



March 22, 2023

David McGrath
Vice President, Regulatory and Clinical Affairs
Lucira Health, Inc.
1412 62nd Street
Emeryville, CA 94608

Re: EUA220333/S001
Trade/Device Name: Lucira COVID-19 & Flu Test
Dated: March 09, 2023
Received: March 09, 2023

Dear Mr. McGrath:

This is to notify you that your request to extend the product shelf life claim for the Lucira COVID-19 & Flu Test from 6 months to 9 months when stored at 15-30°C, based on the results of your completed stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220333/S001 supports the requested updates for use with the Lucira COVID-19 & Flu 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 Lucira COVID-19 & Flu Test issued on November 22, 2022.

Sincerely yours,

Kristian Roth, 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