February 22, 2024

Jennifer Peterson, RAC
Associate Director, Regulatory Affairs
Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018

Re: EUA160021/S001
Trade/Device Name: Abbott RealTi*me* ZIKA
Dated: January 31, 2024
Received: January 31, 2024

Dear Jennifer Peterson:

This is to notify you that your request to update the Instructions for Use (IFU) of the Abbott RealTi*me* ZIKA assay; (1) in response to FDA's request, and (2) to include some additional minor edits and clarifications, is granted. Upon review, we concur that the information submitted in EUA160021/S001 supports the requested updates for use with the Abbott RealTi*me* ZIKA 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 RealTi*me* ZIKA assay issued on November 21, 2016.

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