FDA clears donor screening tests for B. microti infection, 5/18

May 2018—The FDA approved Oxford Immunotec's Imugen *Babesia microti* arrayed fluorescent immunoassay for the detection of antibodies to Babesia 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 There is no FDA guidance for the testing of donor samples for Babesia but the agency plans to issue draft guidance with recommendations for reducing the risk of transfusion-transmitted babesiosis later this year.

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

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