



August 24, 2022

Jinjie Hu  
Axteria BioMed Consulting Inc.  
8040 Cobble Creek Circle,  
Potomac, MD 20854  
Representing: ANP Technologies, Inc.  
8040 Cobble Creek Circle  
Potomac, MD 20854

Re: EUA210448/S001/A001 and EUA210448/S001/A002  
Trade/Device Name: NIDS COVID-19 Antigen Rapid Test Kit  
Dated: June 22, 2022 and August 08, 2022  
Received: June 22, 2022 and August 08, 2022

Dear Jinjie Hu:

This is to notify you that your request to update the NIDS COVID-19 Antigen Rapid Test Kit to extend the shelf-life expiration date to 11 months when stored at 15 - 30°C, based on the results of your ongoing stability studies, is granted. The shelf-life for NIDS COVID-19 Antigen Test External Control Kit will remain six months at 15 – 30°C. Upon review, we concur that the data and information submitted in EUA210448/S001/A001 and EUA210448/S001/A002 support the requested update for the NIDS COVID-19 Antigen Rapid Test Kit. FDA has also updated the Factsheet for Healthcare Provider and Factsheet for Patients 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 NIDS COVID-19 Antigen Rapid Test Kit issued on September 24, 2021.

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