December 23, 2022

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

Re: EUA210234/S007
Trade/Device Name: SCoV-2 Ag *Detect* Rapid Test
Dated: November 16, 2022
Received: November 16, 2022

Dear Estela Raychaudhuri:

This is to notify you that your request to update the authorized labeling of the SCoV-2 Ag *Detect* Rapid Test in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA210234/S007 supports the requested updates for use with the SCoV-2 Ag *Detect* Rapid Test. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients has been updated by FDA consistent with this revision and are included along with this letter. By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 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