



July 28, 2022

Randy J. Prebula
Partner
Hogan Lovells US LLP
555 Thirteen Street NW
Washington, DC 20004
Representing - Lucira Health, Inc.¹

Re: EUA202920-S005
Trade/Device Name: Lucira COVID-19 All-In-One Test Kit
Dated: May 3, 2022
Received: May 3, 2022

Dear Mr. Prebula:

This is to notify you that your request to update the device shelf-life stability claim from 12 months to 18 months when stored at 30±2°C is granted. Upon review, we concur that the data and information submitted in EUA202920-S005 supports the requested updates for use with the Lucira COVID-19 All-In-One Test Kit. FDA has updated the Fact Sheet for Healthcare Providers to reflect language used in more recent authorizations. 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 All-In-One Test Kit issued on November 17, 2020.

Sincerely yours,

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

¹ Cc: David McGrath, John Beasley, and Ghazi Kashmolah from Lucira Health, Inc.
1412 62nd Street
Emeryville, CA 94608
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov