June 24, 2021

Donna Hongo, Ph.D., CLS
Co-Founder, Co-CEO, Compliance Officer
Symbiotica, Inc.
1350 Burton Drive, Suite 210
Vacaville, CA 95687

Re: EUA201081/S001
Trade/Device Name: COVID-19 Self-Collected Antibody Test System
Dated: April 19, 2021
Received: April 21, 2021

Dear Dr. Hongo:

This is to notify you that your request to expand the prescribers of the COVID-19 Self-Collected Antibody Test System to include all licensed healthcare providers is granted. Upon review, we concur that the information submitted in EUA201081/S001 supports the requested updates for use with the COVID-19 Self-Collected Antibody Test System. FDA has updated the EUA Summary to include a minor edit to the Clinical Sensitivity table, and has updated the Healthcare Provider Fact Sheet to reflect information used in more recent authorizations. By submitting this information 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 COVID-19 Self-Collected Antibody Test System issued on April 5, 2021.

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