



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,

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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