U.S. FOOD & DRUG ADMINISTRATION

September 19, 2023

Sharon Young
Senior Manager, Regulatory Affairs
Cue Health, Inc.
4980 Carroll Canyon Road Suite 100
San Diego, CA 92121

Re: EUA230004/S001
Trade/Device Name: Cue Mpox (Monkeypox) Molecular Test
Dated: July 17, 2023
Received: July 17, 2023

Dear Ms. Young:

This is to notify you that your request to update the authorized labeling of the Cue Mpox (Monkeypox) Molecular Test to include (**1**) positive control material for use with your device to fulfill Condition of Authorization "W", and (**2**) data from a study evaluating near LoD performance of your device to fulfill Condition of Authorization "X" listed in the March 17, 2023 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA230004/S001 supports the requested updates for use with the Cue Mpox (Monkeypox) Molecular Test Instructions for Use and Quick Reference Instructions and fulfills Conditions of Authorization "W" and "X" listed in the March 17, 2023, Letter of Authorization. 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 Cue Mpox (Monkeypox) Molecular Test issued on March 17, 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