March 22, 2023

David McGrath
Vice President, Regulatory and Clinical Affairs
Lucira Health, Inc.
1315 63rd Street
Emeryville, CA 94608

Re: EUA220490/S001
Trade/Device Name: Lucira COVID-19 & Flu Home Test
Dated: March 09, 2023
Received: March 09, 2023

Dear Mr. McGrath:

This is to notify you that your request to update the Instructions for Use of the Lucira COVID-19 & Flu Home Test to; (1) extend the product shelf life claim from 6 months to 9 months when stored at 15-30°C, based on the results of your completed stability studies, and (2) provide clarifications to the clinical study description, is granted. Upon review, we concur that the data and information submitted in EUA220490/S001 supports the requested updates for use with the Lucira COVID-19 & Flu Home 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 Home Test issued on February 24, 2023.

Sincerely yours,

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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