



June 10, 2021

Kim Snyder  
Director Regulatory Affairs  
Abbott Molecular Inc.  
1350 East Touhy Ave, Suite 300W  
Des Plaines, IL 60018

Re: EUA202930/S001 and S003  
Trade/Device Name: Alinity m Resp-4-Plex  
Dated: March 22, 2021 and May 7, 2021  
Received: March 23, 2021 and May 7, 2021

Dear Ms. Snyder:

This is to notify you that your request to implement a software change to the Application Specification File on the Alinity m System to Version 3.00 for use with the Alinity m Resp-4-Plex, is granted. Upon review, we concur that the data and information submitted in EUA202930/S001 and S003 supports the requested updates for use with the Alinity m Resp-4-Plex. In addition, FDA have updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect more recent authorizations. 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 Alinity m Resp-4-Plex issued on March 4, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.  
Director, Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



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<b>Final Amendment Package Review and Concurrence Table</b>	
DMD EUA Team Lead	06/09/2021 – Kim Sapsford (DMD/OHT7-OIR/OPEQ/CDRH): Reviewed, concurred and prepared the final amendment package for Division.  <i>Note: The requested change is considered a change to the scope of the EUA (under Condition K. in the March 4, 2021 Letter of Authorization – further this is considered a change to an authorized instrument which can be redelegated to the Director of DMD per the October 30, 2016 memo on Redelegation of Authority for Various Issues Related to EUAs.</i>
Branch Review/Concurrence	N/A
Division Review Review/Concurrence	06/10/2021 – Uwe Scherf (DMD/OHT7-OIR/OPEQ/CDRH): Reviewed, concurred and granted supplement.
Office of Counter Terrorism and Emerging Threats (OCET)/OCS/OC Review/Concurrence	N/A