



September 6, 2023

Elizabeth Mauro  
Director, Global Regulatory Science  
Pfizer Inc.  
66 Hudson Boulevard East  
New York, NY 10001

Re: EUA220333/S004  
Trade/Device Name: Lucira by Pfizer COVID-19 & Flu Test  
Dated: August 25, 2023  
Received: August 25, 2023

Dear Elizabeth Mauro:

This is to notify you that your request to extend the product shelf-life claim for the Lucira by Pfizer COVID-19 & Flu Test from 15-months to 18-months when stored at 15-30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220333/S004 supports the requested updates for use with the Lucira by Pfizer 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 by Pfizer COVID-19 & Flu Test reissued on June 15, 2023.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.  
Director, Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health