



July 18, 2023

B. Scott Ferguson, Ph.D.
CEO
Aptitude Medical Systems Inc.
125 Cremona Drive, Suite 100
Goleta, CA 93117

Re: EUA220389/S004
Trade/Device Name: Metrix COVID-19 Test
Dated: June 6, 2023
Received: June 6, 2023

Dear Dr. Ferguson:

This is to notify you that your request to update the Metrix COVID-19 Test to add an alternative swab option for use with the Metrix COVID-19 Test, is granted. Upon review, we concur that the data and information submitted in EUA220389/S004 supports the requested updates for use with the Metrix COVID-19 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 reissued letter authorizing the emergency use of the Metrix COVID-19 Test issued on May 10, 2023.

Sincerely yours,

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