July 1, 2021

Kim Snyder
Director Regulatory Affairs
Abbott Molecular Inc.
1350 E. Touhy Avenue
Des Plaines, IL 60018

Re: EUA202930/S004
Trade/Device Name: Alinity m Resp-4-Plex
Dated: June 3, 2021
Received: June 4, 2021

Dear Ms. Snyder:

This is to notify you that your request to update the Instructions for Use (IFU) of the Alinity m Resp-4-Plex to: (1) include data from additional inclusivity testing to fulfill a Condition of Authorization and (2) update the format of the positive control vial labels, negative control vial label, AMP tray label, and ACT tray label, is granted. Upon review, we concur that the data and information submitted in EUA202930/S004 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