U.S. FOOD & DRUG ADMINISTRATION

September 28, 2022

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

Re: EUA210619/S008
Trade/Device Name: SCoV-2 Ag *Detect* Rapid Self-Test
Dated: August 9, 2022
Received: August 9, 2022

Dear Estela Raychaudhuri:

This is to notify you that your request to update the SCoV-2 Ag Detect Rapid Self-Test to; (1) revise the dimensions of the 2 tests kit box to a smaller format, (2) include updated contact information and add an additional warning statement on the 1, 2, 5 or 20 test kits, and (3) revise the "SCoV-2 Ag Detect Rapid Self-Test Healthcare Provider Instructions for Use" and the "SCoV-2 Ag Detect Rapid Self-Test Instructions" with updated contact information, is granted. Upon review, we concur that the information submitted in EUA210619/S008 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health