August 10, 2020

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

Re: EUA200180/S002
Trade/Device Name: Smart *Detect* SARS-CoV-2 rRT-PCR Kit
Dated: July 29, 2020
Received: July 29, 2020

Dear Ms. Raychaudhuri:

This is to notify you that your request to update the Smart Detect SARS-CoV-2 rRT-PCR Kit to add Texas Red and ROX as two alternate fluorophores on the E-gene assay probe in the Primer/Probe Mix supplied with the Kit, is granted. Upon review, we concur that the data and information submitted in EUA200180/S002 supports the requested update for use with the Smart Detect SARS-CoV-2 rRT-PCR Kit. In addition, we have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. 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,

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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