U.S. FOOD & DRUG ADMINISTRATION

September 26, 2024

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

Re: EUA230055/S002
Trade/Device Name: CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test
Dated: September 5, 2024
Received: September 5, 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 Test[1] to extend the shelf-life expiration date to 15 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/S002 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,

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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

Enclosure[2]

[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.
[2] Technical Correction issued and the Letter Granting EUA Revision re-signed on September 30, 2024, to correct the EUA number in the original September 26, 2024, Letter from EUA240006 to EUA230055/S002.