July 29, 2020

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

Re: EUA200215/S002
Trade/Device Name: OPTI SARS-CoV-2 RT PCR Test
Dated: July 9, 2020
Received: July 10, 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 fourth extraction method, MolGen PurePrep Pathogens Extraction Kit, for use on Thermo Scientific KingFisher Flex or Duo Prime, along with associated instructions and performance data, (2) to expand use of the OPTI DNA/RNA Magnetic Bead Kit to manual extraction, along with associated instructions and performance data, and (3) make some minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200215/S002 supports the requested updates for use with the OPTI SARS-CoV-2 RT PCR Test. 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 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