July 18, 2020

Rong Wang, Ph.D.
Project Manager
Atila BioSystems, Inc.
740 Sierra Vista Ave., Suite E
Mountain View, CA 94043

Re: EUA200247/A001
Trade/Device Name: iAMP COVID-19 Detection Kit
Dated: April 29, 2020
Received: April 30, 2020

Dear Dr. Wang:

This is to notify you that your request to update the Instructions for Use (IFU) of the iAMP COVID-19 Detection Kit to (1) reduce the sample input volume from 15 to 3 µL, (2) add three additional real-time PCR instruments − Roche LightCycler 480 Instrument II Real-Time PCR System with LightCycler 480 Software Release 1.5.0. or higher; Atila PowerGene 9600 Plus Real-Time PCR System with PowerGene9600 Software; and Applied Biosystems 7500 Real-Time PCR Systems, (3) removal of different cap colors for reagents in the kit, and (4) related procedural edits and instructions in the IFU, including some additional FDA requested warnings, is granted. Upon review, we concur that the data and information submitted in EUA200247/A001 supports the requested updates for use with the iAMP COVID-19 Detection Kit. 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 iAMP COVID-19 Detection Kit issued on April 10, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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Office of Product Evaluation and Quality
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