U.S. FOOD & DRUG ADMINISTRATION

February 12, 2018

Our STN: 125653/3 **SUPPLEMENT APPROVAL**

Roche Molecular Systems, Inc.
Attention: Julie Tai, PhD
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Dear Dr. Tai:

We have approved your request dated November 29, 2017 to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for cobas® Zika to add a mini-pooling claim for testing plasma samples in pools of 6 for cobas® Zika used with cobas® Synergy Core as an optional pooling solution.

We hereby approve the draft package insert labeling submitted under amendment 3, dated February 6, 2018 and the Product Information Card submitted under amendment 3, dated February 6, 2018. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Please submit all final printed labeling as PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

We will include the information contained in the above-referenced supplement in your biologics license application file.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research