



November 30, 2020

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

Re: EUA201849/S002
Trade/Device Name: MassARRAY SARS-CoV-2 Panel
Dated: November 12, 2020
Received: November 13, 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 add a 384-well plate format for higher throughput is granted. Upon review, we concur that the data and information submitted in EUA201849/S002 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,

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