FDA approves first test to screen for Babesia in US blood supply

Press release from US Food and Drug Administration, March 6, 2018:

The U.S. Food and Drug Administration today approved the Imugen Babesia microti Arrayed Fluorescent Immunoassay (AFIA), for the detection of antibodies to Babesia microti (B. microti) in human plasma samples, and the Imugen Babesia microtiNucleic Acid Test (NAT), for the detection of B. microti DNA in human whole blood samples.

These tests are intended to be used as donor screening tests on samples from individual human donors, including volunteer donors of whole blood and blood components, as well as living organ and tissue donors.

“The U.S. blood supply remains the safest in the world thanks in part to the FDA’s ongoing work to enforce standards for blood collection and to identify and respond to potential threats to the nation’s blood supply. While babesiosis is both preventable and treatable, until today, there was no way to screen for infections amongst blood donors,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research.

“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.”

Babesiosis is caused by Babesia parasites that are transmitted by Ixodes scapularis ticks, also known as blacklegged or deer ticks.
*B. microti* is the main species that causes infection in the U.S. There are about 1,000 to 2,000 cases of babesiosis reported in the U.S. each year, with the majority reported from states in the Northeast and upper Midwest. *Babesia* can also be transmitted by transfusion of blood or blood components collected from an infected donor.

The vast majority of people infected with *B. microti* do not have symptoms and are never diagnosed. Some people develop flu-like symptoms, such as fever, headache and body aches.

The U.S. Centers for Disease Control and Prevention (CDC) warns that for certain people, especially those with a weak immune system, it can be a severe, life-threatening disease and that while blood-borne transmission of babesiosis is thought to be uncommon, it is the most frequently reported transfusion-transmitted parasitic infection in the U.S. and remains an important concern.

The investigational use of *Babesia* donor testing has been in place since August 2012 in selected *Babesia* endemic areas under investigational new drug applications (INDs). The use of the investigational tests has resulted in the removal of a significant number of infected units from the blood supply.

The data collected from this testing and from additional studies performed by the manufacturer prevented the release of hundreds of potentially infectious donations and demonstrated that the tests are effective in screening donors for *B. microti* infection. The tests approved today are not intended for use in the diagnosis of babesiosis infections.

These applications were granted **Priority Review**, under which the FDA’s goal is to take action on an application within six months where the agency determines that the product, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.
There currently is no FDA guidance for the testing of donor samples for *Babesia*. However, the FDA is planning to issue draft guidance with recommendations for reducing the risk of transfusion-transmitted babesiosis later this year.

The approval of the Imugen *Babesia microti* AFIA and NAT tests was granted to Oxford Immunotec, Inc. Both assays are in-house tests that can only be performed at the Norwood, Massachusetts facility.