SUPPLEMENT APPROVAL
November 20, 2020

Grifols Diagnostic Solutions, Inc.
Attention: Ms. Amanda Doe
10804 Willow Court
San Diego, CA 92127

Dear Ms. Doe:

We have approved your requests submitted June 11, 2020, received June 12, 2020, to supplement your Biologics License Applications (BLA) under section 351(a) of the Public Health Service Act for the submission of the final package insert following the approval of the Trans BLA Prior Approval Supplement (PAS) which allowed modifications to the Procleix Panther System to facilitate (b) (4) (Reference BL 125121/98 et al.) for the following products:

STN	Name of the Biological Products
BL 125121/104	West Nile Virus (WNV/Nucleic Acid Pooled Testing/Synthetic)
BL 125652/12	Procleix Ultrio Elite Assay
BL 125667/12	Procleix Zika Virus assay
BL 125673/12	Procleix Babesia Assay

We hereby approve the draft package insert labeling submitted with the submission, dated June 11, 2020. 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 at 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, **unless otherwise specified** (**Please see Note below**):

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

Please Note:

CBER's Document Control Center (DCC) will not process any submission received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB) until further notice. Device submissions, for CBER regulated devices, can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at https://www.fda.gov/media/83522/download. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at https://www.fda.gov/industry/electronic-submissions-gateway.

Submissions regarding this file may also be submitted electronically via email at **CBERDCC_eMailSub@fda.hhs.gov**. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics.

We will include the information contained in the above-referenced supplement in your BLA 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