SUPPLEMENT APPROVAL
October 6, 2026

Grifols Diagnostics Solutions Inc.
Attention: Miguel de la Fuente López, PhD
10804 Willow Court
San Diego, CA 92127

Dear Dr. Miguel de la Fuente López:

We have approved your requests received April 14, 2026, submitted under section 351(a) of the Public Health Service Act to update the Instructions for Use written instructions for the manual lysis mix step, additional minor edits to the homogenization step and endogenous substances wording, the removal of specific RLU values from the results interpretation presentation (RLU values are set by the Procleix Panther System software) and additional minor editorial updates that are required for the following biological products:

STN	Name of Biological Products
BL 125673/37*	Procleix® Babesia Assay
BL 125862/1	Procleix® Plasmodium Assay

* Primary STN

LABELING

We hereby approve the draft package insert labeling submitted under amendment # 1, and the draft carton and container labeling submitted under amendment # 1 received June 16 , 2026. 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 devices, and the device identifiers that have been discontinued for the subject devices 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:

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

We will include the information contained in the above-referenced supplements in your BLA files.

Sincerely,

J. Peyton Hobson, PhD
Director (Acting)
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research