



May 25, 2022

Louise Laurent, M.D., Ph.D.
UCSD BCG EXCITE Lab
UCSD Biomedical Sciences Building
9500 Gilman Drive
Room 1202
La Jolla, CA 92093

Re: EUA220159/S001
Trade/Device Name: UCSD EXCITE COVID-19 EL Test
Dated: May 2, 2022
Received: May 2, 2022

Dear Dr. Laurent:

This is to notify you that your request to update the laboratory Standard Operating Procedures and EUA Summary of the UCSD EXCITE COVID-19 EL Test to update the specimen stability claim to (1) up to 96 hours at 4 – 30°C and (2) up to 66 hours at 4 – 30°C with temperature excursions up to 40°C not to exceed 20 hours, is granted. Upon review, we concur that the data and information submitted in EUA220159/S001 supports the requested updates for use with the UCSD EXCITE COVID-19 EL 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 UCSD EXCITE COVID-19 EL Test issued on April 7, 2022.

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