July 27, 2020

Chitra Edwin, Ph.D., RAC
Senior Principal Advisor Regulatory Affairs and Quality Systems
Covance
5353 Wayzata Blvd. #505,
Minneapolis, MN 55416

Re: EUA200119/A001
Trade/Device Name: Allplex 2019-nCoV Assay
Dated: April 28, 2020
Received: April 28, 2020

Dear Dr. Edwin:

This is to notify you that your request to update the Instructions for Use (IFU) of the Allplex 2019-nCoV Assay to; (1) add additional extraction methods for use with the test, STARMag 96 x 4 Universal Cartridge Kit (extraction kit)) (Seegene) using Microlab NIMBUS IVD instrument (Microlab), STARMag 96 X 4 Viral DNA/RNA 200 C Kit (extraction kit)) (Seegene) using Microlab STARlet IVD instrument (Microlab), AdvanSure NA EX Kit (extraction kit) using AdvanSure E3 Instrument System (LG Chem), QIAamp DSP Viral Mini Kit using QIAcube instrument (QIAgen), Ribospin vRD Viral RNA/DNA Extraction Kit (GeneAll) (manual), MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, using KingFisher Flex instrument and the MagNA Pure DNA and Viral NA Small Volume Kit using Roche MagNA Pure 96, (2) add two real-time PCR instruments, the Applied Biosystem 7500 Real-Time PCR (AB7500) and the Applied Biosystem 7500 Fast Dx Real-Time PCR instrument (AB7500 Fast Dx)], for use with the test, (3) update the *in silico* inclusivity testing in the performance section, and (4) make some general minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200119/A001 supports the requested updates for use with the Allplex 2019-nCoV Assay. The Food and Drug Administration (FDA) also requested some minor updates to the intended use to reflect more recent authorizations and the Healthcare Provider and Patient Fact sheets have been updated accordingly. By submitting this amendment for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Allplex 2019-nCoV Assay issued on April 21, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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