## Community Blood Services Now Testing Donors for Babesia Microti Antibodies

(October 2015) The Blood Centers Division of Blood Systems has begun using an investigational kit to test for antibodies to Babesia microti in all blood donations collected in New Jersey and New York by Community Blood Services. Blood Systems is the parent organization of Community Blood Services, which is headquartered in Montvale, New Jersey. Community Blood Services is the first and only New Jersey blood center providing this testing.

Babesia microti is a tick-borne protozoan parasite that can be transmitted through blood transfusion from an infected donor. B. microti is the infectious agent that can cause babesiosis, a sometimes-serious malaria-like illness. Individuals infected with B. microti may not develop symptoms and can harbor parasites in their blood for months. Symptoms usually develop within one week to several months after exposure and can include fever, chills, body aches and fatigue. Hemolytic anemia and thrombocytopenia are common. Asplenic, immunosuppressed or elderly individuals may be at increased risk for life-threatening infection. Cases of tick-borne and transfusion-transmitted babesiosis (TTB) can be fatal.

Currently, of the U.S. states where babesiosis is endemic, nine states in the Northeast and the upper Midwest are responsible for >95% of CDC-reported cases. Community Blood Services collects blood from donors in two of the affected areas, New York and New Jersey. B. microti antibodies, indicating exposure to the parasite, are carried in the blood in 1% or more of the population in highly endemic areas. Although B. microti transmission is seasonal and coincides with tick activity (May-September), transfusion-transmitted infections are reported year-round from intermittent, asymptomatic parasite circulation in donors' blood (two-seven months or longer after infection).

Although no FDA-approved donor testing method is currently available, TTB cases have resulted in an <u>AABB recommendation</u> that hospitals and blood centers in endemic areas should consider appropriate available interventions. Blood Systems is one of the first U.S. blood providers to implement testing for B. microti antibodies at Creative Testing Solutions. Creative Testing Solutions has an exclusive arrangement with Immunetics, Inc. to test for B. microti antibodies using an enzyme immunoassay under an Investigational New Drug (IND) protocol. All blood and platelets collected by Community Blood Services will be tested at Creative Testing Solutions.

In a <u>published study</u> of serologic reactivity assessed by this test, donor repeat-reactive (RR) rates were 0.92% in a high-risk endemic area, 0.54% in a lower-risk area, and 0.16% in a non-endemic area. The infectivity of donors found to be RR by this test is presently unknown, but Lookback studies using alternate antibody detection and nucleic acid testing suggest that <20% of recipients of antibody-positive donor red cells or red-cell-containing platelets develop evidence of infection. Data from a 2013 study are provided in the following table.

Sample Category	B. microti EIA Initially-Reactive	B. microti EIA Original C/O	Repeat-Reactive Revised C/O	IFA Positive
High-risk Endemic Area Donors (Suffolk County, NY) (n = 13,668)	0.71% (97)	0.56% (76)	0.29% (40)	0.25% (34)
(Minneapolis, MN) (n = 4,583)	0.33% (15)	0.37% (17)	0.15% (7)	0.04% (2)
Non-endemic Area Donors (New Mexico) (n = 8,451)	0.51% (43)	0.39% (33)	0.15% (13)	0.07% (6)

Donors who test repeat-reactive for B. microti antibodies will be indefinitely deferred from future donations. Additionally, we will perform Lookback investigations to identify donations made within the preceding 12 months and notify affected transfusion services so that all in-date components are not transfused. We will request that affected transfusion services initiate recipient tracing and perform follow-up testing according to their facility's standard operating procedures.

For additional information about babesiosis, consult resources available on the <u>CDC</u> and <u>AABB</u> websites. For questions about any of Blood Systems' protocols, please call 201-389-0450.