



January 14, 2025

Aiiso Hx Yang
COO & VP
CorDx, Inc.
9540 Waples Street, #C
San Diego, CA 92121

Re: EUA230055/S003
Trade/Device Name: CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test
Dated: December 31, 2024
Received: December 31, 2024

Dear Aiiso Hx Yang:

This is to notify you that your request to update the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test¹ to extend the shelf-life expiration date to 19 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA230055/S003 supports the requested update for the CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid 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 CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test issued on March 21, 2024.

Sincerely yours,

Joseph Briggs, 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

¹ Note the shelf-life for the CorDx Tyfast Flu A/B & COVID-19 Multiplex Control Swab Kit was not evaluated as part of this study and remains at 6 months when stored at 2°C – 30°C.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov