



May 26, 2022

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

Re: EUA210619/S005
Trade/Device Name: SCoV-2 Ag *Detect* Rapid Self-Test
Dated: May 9, 2022
Received: May 9, 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 to 13 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/S005 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,

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