

Technology in **Tick**borne Diseases

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Enhanced IgM and Chemiluminescence-based Antibody detection on Vibrant Immunochip

Patients in early stages of Lyme disease and those who have been treated with antibiotics may not exhibit detectable levels of antibody using traditional methods such as ELISA. For low analyte concentrations such as this, chemiluminescence-based immunoassays are the assays of choice because they enable a more sensitive detection.

The chemiluminescence-based assay on the Vibrant platform enables the detection of lower level of antibodies in comparison to the ELISA testing available currently in other commercial labs. Comparison of chemiluminescence based assays and ELISA based assays have shown the superiority of the former particularly in the case of Lyme disease².



Published Accuracy You Can Trust

VIBRANT COMMITMENT TO QUALITY AND ACCURACY

- All products manufactured in Class 10K Cleanroom
- ISO 13485 Certified Manufactured Facilities
- CLIA and CAP Accredited Lab testing
- High Accuracy of over 98%
- Higher Sensitivity and Specificity

Vibrant has completed all four rounds of CDC sample validation, including both non-blinded and blinded sample verification. <u>Publication in Nature Scientific Report 2020</u>.





Enhanced IgM for early detection

High levels of IgG may mask low levels of IgM in patient sera³ and could lead to false negatives which is the issue with current commercially available testing for Lyme and tick-borne infections. Several applications of stripping IgG antibodies to improve IgM binding have been developed⁴. Vibrant has a novel assay which is designed to remove excess IgG and rheumatoid factor enabling better availability of the IgM antibody to bind with the antigen. *



Advantages of Multiplex PCR on chip

- Increased Sensitivity due to multiple target genes
- Nested amplifications enable up to 16000 fold increase in amplification in comparison to traditional methods
- Enables simultaneous accurate identification of biochemically unusual strains of pathogen
- Facilitates much earlier detection of the microorganism because the assay is independent of the host's antibody response
- Allows monitoring of the efficacy of an antibiotic regime
- Use higher quantity of blood for extraction, bead beating for reduced biofilm effects



Co-Infections

In contrast, Vibrant testing is able to provide superior sensitivity to these tests by including more whole cell sonicate and recombinant antigens from several species of tickborne co-infections on the ImmunoBlot. Multiplex pillar plate format allows for detecting multiple co-infections at the same time, enabling broad-spectrum testing at low cost.



Immunochip

- Fully automated technology eliminates inter-sample variability
- ISO 13485 GMP manufactured antigens are coupled to a silicon chip
- No gel matrix effects
- Multiple antigens tested in the same well
- Antigen set continues to increase with new literature
- High reproducibility due to high automation

*A chemiluminescence based assay with enhanced binding of IgM provides the twin advantages of better detection and accurate results. These advantages coupled with the complete set of antigens tested on the Vibrant chip make it the ideal test for detection of Tickborne infections.

	and charge
	 Large result variability on reproducibility of and isolation, concent Cross-reactivity of ant and other antigens co
Traditional PCR	• Sensitivity is low b
	agent is not present
	tissue and bodily fluic
	• Lyme bacteria have t
	biofilms and can eva
	detection

Platform

ELISA

Key limitations of

Existing Technology

Current diagnostics for

tickborne diseases have

severe shortcomings

multiplexing of larger antigen sets • Overlap between similar molecular Western Blot weight proteins makes it impossible to differentiate, often leads to high quantities of false positives, false negatives, or the wrong positives

• Misses up to 60% of acute cases

of nanogram quantities • Only 1 protein per well Expensive and laborious

Chromogenic detection, low sensitivity

• Can never be scaled for cost and

Limitations

- ImmunoBlot Has the same limitation as western blot for the differentiation of proteins by size
 - y because it relies protein separation tration of the gel
 - tibodies with TBRF onfounds findings
 - ecause infectious in high levels in ds
 - the ability to form de traditional PCR
 - Traditional methods do not have target enrichment methods to lower limit of detection