U.S. FOOD & DRUG ADMINISTRATION

February 7, 2022

Jennifer Topor
Abbott Molecular Inc.
1300 E. Touhy Avenue
Des Plaines, IL 60018

Re: EUA202930/S005
Trade/Device Name: Alinity m Resp-4-Plex
Dated: September 3, 2021
Received: September 8, 2021

Dear Ms. Topor:

This is to notify you that your request to provide data supporting modification to the reaction vessel clamp height resulting in an update to the Application Specification File from version 4.00 to version 5.00, as well as to update the authorized labeling of the Alinity m Resp-4-Plex to include use with pierceable caps on the Alinity m instrument and update the *in silico* inclusivity data, is granted. Upon review, we concur that the data and information submitted in EUA202930/S005 supports the requested updates for use with the Alinity m Resp-4-Plex. 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