

## 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:** Early development

**Inventors:** Sanjai Kumar, Peter Krause, Nitin Verma

### Intellectual Property:

- PRV 62/580588 – 11/1/2017
- PCT/US18/058723 filed 11/1/18, [WO2019/089936A1](#) pub 5/9/2019

### Publications:

- 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](#)

**Product Area:** Diagnostic, Screening Tool, *Babesia microti*

**FDA Reference No:** E-2017-031

### Licensing Contact:

Ken Millburne, J.D.

FDA Technology Transfer Program

Email: [FDAInventionlicensing@fda.hhs.gov](mailto:FDAInventionlicensing@fda.hhs.gov)

Phone: 240-402-2245