April 26, 2021

Karthik Musunuri
Chief Executive Officer
ADVAITE, Inc.
5 Great Valley Parkway, Suite 125
Malvern, PA 19355

Re: EUA202686/S001
Trade/Device Name: RapCov Rapid COVID-19 Test
Dated: EUA202686/S001 – March 13, 2021
EUA202686/S002 – March 15, 2021

EUA202686/S002
Trade/Device Name: RapCov Rapid COVID-19 Test
Received: EUA202686/S001 – March 15, 2021
EUA202686/S002 – March 17, 2021

Dear Karthik Musunuri:

This is to notify you that your request for (1) review of the agreed upon post-authorization POC clinical agreement study for the RapCov Rapid COVID-19 Test and, (2) updating the Instructions for Use to update the shelf-life stability of the RapCov Rapid COVID-19 Test from 5 months at room temperature and 9 months at 2-8° C to 8 months when stored at 2-37°C is granted. Upon review, we concur that the information submitted in EUA202686/S001 and EUA202686/S002 supports the requested updates for use with the RapCov Rapid COVID-19 Test. FDA also made minor updates to the IFU, Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting these revisions 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 RapCov Rapid COVID-19 Test issued on January 11, 2021.

Sincerely yours,

Uwe Scherf -S

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