

## 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

**A. 510(k) Number:**

k032713

**B. Analyte:**

*Borrelia burgdorferi* IgM & IgG Western Blot Test Kit

**C. Type of Test:**

Western Blot Test

**D. Applicant:**

Boston Biomedica, Inc.

**E. Proprietary and Established Names:**

BBI *Borrelia burgdorferi* IgM & IgG Western Blot Test Kit

**F. Regulatory Information:**

1. Regulation section:  
21 CFR 866.3830; Treponema pallidum treponemal test reagents
2. Classification:  
Class II
3. Product Code:  
LSR; Reagent, *Borrelia* Serological Reagent
4. Panel:  
Microbiology (83)

**G. Intended Use:**

1. Intended use(s):

The Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit is an *in vitro* qualitative assay for the detection of IgM and IgG antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in testing human serum samples that have been found positive or equivocal using an enzyme immunoassay (EIA) or immunofluorescence assay (IFA) test procedure for *B. burgdorferi* antibodies. Positive results from this Western blot assay are supportive evidence of infection with *B. burgdorferi*, the causative agent of Lyme disease.

The BBI *B. burgdorferi* IgM Western Blot is especially useful for detection of the acute stage of *B. burgdorferi* infection. The BBI *Borrelia burgdorferi* IgG Western Blot is especially useful after the acute phase of *B. burgdorferi* infection, which is usually a month or more from onset of symptoms. After this early period, seroconversion usually occurs and infected patients are found to be Western blot positive for IgG. Often the onset of infection or symptoms is unknown, and therefore it is recommended that the BBI

*Borrelia burgdorferi* IgM and IgG Western Blots be used together for optimal patient care.

2. Indication(s) for use:

The Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Kit is an *in vitro* qualitative assay for the detection of IgM and IgG antibodies to *Borrelia burgdorferi* in human serum. It is intended for use in testing human serum samples that have been found positive or equivocal using an enzyme immunoassay (EIA) or immunofluorescence assay (IFA) test procedure for *B. burgdorferi* antibodies.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

Not applicable

### H. Device Description:

Patient serum is diluted and incubated with IgM and IgG blot strips to allow antibodies to bind to specific proteins. The strips are then washed to remove non-binding antibody. Bound antibody reacts in the next incubation with either IgM Conjugate containing heterologous anti-Human IgM or IgG Conjugate containing anti-Human IgG, each conjugated to alkaline phosphatase. After removing unbound conjugate, any bound conjugate is visualized by adding a substrate solution that precipitates a dark blue insoluble product at the site of binding.

### I. Substantial Equivalence Information:

1. Predicate device name(s):

MarDx *B. burgdorferi* IgG Marblot Strip Test System

2. Predicate K number(s):

k950829

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Procedure	Qualitative; <i>B. burgdorferi</i> antibodies to specific protein bands.	Qualitative; <i>B. burgdorferi</i> antibodies to specific protein bands.
Assay	Western blot	Western blot
Specimen Type	Serum	Serum
Differences		
Item	Device	Predicate
<u>Not applicable</u>		

### J. Standard/Guidance Document Referenced (if applicable):

Not applicable

**K. Test Principle:**  
Western Blot Test

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

The reproducibility of BBI-Biotech *B. burgdorferi* IgM Western blot was assessed using a commercially available 15 member panel (Boston Biomedica, PTI-202) consisting of undiluted specimens from patients with evidence of *B. burgdorferi* exposure. This panel was tested at each laboratory site (2 sites) on separate days, in either two or three runs per site, for a total of eight observations. The percent agreement to the expected interpretation was then calculated for each site and found to be 100%.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Not applicable

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

The specificity of the IgG Western blot kit was 99% when used to test random healthy blood donors (99) from a region not endemic for Lyme disease. The specificity was 100% for 105 normals from endemic region.

The cross reactivity of the BBI-Biotech *B. burgdorferi* IgM Western blot was assessed using samples from patients with potentially interfering conditions or infections and with samples from randomly selected healthy donors from non-endemic and endemic Lyme disease regions. No IgG cross reactivity was observed with the samples tested.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The Boston Biomedica's *B. burgdorferi* IgM Western blot device has been cleared under k980351. The following data represent the performance of *B. burgdorferi* IgG Western Blot Test.

**Sensitivity:** Of 55 patients presenting with culture confirmed *B. burgdorferi* infection and erythema migrans, 6 (11%) were positive for IgG. When the BBI *B. burgdorferi* IgG Western Blot was compared to a predicate, 84% agreement between the two devices was observed.

**Prospective sample study:** Randomly selected samples from seventy patients presenting with symptoms of Lyme disease that had tested positive by an EIA have been tested by the IgG device. No other clinical information is available on these donors. The positivity of these samples was found to be 43% (30/70).

**CDC Panel:** The CDC panel consisted of 47 individual donor specimens, 31 of which were confirmed by culture or erythema migrans to be infected with *B. burgdorferi*, 11 of which had clinical histories suggestive of infection, and 5 of which were negative controls. The overall sensitivity was found to be 36% (15/42). The 5 controls tested negative.

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a and b are not applicable):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

**M. Conclusion:**

The Performance characteristics reported here for the device indicate that it is comparable to the other such test kits currently in the market.