, we concur that the data and information submitted in EUA203022/S003 supports the requested updates for use with the COVID-Flu Multiplex Assay. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. 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 COVID-Flu Multiplex Assay issued on July 1, 2021.

Sincerely yours,

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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