U.S. FOOD & DRUG ADMINISTRATION

May 29, 2020

Theron Gober
Director, Regulatory and Quality
OPTI Medical Systems, Inc.
235 Hembree Park Drive
Roswell, GA 30076

Re: EUA200215/A001
Trade/Device Name: OPTI SARS-CoV-2 RT PCR Test
Dated: May 13, 2020
Received: May 13, 2020

Dear Mr. Gober:

This is to notify you that your request to update the Instructions for Use (IFU) of the OPTI SARS-CoV-2 RT PCR Test to; (1) add a third extraction method, the OPTI DNA/RNA Magnetic Bead Kit, for use on Thermo Scientific KingFisher Flex or Duo Prime instruments, and the associated instructions, and (2) make some minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200215/A001 supports the requested updates for use with the OPTI SARS-CoV-2 RT PCR Test. 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 OPTI SARS-CoV-2 RT PCR Test issued on May 6, 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