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

March 10, 2016

Lisa A. Shadorf
Official Correspondent
First Diagnostic Corporation
8411 Fairview Ct
Lone Tree, CO 80124
info@firstdiagnostic.com

Document Number: GEN1600119
Original: March 4, 2016
Amended: March 10, 2016

Dear Ms. Shadorf:

It has come to our attention that you are currently marketing the ATFirst's One Step Zika Antibody Test, which is intended "for the simultaneous detection and differentiation of IgG and IgM antibodies to Zika Virus in human serum, plasma or whole blood". The ATFirst's One Step Zika Antibody Test appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act.

Based on our review of your website and other materials, we believe you are offering a high risk test that has not been the subject of premarket clearance, approval, or Emergency Use Authorization review by the Food and Drug Administration (FDA). In light of the current public health emergency, it is particularly important for the FDA to review information related to your ATFirst's One Step Zika Antibody Test's design, validation, and performance characteristics.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-4684
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Lisa A. Shadorf
First Diagnostic Corporation

We look forward to discussing this with you, and are committed to working with you as we strive to protect the public health. Please contact us within seven (7) days to schedule a meeting. If you have questions relating to this matter, please feel free to call Patricia Spillar at 301-796-6191.

Sincerely yours,

James L. Woods -A
2016.03.10 13:50:43 -05'00'

James L. Woods
Deputy Director Patient Safety
And Product Quality
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health