June 3, 2020

Estela Raychaudhuri,
President
InBios International, Inc.
307 Westlake Ave. North. SUITE 300,
SEATTLE, WA 98109

Re: EUA200180/A001
Trade/Device Name: Smart *Detect* SARS-CoV-2 rRT-PCR Kit
Dated: May 26, 2020
Received: May 26, 2020

Dear Ms. Raychaudhuri:

This is to notify you that your request to update the Instructions for Use (IFU) of the Smart Detect SARS-CoV-2 rRT-PCR Kit to; (1) add two additional rRT-PCR master mix options – Option 1 Master Mix Components A, B, and C and Option 2 Luna Probe One-Step RT-qPCR Kit (No ROX) plus Master Mix Component A, for use with the test, (2) include a troubleshooting section, and (3) make some additional minor clarifications and edits, is granted. We also concur with the revision to the kit and component labels provided. Upon review, we concur that the data and information submitted in EUA200180/A001 supports the requested updates for use with the Smart Detect SARS-CoV-2 rRT-PCR Kit, and we have also updated the Healthcare Provider and Patient Fact Sheets. By submitting this amendment 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 Smart Detect SARS-CoV-2 rRT-PCR Kit issued on April 7, 2020.

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