United Blood Services in Fargo begins testing donors for *Babesia microti* antibodies

(September 16, 2015)—Today, the Blood Centers Division of Blood Systems sent a blood service notice via email informing blood service customers that on or shortly after September 21, 2015, Blood Systems will begin using an investigational kit to test for antibodies to *Babesia microti* in all blood donations collected in New Jersey, New York and Minnesota by Community Blood Services in Montvale, New Jersey, or United Blood Services in Fargo, North Dakota. Blood Systems is the parent organization of Community Blood Services and United Blood Services.

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 1 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. United Blood Services in Fargo and Community Blood Services collect blood from donors in some of these affected areas. *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 (2-7 months or longer after infection).

Although no FDA-approved donor testing method is currently available, TTB cases have resulted in an AABB recommendation 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 the New Jersey and Fargo blood centers in endemic states will be tested at Creative Testing Solutions.

In a published study 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 Repeat-reactive		IFA Positive
		Original C/O	Revised C/O	
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)

Source: Immunetics, Inc.

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 CDC and AABB websites. For questions about any of Blood Systems' testing protocols for donated blood, please contact your local blood center's medical director.