March 30, 2022

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

Re: EUA202930/S006
Trade/Device Name: Abbott Alinity m Resp-4-Plex assay
Dated: February 19, 2022
Received: February 19, 2022

Dear Ms. Topor:

This is to notify you that your request to update the Amp-Detect Motion Profile used with the Abbott Alinity m Resp-4-Plex assay to change the rate at which the ejector bar on the Amplification Detection Unit makes contact and lifts the Reaction Vessel out of the thermal block after thermocycling, is granted. Upon review, we concur that the data and information submitted in EUA202930/S006 supports the requested updates for use with the Abbott Alinity m Resp-4-Plex assay. 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 Abbott Alinity m Resp-4-Plex assay issued on March 4, 2021.

Sincerely yours,

_____

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