DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stacy Ferguson
Regulatory Affairs Project Manager
Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018

January 6, 2017

Re: EUA160021/A001
Trade/Device Name: Abbott RealTi*m*e ZIKA
Dated: December 09, 2016
Received: December 12, 2016

Dear Ms. Ferguson:

This is to notify you that your request to modify the Intended Use of the Abbott RealTi*m*e ZIKA assay to include EDTA whole blood as an additional authorized specimen type for detection of Zika virus has been granted.

Upon review, we concur that the data submitted in EUA160021/A001 supports the modification of the Intended Use to include EDTA whole blood as an authorized specimen type. We also concur with the related updates of the Instructions for Use and the Fact Sheets for the Abbott RealTi*m*e ZIKA assay that reflect the addition of EDTA whole blood. By submitting this amendment 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*m*e ZIKA assay issued on November 21, 2016.

Sincerely yours,

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