



April 12, 2024

Tyler Chozinski, Ph.D.  
Head of Scientific and Medical Affairs  
Aptitude Medical Systems Inc.  
125 Cremona Drive, Suite 100  
Goleta, CA 93117

Re: EUA220389/S006  
Trade/Device Name: Metrix COVID-19 Test  
Dated: March 26, 2024  
Received: March 26, 2024

Dear Dr. Chozinski:

This is to notify you that your request to update the Metrix COVID-19 Test to extend the shelf-life expiration date to 18 months when stored at 15-30°C, based on the results of your real-time stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220389/S006 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,

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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