



Our STN: BL 125673/32

**SUPPLEMENT APPROVAL
December 16, 2025**

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 July 2, 2025, submitted under section 351(a) of the Public Health Service Act for Procleix Babesia Assay for a change to the Open Bottle Stability claim from 30 days to 90 days for the Parasite Transport Medium used with the Procleix Babesia assay.

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