August 20, 2020

Karen Gutekunst, Ph.D.
Vice President Regulatory Affairs
Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122, USA

Re: EUA201574/S001
Trade/Device Name: Illumina COVIDSeq Test
Dated: July 10, 2020
Received: July 10, 2020

Dear Dr. Gutekunst:

This is to notify you that your request to update the Instructions for Use (IFU) of the Illumina COVIDSeq Test to: (1) add the use of the Zymo Quick-DNA/RNA Viral MagBead extraction method, (2) add additional sequencing instruments (NextSeq 500, NextSeq 550, and NextSeq 550Dx) each running software version 4.0, (3) update the Illumina DRAGEN COVIDSeq Test Pipeline to software version 1.2 to accommodate the new sequencing instruments, (4) add the SP flow cell for use on the previously authorized NovaSeq 6000 instrument, (5) replace 6 out of 384 sequencing library indexes for better color balance and read quality, and (6) include cloud-based implementation of DRAGEN COVIDSeq Test Pipeline, is granted. Upon review, we concur that the data and information submitted in EUA201574/S001 supports the requested updates for use with the Illumina COVIDSeq 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 Illumina COVIDSeq Test issued on June 9, 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