

# **Enhanced Chemiluminescent Enzyme-Linked Immunosorbent Assay** for Detection of Antibodies Against Babesia Microti

## **Technology Summary**

Human babesiosis is caused by an intraerythrocytic protozoan parasite which infects red blood cells. The most common Babesia species found in the United States is Babesia microti transmitted via the deer tick, Ixodes scapularis to humans and its natural host, white-footed mice. Most cases of human babesiosis in healthy individuals are asymptomatic but the disease can be fatal in the elderly, immunocompromised, and asplenic individuals. Babesiosis can additionally be transmitted by transfusion of blood and blood products collected from infected donors. There is no standardized testing of babesiosis in the U.S. and transfusion-transmitted babesiosis (TTB) is a major blood safety concern.

A highly sensitive and specific Enhanced Chemiluminescence Enzyme Linked Immunosorbent Assay (ECL-Bm ELISA) for detection of B. microti antibodies in human plasma/serum samples has been developed that utilizes a combination of three novel B. microti molecules as plate coating antigens [B. microti Serine Repeat Antigen (BmSERA), B. microti Maltese Cross Form Related Protein (BmMCFRP), B. microti Piroplasma  $\beta$ -strand domain (BmPi $\beta$ S)]. These antigens were identified by the genome-wide immuno-screening of a B. microti cDNA phage display library against a pool of human sera from babesiosis patients. These antigens have shown reactivity against babesiosis patient sera: BmSERA: 93%; BmMCFRP: 75%; and BmPi $\beta$ S: 73%. A combination of these three antigens recognized 27/28 (96%) of babesiosis positive and 0 of 15 (0%) babesiosis negative serum samples.

#### **Potential Commercial Applications**

Babesia testing in donor blood

#### **Competitive Advantages**

- high sensitivity (96%)
- specificity (100%)
- amenable to high throughput (recombinant proteins antigen)
- suitable for donor on site screening (ELISA)

Development Stage: In vitro data, preclinical

Inventors: Sanjai Kumar, Peter Krause, and Nitin Verma

### Publication(s):

Verma, N. et. al. Antigen Discovery, Bioinformatics and Biological Characterization of Novel Immunodominant Babesia microti Antigens. Sci Rep. 2020 Jun 12;10(1):9598. PMID: 32533024

Grabias, B. et. al. Superior real-time polymerase chain reaction detection of Babesia microti parasites in whole blood utilizing high-copy BMN antigens as amplification targets. Transfusion. 2018 Aug;58(8):1924-1932. PMID: 29664114

## **Intellectual Property:**

U.S. Patent US20210181190A1 was filed November 1, 2018 WIPO (PCT) WO2019089936A1 was filed November 1, 2018

Product Area: Diagnostic, Screening Tool, Babesia microti

FDA Reference: E-2017-031

# **Licensing Contact:**

FDA Technology Transfer Program

Email: FDAInventionLicensing@fda.hhs.gov