DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Eli Mordechai, Ph.D.
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March 23, 2016

Document Number: GEN1600153

Dear Dr. Mordechai:

It has come to our attention that you are currently marketing the Zika Virus–Blood–PCR test, which is intended to test blood for the presence of the Zika virus. The Zika Virus-–Blood–PCR 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 various 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 Zika Virus–Blood–PCR 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

Eli Mordechai, Ph.D.
Medical Diagnostic Laboratories, L.L.C.

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,

Michelle Rodriguez -S
2016.03.23 16:02:10 -04'00' for

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