DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

October 21, 2016

Julie Kliegl, Ph.D.
President
Viracor-IBT Laboratories, Inc.
1001 NW Technology Drive
Lee's Summit, MO 64086

Re: Zika Virus IgG
Zika Virus IgG and IgM Panel

Refer to CMS case #508174

Dear Dr. Kliegl:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing the following products in the United States without marketing clearance, approval, or marketing authorization in violation of the Federal Food, Drug, and Cosmetic Act (the Act):

1) Zika Virus IgG (Test Code: 30293) intended for "the qualitative detection of Zika virus IgG antibodies in serum or plasma to aid in the diagnosis of Zika virus infection" (http://www.viracoribt.com/Test-Catalog/Detail/Zika-Virus-IgG)
2) Zika Virus IgG and IgM Panel (Test Code: 403547P), which includes the Zika Virus IgG test, and is intended for use in the diagnosis of Zika virus infection (http://www.viracoribt.com/Test-Catalog/Detail/Zika-Virus-IgG-and-IgM-Panel)

Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. FDA has not issued an emergency use authorization (EUA) under section 564 of the Act (21 U.S.C. § 360bbb-3) for these devices.[1] Although FDA issued an EUA for your firm's Zika Virus

[1] On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus. Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Real-time RT-PCR test, that EUA does not authorize the emergency use of other *in vitro* diagnostic tests, such as the Zika Virus IgG test and the Zika Virus IgG and IgM Panel.

FDA has reviewed your website (http://www.viracoribt.com), and determined that the devices identified above are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. These devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the Agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency (21 CFR 807.81(b)). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our review revealed that you are offering these tests that may pose significant risks to patients and the public. Your Zika Virus IgG and Zika Virus IgG and IgM Panel must not be distributed and used for clinical diagnosis until they are cleared, approved, or granted marketing authorization. In light of the current Zika virus public health emergency, it is particularly important for the FDA to review information related to your devices' design, validation, and performance characteristics.

Our office requests that Viracor-IBT Laboratories, Inc. immediately cease activities that result in the misbranding or adulteration of the Zika Virus IgG and Zika Virus IgG and IgM Panel, such as the commercial distribution of the devices for the uses discussed above. Additionally, we request that you promptly notify each affected client, including patients and doctors, about the issue, and provide us copies of these notification letters.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address the systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. Your firm's response should be comprehensive and address all violations included in this letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 3540
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS#508174 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Uwe Scherf, M.Sc., Ph.D., at 301-796-5456 or Uwe.Scherf@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely yours,

Alberto Gutierrez -S

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health