



February 26, 2025

Tyler Chozinski, PhD
Head of Scientific and Medical Affairs
Aptitude Medical Systems Inc.
125 Cremona Dr Ste 100
Goleta, CA 93117

Re: EUA220389/S007
Trade/Device Name: Metrix COVID-19 Test
Dated: December 12, 2024
Received: December 16, 2024

Dear Dr. Chozinski:

This is to notify you that your request is granted to update the Metrix COVID-19 Test to add use of the Metrix Reader (Gen 2) and make the associated authorized labeling updates. Upon review, we concur that the data and information submitted in EUA220389/S007 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 letter authorizing the emergency use of the Metrix COVID-19 Test reissued May 10, 2023.

Sincerely yours,

Joseph Briggs, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health