



September 2, 2020

Randee Lunn, MT (ASCP)
Quality Assurance Director
Boston Heart Labs
200 Crossing Blvd.
Framingham, MA 01702

Re: EUA200659/S001
Trade/Device Name: Boston Heart COVID-19 RT-PCR Test
Dated: August 13, 2020
Received: August 27, 2020

Dear Ms. Lunn:

This is to notify you that your request to update the Instructions for Use (IFU) of the Boston Heart COVID-19 RT-PCR Test to; (1) update the test method for use with the Agilent Bravo automated liquid handler, is granted. Upon review, we concur that the data and information submitted in EUA200659/S001 supports the requested updates for use with the Boston Heart COVID-19 RT-PCR Test. The Intended Use has also been updated to reflect more recent authorizations. 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 Boston Heart COVID-19 RT-PCR Test issued on July 16, 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