



March 3, 2022

Estela Raychaudhuri  
President  
InBios International, Inc.  
307 Westlake Avenue N, Suite 300  
Seattle, WA 98109

Re: EUA210619/S002  
Trade/Device Name: SCoV-2 Ag *Detect* Rapid Self-Test  
Dated: February 15, 2022  
Received: February 16, 2022

Dear Estela Raychaudhuri:

This is to notify you that your request to update the SCoV-2 Ag *Detect* Rapid Self-Test to extend the shelf-life expiration date of the SCoV-2 Ag *Detect* Rapid Self-Test to 10 months, when stored at 15°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 EUA210619/S002 support the requested update for the SCoV-2 Ag *Detect* Rapid 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 SCoV-2 Ag *Detect* Rapid Self-Test re-issued on January 25, 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