



April 30, 2024

Jiayi Zhang  
Regulatory Affairs Manager  
CTK Biotech, Inc.  
13855 Stowe Dr.  
Poway, CA 92064

Re: EUA220401/S001  
Trade/Device Name: ImmuView COVID-19 Antigen Home Test  
Dated: April 9, 2024  
Received: April 9, 2024

Dear Jiayi Zhang:

This is to notify you that your request to update the ImmuView COVID-19 Antigen Home Test to extend the shelf-life expiration date to 20 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 EUA220401/S001 supports the requested update for the ImmuView COVID-19 Antigen Home 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 ImmuView COVID-19 Antigen Home Test issued on December 20, 2022.

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