



September 20, 2023

Muriel Wood
President
BioSynchronicity Corporation
12835 Bel Red Rd, Suite 327
Bellevue, WA 98005

Re: EUA220346/S004
Trade/Device Name: C-Sync COVID-19 Antigen Test
Dated: August 13, 2023
Received: August 14, 2023

Dear Muriel Wood:

This is to notify you that your request to extend the product shelf-life claim for the C-Sync COVID-19 Antigen Test from 6-months to 12-months when stored at 2-30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220346/S004 supports the requested updates for use with the C-Sync COVID-19 Antigen Test. 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 C-Sync COVID-19 Antigen Test issued on March 24, 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