March 16, 2023

Rachael Chen
Axteria BioMed Consulting Inc.
Representing: CorDx, Inc.
9540 Waples St. Unit C
San Diego, CA 92121

Re: EUA220303/S002
Trade/Device Name: CorDx COVID-19 Ag Test
Dated: January 24, 2023
Received: January 24, 2023

Dear Rachael Chen:

This is to notify you that your request to update the Instructions for Use (IFU) of the CorDx COVID-19 Ag Test to include results of additional reactivity studies, is granted. Upon review, we concur that the data and information submitted in EUA220303/S002 supports the requested updates for use with the CorDx COVID-19 Ag 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 COVID-19 Ag Test issued on November 21, 2022.

Sincerely yours,

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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