



February 21, 2023

Kyle Rose  
Rook Quality Systems  
Representing:  
Watmind USA  
4780 I 55 N, Suite 450  
Jackson, MS 39211

Re: EUA220042/S003  
Trade/Device Name: Speedy Swab Rapid COVID-19 Antigen Self-Test  
Dated: October 21, 2022  
Received: October 21, 2022

Dear Kyle Rose:

This is to notify you that your request to update the Speedy Swab Rapid COVID-19 Antigen Self-Test to extend the shelf-life expiration date to 21 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220042/S003 support the requested update for the Speedy Swab Rapid COVID-19 Antigen Self-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 Speedy Swab Rapid COVID-19 Antigen Self-Test issued on July 8, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.  
Director, Division of Microbiology Devices  
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health