U.S. FOOD & DRUG ADMINISTRATION

SUPPLEMENT APPROVAL
December 5, 2024

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

Dear Amanda Doe:

We have approved your requests received September 27, 2024 to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to update the Procleix® Zika Virus assay and the Procleix® Babesia Assay package inserts to include an additional statement within the Storage and Handling Instructions to manually track the time reagents spend at room temperature when not onboard the Panther instrument for the following products:

STN	Name of Biological Products
BL 125667/27*	Procleix® Zika Virus assay
BL 125673/29	Procleix® Babesia assay

*Primary STN

We hereby approve the draft package insert labeling received with the supplements on September 27, 2024. 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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:

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 supplements in your BLA files.

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