



August 3, 2023

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

Re: EUA220333/S003
Trade/Device Name: Lucira by Pfizer COVID-19 & Flu Test
Dated: July 25, 2023
Received: July 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 12 months to 15 months when stored at 15-30°C, based on the results of your ongoing stability studies, is granted. In addition, we concur with the minor update to the Lucira by Pfizer COVID-19 & Flu Test box label. Upon review, we concur that the data and information submitted in EUA220333/S003 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,

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