August 20, 2020

Roderick Castillo
Director, Regulatory and Clinical Affairs
Cue Health Inc
4890 Carroll Canyon Road Suite 100
San Diego, CA 92121

Re: EUA2000248/A001
Trade/Device Name: Cue COVID-19 Test
Dated: July 6, 2020
Received: July 6, 2020

Dear Mr. Castillo:

This is to notify you that your request to update the Instructions for Use (IFU) of the Cue COVID-19 Test to: (1) add testing of previously collected nasal specimens in viral transport media and (2) update the test protocol and Quick Reference Index to include instructions for the new specimen type, is granted. Upon review, we concur that the data and information submitted in EUA200248/S001 supports the requested updates for use with the Cue COVID-19 Test. By submitting this amendment 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 Cue COVID-19 Test issued on June 10, 2020.

Sincerely yours,

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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