July 24, 2023

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

Re: EUA220346/S001, EUA220346/S002 and EUA220346/S003
Trade/Device Name: C-Sync COVID-19 Antigen Test
Dated: May 1, 2023, June 20, 2023, and June 23, 2023
Received: May 1, 2023, June 20, 2023, and June 23, 2023

Dear Muriel Wood:

This is to notify you that your request to update the C-Sync COVID-19 Antigen Test to (1) provide shelf-life stability results for the External Quality Controls for C-Sync COVID-19 Antigen Test formulated as originally authorized, (2) update the C-Sync COVID-19 Antigen Test Instructions for Use to include additional analytical reactivity results and to fulfill Condition W of the March 24, 2023 Letter, and (3) replace the originally authorized lyophilized External Quality Controls with two positive control swabs and one negative control swab and to fulfill Condition U of the March 24, 2023 Letter, is granted. Upon review, we concur that the data and information submitted in EUA220346/S001, EUA220346/S002 and EUA220346/S003 support the requested updates for 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,

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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