U.S. FOOD & DRUG ADMINISTRATION

January 27, 2021

Glenn Wise, RAC (US), CSQE, CQA
Manager, Software Quality Engineering
Agena Bioscience Inc.
4755 Eastgate Mall
San Diego, CA 92121 USA

Re: EUA201849/S003
Trade/Device Name: MassARRAY SARS-CoV-2 Panel
Dated: November 25, 2020
Received: November 27, 2020

Dear Mr. Wise:

This is to notify you that your request to update the Instructions for Use (IFU) of the MassARRAY SARS-CoV-2 Panel to: (1) provide a summary of a post-authorization clinical study to fulfill Condition of Authorization M in the October 26, 2020 Letter of Authorization, (2) add a PCR thermal cycler qualification procedure, and 3) add an Instrument Operation Manual Addendum for emergency use of the MassARRAY system for use with the MassARRAY SARS-CoV-2 Panel is granted. Upon review, we concur that the data and information submitted in EUA201849/S003 supports the requested updates for use with the MassARRAY SARS-CoV-2 Panel. 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 MassARRAY SARS-CoV-2 Panel issued on October 26, 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

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