Creative Testing Solutions®

INTERPRETATION INFORMATION SHEET

Babesia NAT Assay

FDA Guidance dated May 2019 classifies babesiosis as a relevant transfusion-transmitted infection. The guidance further recommends regional testing or pathogen reduction using FDA-licensed and approved devices for blood donations collected in Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin and Washington, D.C.

Creative Testing Solutions screens blood donations for *Babesia* species RNA in specimens from blood donations collected in the locations described above or upon request. This testing uses Transcription-Mediated Amplification (TMA) Nucleic Acid Testing (NAT).

Babesia NAT is routinely performed by first preparing a lysate of each whole blood specimen, pooling lysate preparations from multiple donor specimens, as prescribed by the manufacturer's instructions for use, then testing the pooled lysate for the presence of *Babesia* spp. RNA. If the pool is reactive, the individual donation samples in the pool are individually tested (IDS) to identify the reactive donation. An alternate sample from each individual *Babesia* reactive donation is retested to verify consistent reactivity. This retest is performed to help with appropriate donor counseling only and cannot be used for donor or donation management. Further information is available in the FDA Guidance referenced below.

There is no currently approved confirmatory assay for individuals testing positive with the *Babesia* NAT assay. The responsible physician may perform additional testing such as alternative *Babesia* NAT and/or diagnostic antibody tests which are not currently indicated for use in donor screening. The results of such testing cannot be used to requalify a deferred donor with a reactive screening test using a licensed NAT.

References:
Grifols Diagnostic Solutions, Inc., Procleix *Babesia* Assay Instructions for Use, 2019-06. GDSS-IFU-000030 v. 2.0
https://www.fda.gov/media/114847/download Content source: US Food & Drug Administration; Vaccines, Blood & Biologics; Biologics Guidances; Blood Guidances. Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry. May 2019

Revision History

Revision	Implemented	Reason
Initial Release	04/20/2020	Implementation of licensed *Babesia* NAT donor screening