



August 24, 2020

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

Re: EUA200180/S003
Trade/Device Name: Smart *Detect* SARS-CoV-2 rRT-PCR Kit
Dated: August 13, 2020
Received: August 13, 2020

Dear Ms. Raychaudhuri:

This is to notify you that your request to update the Smart Detect SARS-CoV-2 rRT-PCR Kit instructions for use (IFU) to (1) add the Hamilton MagEx Star automated liquid handling system in combination with the MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit as an automated RNA extraction method, and (2) add the CFX384 Touch Real-Time PCR Detection System (Bio-Rad) as an additional real-time RT-PCR instrument, is granted. Upon review, we concur that the data and information submitted in EUA200180/S003 supports the requested update for use with the Smart Detect SARS-CoV-2 rRT-PCR Kit. By submitting this EUA revision request 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,

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