



March 3, 2022

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

Re: EUA210234/S002  
Trade/Device Name: SCoV-2 Ag Detect Rapid Test  
Dated: November 4, 2021  
Received: November 5, 2021

Dear Estela Raychaudhuri:

This is to notify you that your request to update the SCoV-2 Ag Detect Rapid Test to extend the shelf-life expiration date of the SCoV-2 Ag Detect Rapid 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 EUA210234/S002 support the requested update for the SCoV-2 Ag Detect Rapid 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 Test re-issued on September 3, 2021.

Sincerely yours,

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