



September 20, 2023

Bryce Whited, Ph.D.
Director of Regulatory Affairs, CSSi LifeSciences
Representing:
BioTeke USA, LLC
900 Brickell Key Boulevard, Suite 2304
Miami, FL 33131

Re: EUA220400/S001 & S002
Trade/Device Name: Bio-Self COVID-19 Antigen Home Test
Dated: June 26, 2023 and August 16, 2023
Received: June 26, 2023 and August 16, 2023

Dear Dr. Whited:

This is to notify you that your request to (1) extend the product shelf-life claim for the Bio-Self COVID-19 Antigen Home Test from 6-months to 12-months when stored at 2-30°C, based on the results of your ongoing stability studies, and (2) provide additional analytical reactivity data, performed to fulfill Condition of Authorization S. of the May 22, 2023 letter, is granted. Upon review, we concur that the data and information submitted in EUA220400/S001 & S002 supports the requested updates for use with the Bio-Self COVID-19 Antigen Home Test and fulfills Condition of Authorization S. of the May 22, 2023 letter. 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 Bio-Self COVID-19 Antigen Home Test issued on May 22, 2023.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health