



It Has Come to Our Attention Letter

Dr. James Versalovic
Texas Children's Hospital
1102 Bates Avenue
Suite 830
Houston, TX 77030
jamesv@bcm.edu

March 2, 2016

Dr. James M. Musser
Houston Methodist Hospital
6565 Fannin Street Houston, TX
77030
immusser@houstonmethodist.org

Document Number: GEN1600109

Dear Dr. Versalovic and Dr. Musser:

It has come to our attention that you are currently marketing the Zika Direct Test, which is intended to be used as a rapid diagnostic test to identify virus-specific RNA sequences to directly detect Zika virus. The Direct Zika 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 promotional 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). The FDA would like to better understand the test's design, validation and performance characteristics, and in addition, CDC and CMS have asked us to review the science behind your test. We believe that due to the current public health emergency it is appropriate for the Food and Drug Administration to review information related to the development of the test.

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

Dr. James Versalovic, Texas Children's Hospital
Dr. James M. Musser, Houston Methodist Hospital

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,

Donald J. St Pierre -A

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