U.S. FOOD & DRUG ADMINISTRATION

February 10, 2023

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

Re: EUA220389/S002
Trade/Device Name: Metrix COVID-19 Test
Dated: December 20, 2022
Received: December 20, 2022

Dear Dr. Ferguson:

This is to notify you that your request to update the Instructions for Use of the Metrix COVID-19 Test to; (1) include usability testing results of saliva collection from two and three year old children (assisted by an adult) completed to fulfill Condition of Authorization T. of the Letter of Authorization issued on October 18, 2022, (2) add an alternative supplier for nasal swabs for use with the test, (3) add a new packaging configuration to include 25 tests in one kit per Condition of Authorization N. of the Letter of Authorization issued on October 18, 2022, and (4) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA220389/S002 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 issued on October 18, 2022.

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