FDA OKs screening tests for tick-borne parasite

March 19, 2018—The FDA approved Oxford Immunotec's Imugen *Babesia microti* arrayed fluorescent immunoassay for the detection of antibodies to *B. microti* in human plasma samples and the Imugen *Babesia microti* nucleic acid test for the detection of *B. microti* DNA in human whole blood samples.

Babesiosis, which is caused by Babesia parasites that are transmitted by blacklegged (deer) ticks, is the most frequently reported transfusion-transmitted parasitic infection in the U.S., according to the FDA. There is no FDA guidance for the testing of donor samples for Babesia, but the agency plans to issue draft guidance with recommendations for reducing the risk of transfusion-transmitted babesiosis later this year.

"While babesiosis is both preventable and treatable, until today, there was no way to screen for infections amongst blood donors," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a March 6 statement. "Today's actions represent the first approvals of Babesia detection tests for use in screening donors of whole blood and blood components, and other living donors."

Both assays are in-house tests that can only be performed at Imugen's Norwood, Mass., facility. The tests approved are not intended for use in the diagnosis of babesiosis infections.

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