VibrantWellness

Comparing Vibrant Lyme and Co-Infections Microarray Technology with ELISA and Blot-Based Technology

Introduction

The introduction of Lyme and Co-Infection Microarray technology marks a significant shift in the approach to diagnosing Lyme disease and its associated co-infections. This method addresses the constraints of traditional ELISA and blot-based assays by enabling the simultaneous testing of multiple antigens from a range of pathogens. This whitepaper presents a detailed comparison between the proprietary microarray platform and the conventional methods, highlighting its capacity to deliver more consistent and sensitive results.

In the following pages, we outline the results of the first clinical study of the Lyme disease microarray, including findings demonstrating improved sensitivity and specificity in detecting Lyme disease antigens, as published in **Nature Scientific Reports.**[1] The paper further discusses the subsequent clinical study, which expands the scope to include a comprehensive analysis of co-infections commonly associated with Lyme disease.

Through an extensive review of global clinical validations,[2] we provide a thorough examination of the effectiveness of the microarray platform. These studies incorporate thousands of samples from multiple sources and offer a complete view of the platform's diagnostic capabilities. The aim of this paper is to present an in-depth and transparent evaluation of the Vibrant proprietary microarray technology, reinforcing our dedication to enhancing the accuracy and reliability of infectious disease diagnostics.

Identifying the Need for Microarray Technology

Ticks are carriers of multiple pathogens that can threaten human health. Prior to the advent of the Vibrant Microarray, tickborne testing methods were limited to ELISAs, Western blots, or immunoblots, which could only test for a single organism or antigen at a time. This created a need to run multiple blot assays or ELISAs to cover the wide range of tickborne pathogens, complicating diagnosis. Furthermore, ELISAs and Blot-based assays have limitations, including insufficient sensitivity, inconsistent reproducibility, and the subjective interpretation of positive results, leading to inconsistent results. A broad comparison of the technologies is provided in the table below, underscoring the significant advances made by the Vibrant Microarray technology.

Comparison: Vibrant Microarray Technology Versus ELISA and Blot-Based Methods

Vibrant Proprietary Microarray*	ELISA	Western Blot	Immuno Blot
Multiple antigens of multiple organisms in single array	One antigen per well	One organism per blot	One organism per blot
Quantified amount of antigen - high reproducibility	Variable concentrations in each well - high variability	Variable concentration of antigens in each band due to varying initial set of cells- high variability	Variable concentration of antigens in each band due to varying amount of antigen sprayed – high variability
High Density of antigen on each chip - captures low levels of antibodies - high sensitivity	Low density of antigen on each chip - only captures high levels of antibodies - low sensitivity	Low density of antigen on each blot - only captures high levels of antibodies - low sensitivity	Low density of antigen on each blot due to spraying of antigens – low sensitivity
No matrix effects - antigens presented for antibody binding similar to how interaction happens in the human body	Antigen presented in a polymer matrix	Antigen presented in gel matrix	Antigen present in nitrocellulose matrix
Antigens separated at chip level and multiplexed across type and organism	No multiplexing	Antigens of similar mass to charge ratios overlap, limited multiplexing	Antigens separated by spraying, limited multiplexing
Antigens are in native form – whole cell sonicate, recombinant, or peptide	Antigens are in native form or denatured due to process of attachment	Antigens maybe denatured or charged to make them adhere to gels introducing variability	Antigens may be denatured due to spraying
Low sample volume requirement	High volume requirement	High sample volume requirement	High sample volume requirement
Amplified chemiluminescence - high sensitivity as even low levels of antibodies are detected	Chromogenic - low sensitivity since signal is weak or absent with low antibody levels	Chemiluminescence - intermediate sensitivity	Fluorescence (high noise) or chemiluminescence
Assays highly automated with no human intervention - fast turnaround time	Labor-intensive with element of handling errors - moderate turnaround time	Labor-intensive with element of handling errors - slow turnaround	Labor-intensive with handling of paper strips leading to subjective errors, non-specific binding of antibody to nitrocellulose – slow turnaround
High-end automated manufacturing with ISO 13485 in clean rooms - high accuracy	Low-tech manufacturing	Low-tech manufacturing	Low-tech manufacturing

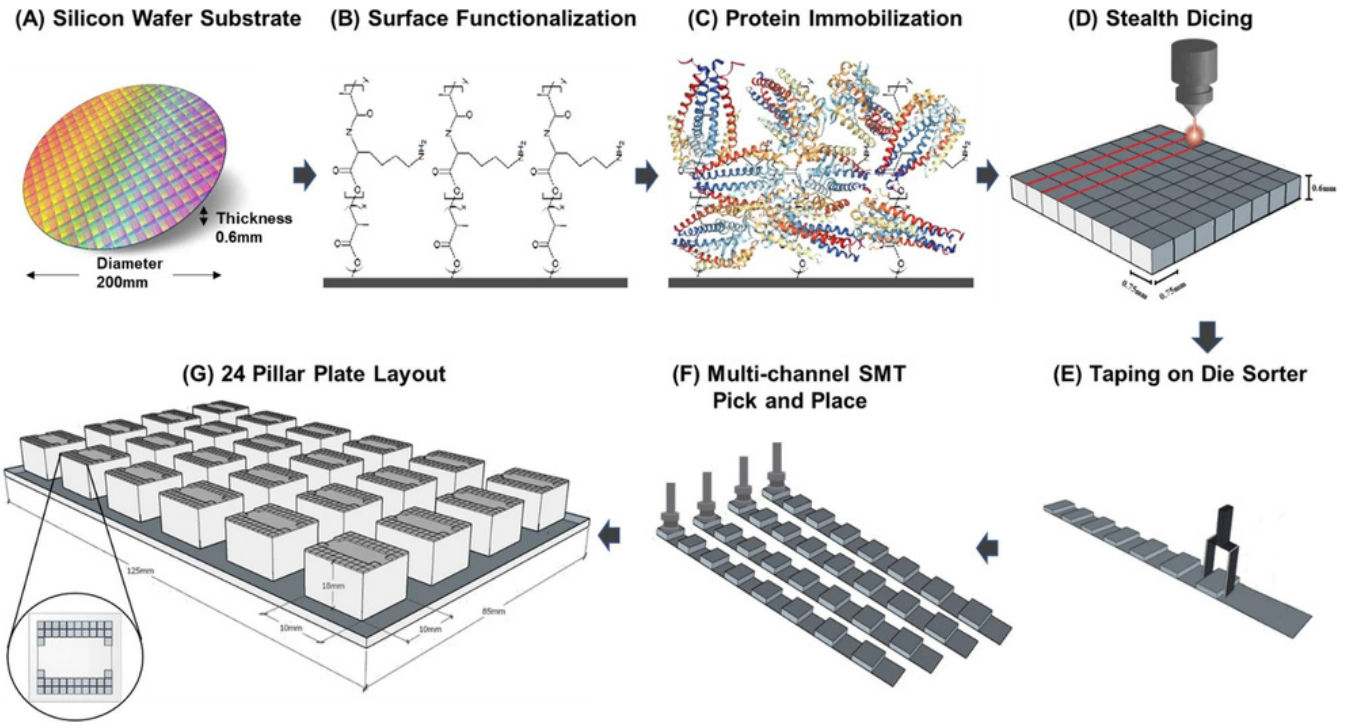
Initial Clinical Validation of Lyme Disease Microarray

The initial clinical evaluation of our Lyme disease microarray incorporated over 15 antigens. These included C6 peptide, key recombinant proteins such as OspA and OspB, and whole-cell lysates from the B31 and 297 strains of Borrelia burgdorferi. As published in Nature Scientific Reports,[3] this array demonstrated an improved testing sensitivity of 100% and a specificity of 97%.

The main components of the Lyme Immunochip platform included the following:

- Multiple silicon-based 0.70 × 0.70 mm 2microchips that are laser-diced from antigen-immobilized wafers
- A customized 24-well compatible plate containing 24 pillars, each with 44 microchips that are picked and placed into a multiplex microarray assembly
- A high-resolution imager capable of simultaneously detecting chemiluminescent signals from labeled antigen–antibody reactions at each microchip throughout the multiplex microarray
- Each chip can be considered analogous to an individual band in a Western blot. However, the proteins are physically separated, eliminating cross-reactive issues seen in blot-based assays for proteins with similar mass.

Each chip can be considered analogous to an individual band in a Western blot. However, the proteins are physically separated, eliminating cross-reactive issues seen in blot-based assays for proteins with similar mass.



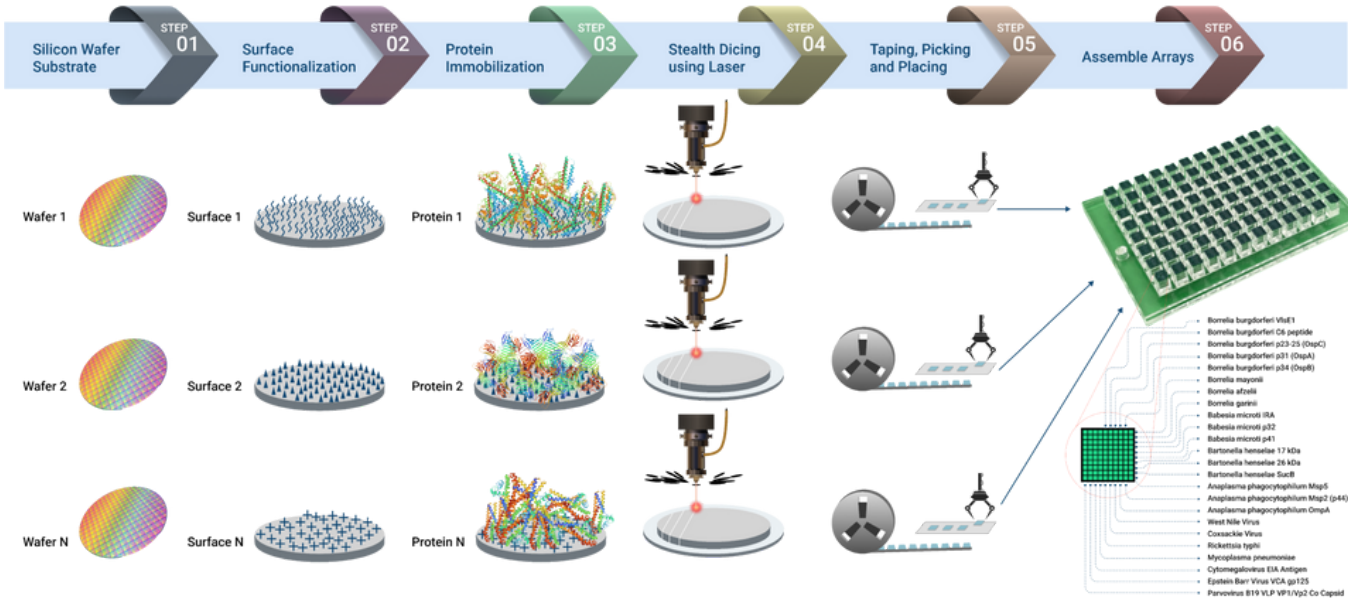
To validate the clinical performance of the Lyme Immunochip, we tested a cohort of blinded samples (N = 90) acquired from the CDC LSR. We interpreted them by criteria achieved via the training set. After incorporating the enhanced IgM assay, we compared the single-tier Immunochip to the standard two-tiered serologic testing, as shown in the table below. **Testing sensitivity for Lyme was 100%, while the specificity of testing was 95.2%.[4]**

Cohort and subject type	n	Vibrant Lyme Immunochip				Standard two-tiered testing	
		Enhanced IgM		Standard			
		Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Complete panel with established markers	130	72.3	97.6	66	97.6	63.8	97.6
Complete panel with investigational markers	130	100	95.2	74.5	94	NA	NA

Second Clinical Validation of Lyme Disease Microarray

Research has shown that up to 50% of Chronic Lyme disease could be positive for co-infections, and over 30% of Lyme patients have two or more co-infections. Testing for Lyme disease and its co-infections is critical for accurate diagnosis and determining appropriate treatment for patients. This led us to the development of the Lyme and Co-infections Microarray. To address the issues associated with ELISAs and blot-based assays, we pioneered the development of a novel multiplex microarray platform that could multiplex and test across the spectrum of infectious agents that can cause Lyme disease and/or co-infections.

The method to manufacture the Lyme and co-infections microarray is shown below.



Step 1: At the top left of this image, you'll notice a circular silicon wafer—the starting material. One wafer is used per antigen per organism of interest. The antigen can be of any type – whole-cell lysate, recombinant protein, or peptide.

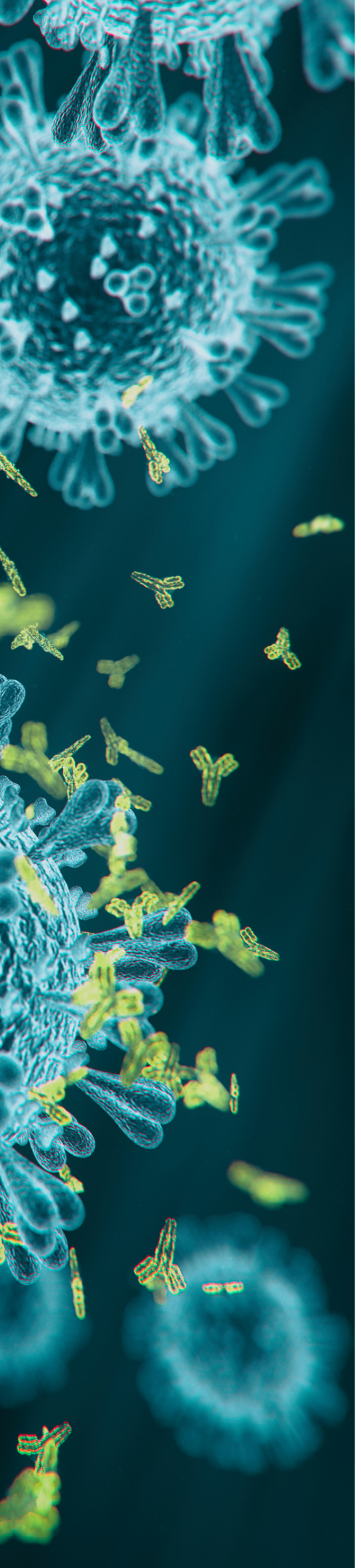
Steps 2 and 3: Each wafer is modified and coupled with an antigen. By the end of step three, there are multiple wafers—each with a unique antigen.

Step 4: Wafers are cut into smaller chips, which can be assembled in the format of the pillar plate shown to the right of the image in steps 5 & 6.

Step 6: The pillar plate is assayed with the patient's serum, enabling antibodies to interact with multiple chips simultaneously, each representing one antigen.

The Lyme and Co-infections Microarray multiplex testing for over 15 infectious agents, using over 80 antigens, is listed below.

Pathogen (Tick, if any)	Cell Lysate / Peptide	Recombinant Antigen(s)
B. burgdorferi (I.scapularis)	Whole-cell lysate - B31 strain, 297 strain. C6 peptide	VlsE1, DbpB, OspC, p28, p30, OspA, OspB, BmpA, p41, p45, p58, p66, p83-93
B. mayonii (I. scapularis)	Whole-cell lysate	
B. afzelii (I. ricinus, I. persulatus)		BmpA, DbpA, OspA, OspC, p100
B. garinii (I. ricinus, I. persulatus)		DBpA, OspC
B. bavariensis (I. uriae, I. persulcatus)		p58, VlsE1, DbpA
B. spielmanii (I. ricinus)		DBpA, OspC
B. hermsii (O. hermsi)	Whole-cell lysate	
B. turicatae (O. turicatae)	Whole-cell lysate	
B. miyamotoi (I. dentatus, I. ricinus, I. scapularis, I. pacificus)		GlpQ
B. andersonii (I. dentatus)	Whole-cell lysate	
B. maritima (I. spinipalpis)	Whole-cell lysate	
B. californiensis (I. jellisonii, I. spinipalpis, I. pacificus)	Whole-cell lysate	
B. bissettiae (I.scapularis, I. persulatus, I. spinipalpis, I. pacificus)	Whole-cell lysate	
B. lusitaniae (I. ricinus)	Whole-cell lysate	
B. valaisiana (I. ricinus, I. nippopensis, I. columnae)	Whole-cell lysate	
B. yangtzensis (I. granulatus, I. nipponensis)	Whole-cell lysate	
B. turcica (H. aegypticum)	Whole-cell lysate	
Babesia microti (I. ricinus, I. scapularis, blood transfusions, perinatal)	Whole-cell lysate	IRA, p32, p41
Babesia duncani (I. ricinus, I. scapularis, blood transfusions, perinatal)	Whole-cell lysate	
Bartonella henselae		17kDa, 26kDa, SucB
Bartonella elizabethae	Whole-cell lysate	
Bartonella vinsonii	Whole-cell lysate	
Bartonella quintana	Whole-cell lysate	
Anaplasma phagocytophilum (I. scapularis, I. ricinus)		MSP5, MSP2, OmpA
Ehrlichia chaffeensis (Amblyomma americanum)	Whole-cell lysate	
Rickettsia typhi (Flea Xenopsylla cheopis, Ctenocephalides felis))		OmpB, surface antigen
Powassan virus (Hemaphysalis longicornis, I. scapularis, I.cookei)		NS1
Tick-borne encephalitis virus (I. ricinus, I. persulcatus)		NS1
West Nile virus (I. ricinus, O. moubata)		NS1
Coxsackie virus (Amblyomma americanum)		VP1
Cytomegalovirus		EIA, GlyB, p150, p28, p52, pp65, p38
Epstein Barr virus		EA, EBNA1, VCA gp125, p18, p23
Parvovirus B19		VLP VLP2, VLP VP1/VP2 Co Capsid
Toxoplasma gondii (Multiple Ticks)	Whole-cell lysate	MIC3, p24, p29, p30
HSV-1		gG-1
HSV-2		gG-2
HHV-6	Whole-cell lysate	



Antigen Technology

The ability to multiplex across different antigen types is a specific highlight of the Vibrant Microarray design. The Vibrant Microarray uses all three antigen technologies listed below. The optimum antigen is picked through extensive validation using clinical samples, as discussed in the following section. Each batch of antigen undergoes a high-quality QC check to match biological activity. Only antigens passing analytical and Bio QC are used in the manufacture of the microarray.

1. **Recombinant Technology:** Involves producing a specific protein of an organism using the sequenced DNA information and a host organism, which can produce the protein in large quantities. For instance, a protein like OspC of Borrelia burgdorferi can be made in significant quantities by inserting the OspC gene into a host organism like E.Coli, which then keeps producing the protein. When the desired amount of protein is synthesized, it can be separated, purified, and used for any specific application. Vibrant manufactures in-house and utilizes external vendors who manufacture recombinant proteins, which are then attached to our chips for antibody detection.

2. **Whole-Cell Sonicate Technology:** Involves combining all proteins of an organism, including surface and intracellular proteins, , by breaking open the cell walls to create an antigen medley, allowing access to complete immune reactivity. The organism is cultured with the appropriate temperature, oxygen levels, and pH. The cells are then sonicated to break open the cell walls to release their contents. This mixture is then purified and used as an antigen for antibody detection. Whole-cell sonicates are recommended as the first tier of testing for Borrelia burgdorferi and are used to test for antibodies to all of an organism's proteins simultaneously.

3. **Peptide Technology:** A peptide is a specific region of a protein typically less than 50 amino acids long. Antibodies are well known to bind to peptides. Testing antibody binding to specific protein regions helps with a more specific detection. For instance, the C6 peptide, a widely used antigen of Borrelia burgdorferi, is a part of the species' vlsE1 protein. Currently, Vibrant synthesizes the peptides using photolithography. We have identified a set of peptide antigens for multiple organisms across different proteins and will launch a Vibrant Lyme and Co-infections peptide microarray for the highest specificity and detection sensitivity in the future.

Additional Clinical Validation

Vibrant ran a large study of 2990 samples,[5] which were clinically validated by a physician on the microarray to establish the sensitivity and specificity testing. This was evaluated at the level of IgM and IgG antibodies. The cohort of samples used is shown below, along with the sources and basis of diagnosis.

Pathogen	N	Source (scientist/company)	Basis of Diagnosis
Borrelia burgdorferi	298	CDC, Private Clinics	RT-PCR, Physician
Babesia microti	70	Parasitology Laboratory, Wadsworth Center (NYSDOH)	RT-PCR, Blood, Smear
Babesia microti	118	Seracare, Boca Bio, Private Clinics	Serology, RT-PCR
Babesia microti	26	Renata Welc-Falęciak (University of Warsaw), Agnieszka Pawełczyk (Warsaw Medical University)	Physician
Bartonella henselae	119	Private clinics	RT-PCR, Physician
Bartonella henselae	26	Renata Welc-Falęciak (University of Warsaw), Agnieszka Pawełczyk (Warsaw Medical University)	Physician
Bartonella henselae	10	Dimosthenis Chochlakis (University of Crete)	Physician
Anaplasma phagocytophilum	118	Private clinics, Boca Bio	RT-PCR, Serology
Anaplasma phagocytophilum	26	Renata Welc-Falęciak (University of Warsaw), Agnieszka Pawełczyk (Warsaw Medical University)	Physician
Ehrlichia chaffeensis	120	Private clinics, Boca Bio	RT-PCR, Serology
Ehrlichia chaffeensis	26	Renata Welc-Falęciak (University of Warsaw), Agnieszka Pawełczyk (Warsaw Medical University)	Physician
Rickettsia typhi	70	Lucas Blanton (University of Texas Medical Branch)	Physician
Rickettsia typhi	124	Private clinics	RT-PCR, Physician
Powassan virus	127	Private clinics	RT-PCR, Physician
Tick-borne encephalitis	111	Daniel Růžek (Czech Academy of Sciences)	Physician
Tick-borne encephalitis	124	Private clinics	RT-PCR, Physician
West Nile virus	20	Gheyath K. Nasrallah (Weill Cornell Medicine-Qatar)	Physician
West Nile virus	124	Private clinics	RT-PCR, Physician
Coxsackie virus	45	iSpecimen	Serology
Coxsackie virus	124	Private clinics	RT-PCR, Physician
Cytomegalovirus	43	DLS	Serology
Cytomegalovirus	138	Daniele Lilleri (Fondazione IRCCS Policlinico San Matteo)	Physician
Cytomegalovirus	96	Private Clinics	RT-PCR, Physician
Cytomegalovirus	37	Seracare	Serology
Epstein Barr virus	20	Gheyath K. Nasrallah (Weill Cornell Medicine-Qatar)	Physician
Epstein Barr virus	43	Seracare	Serology
Epstein Barr virus	14	iSpecimen	Serology
Epstein Barr virus	96	Private clinics	RT-PCR, Physician
Parvovirus B19	124	Private clinics	RT-PCR, Physician
Toxoplasma gondii	24	Seracare	Serology
Toxoplasma gondii	124	Private clinics	RT-PCR, Physician
HSV-1	20	Gheyath K. Nasrallah (Weill Cornell Medicine-Qatar)	Physician
HSV-1	31	Seracare	Serology
HSV-1	96	Private clinics	RT-PCR, Physician
HSV-2	19	Gheyath K. Nasrallah (Weill Cornell Medicine-Qatar)	Physician
HSV-2	27	Seracare	Serology
HSV-2	96	Private clinics	RT-PCR, Physician
HHV-6	20	Gheyath K. Nasrallah (Weill Cornell Medicine-Qatar)	Physician
HHV-6	96	Private clinics	RT-PCR, Physician

The summarized sensitivity and specificities are shown below. The data is shown under IgM alone, IgG alone, and comparable gold standards of testing.

Pathogen	IgM		IgG		Gold Standard [34-48]	
	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Borrelia burgdorferi	60	100	94	100	**Early**: 30-40 **Late:** 70-100	95-100
Babesia microti	79	98	91	97	70-80	94-100
Bartonella henselae	81	99	96	99	100	96.8
Anaplasma phagocytophilum	94	100	100	100	80-100	95-100
Ehrlichia chaffeensis	84	100	100	99	83	100
Rickettsia typhi	86	100	83	100	80-100	91-100
Powassan virus	100	100	100	100	89	35-84
Tickborne encephalitis	78	99	92	99	94-100	>95
West Nile virus	25	100	80	100	80-95	94-100
Coxsackie virus	56	100	100	100	94-97	100
Cytomegalovirus	100	100	100	100	89.2	95
Epstein Barr virus VCA	100	100	96	100	80-95	>95
Epstein Barr virus EBNA1	95	100	96	100	80-95	>95
Parvovirus B19	90	99	98	98	>90	>90
Toxoplasma gondii	100	99	100	100	>90	>95
HSV-1	100	100	98	100	97-100	98
HSV-2	100	100	98	100	97-100	98
HHV-6	95	100	95	100	>95	>95

As seen here, multiple antigens for each organism demonstrated superior performance, with the highest sensitivities and specificities of the Vibrant Microarray. These 2990 samples from researchers around the world were run on the multiplex microarray for over 15 tickborne infections, which is unprecedented.

Vibrant Research and Roadmap

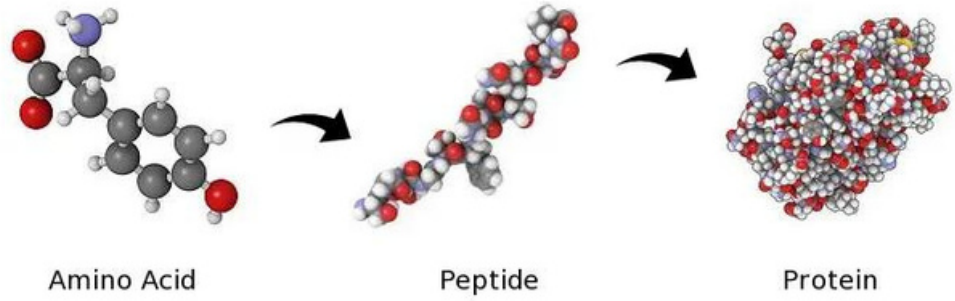
Vibrant is a research-driven company at its core. In addition to our collaboration with leading infectious disease experts for tickborne microarray validation, we are actively engaged in continuous improvement of the testing paradigm.We strive to improve the overall understanding of tickborne diseases under specific peptide-level reactivity and overlap with autoimmunity and other conditions like arthritis, neuroborreliosis, and carditis. As elaborated below, we are equally committed to investigating novel pathogens using tick surveys across the USA and Europe.

Vibrant Peptide Microarray

Vibrant has previously improved the testing landscape with peptide-level testing offered for celiac disease and wheat sensitivity and enhanced antibody detection in rheumatoid arthritis, and several other diseases. Peptides are a sequence of amino acids, typically less than 50, that are smaller parts of proteins. In most biological interactions, the activity happens more frequently at the peptide level and less so at the protein level as a whole. Vibrant's Lyme and Co-infection ***peptide microarray*** is under validation and has already shown a significant advantage—the ability to test at the peptide levels as compared to the recombinant proteins.

As shown in the illustration below, Amino acids combine to form peptides (<50 a.a) and proteins (>50 a.a). Some proteins may even be up to 1000 amino acids in length. Longer amino acid sequences make the protein fold multiple times; hence, all of the amino acids are not exposed at the outer surface of the protein. ***A protein, therefore, contains a lot of amino acid sequences internal to its structure.***

Proteins are three-dimensional molecules made of amino acids. When the immune system encounters a pathogen and its proteins, it cuts open the proteins to produce antibodies to different regions, both internal to the protein and external. A recombinant antigen cannot capture the complete set of antibodies produced against a pathogen's protein. It will miss capturing the antibodies that are created against the peptides internal to the protein structure.



The Peptide microarray contains epitopes that are inaccessible or cryptic in the native protein structure, along with peptides that make up the outer surface of the protein. By using peptides, we can more effectively target and detect these epitopes, providing insights into antibody recognition, immune responses, and overlap with other diseases, including molecular mimicry.

Lyme Disease Overlaps With Arthritis, Carditis, and Neuroborreliosis

There are various pathways proposed for the development of Arthritis, Carditis, and Neuroborreliosis, which is an area of particular interest to our research. Along with critical thought leaders in the space, we're engaged in groundbreaking research to identify the root causes and mechanisms of these conditions. Below are specific antigens we are investigating at the recombinant protein and peptide levels.

Lyme Arthritis

Human leukocyte function-associated antigen 1α (LFA-1α) and OspA or p31

The leukocyte function-associated antigen 1α (LFA-1α) is a protein found in humans that has several roles in immune function, including apoptosis and proliferation of lymphocytes. Studies have previously identified sequence overlap between LFA-1α and the Borrelia protein OspA. This sequence homology results in the cross-reactivity of anti-OspA antibodies with LFA-1α in patients with Lyme arthritis. This cross-reactivity may explain the immune responses observed in Lyme arthritis.

Human MAWD-BP and OspA or p31

MAWD is a human protein involved in cell signaling pathways, and MAWD-BP is expressed in all tissues, including synoviocytes. Studies have identified eight similar sequences in MAWD-BP and the Borrelia protein OspA. The sequence similarity between these two proteins results in the cross-reactivity of anti-OspA antibodies with MAWD-BP, which is observed in patients with Lyme arthritis.

T-span7 and OspA or p31

T-span7 is a newly identified human glycoprotein that shares six sequences with OspA or p31 of B. burgdorferi. Cross-reactivity of anti-OspA antibodies with T-span7 was observed in a few Lyme arthritis patients.

ECGF, a peptide derived from the Endothelial Cell Growth Factor, is a newly identified autoantigen in Lyme arthritis. ECGF has sequence homology with a peptide derived from the BB-0580 of the Lyme spirochete. Autoantibodies against ECGF were observed in a few Lyme arthritis patients. Currently, we are investigating the cross-reactivity of OspA with ECGF using a peptide microarray.

MMP10 B. burgdorferi interacts closely with host proteins like MMP-10. proMMP-10 may be cleaved to active MMP-10 by spirochete-bound plasmin. Due to this structural mimicry between a B-cell epitope of MMP-10 and a Borrelia protein, there is a possibility of cross-reactivity of antibodies. It is likely for this reason that,autoantibodies against MMP-10 are observed in patients with Lyme arthritis.

Annexin A2 is a receptor for plasminogen and tissue plasminogen activator. The Lyme spirochete usually binds to both plasminogen and tissue plasminogen activators, which leads to the bacteria spreading in the host. The bacteria may also bind to annexin, leading to the phagocytosis of annexin A2. This process may explain the high levels of antibodies against annexin A2 found in patients with Lyme arthritis.

Lyme Carditis

apoB100

The Lyme spirochete acquires lipid molecules from the host, giving the bacteria a similar lipid composition. Autoantibodies may be released against the host lipoproteins that bind to the bacterial lipids, resulting in an immune response. ApoB100 can be considered an autoantigen of Lyme carditis, as autoantibodies against this lipoprotein are observed in patients with Lyme carditis.

Cardiac Myosin

Research has suggested that the inflammatory response triggered by B. burgdorferi could induce autoantibodies against components of cardiac tissue. We are investigating the presence of autoantibodies against cardiac myosin and other proteins in cardiac tissue to analyze their potential role in tissue damage and heart inflammation.

Lyme Neuroborreliosis

Synaptojanin isoform X5 and OspC or p23-p25 (afzelii)

The OspC or p23-25 of B. afzelii shares sequences similar to those of the human synaptojanin isoform X5. Both proteins contain the same C-terminal PKKP motif, resulting in the autoimmune response against synaptojanin isoform X5, which is potentially associated with neuroborreliosis.

Several bacteria and viruses recognize gangliosides as receptors. Studies have shown that B. burgdorferi binds to galactocerebroside and adheres to and damages glial cells. The Lyme spirochete may adhere to the surface gangliosides present in neural cells. This may trigger the release of antibodies against gangliosides, resulting in antibody-ganglioside complexes that may deposit on nerves, leading to the symptoms observed in Lyme neuroborreliosis.

Human tryptase and OspC or p23-p25 (afzelii)

The OspC or p23-25 of B. afzelii shares sequence similarities with human tryptase. Both proteins contain the same C-terminal PKKP motif, which results in the autoimmune response against tryptase. Human tryptase is present in mast cells, which have been suggested to play a key role in neuroborreliosis.

Tick Surveys

apoB100

The Lyme spirochete acquires lipid molecules from the host, giving the bacteria a similar lipid composition. Autoantibodies may be released against the host lipoproteins that bind to the bacterial lipids, resulting in an immune response. ApoB100 can be considered an autoantigen of Lyme carditis, as autoantibodies against this lipoprotein are observed in patients with Lyme carditis.

Cardiac Myosin

Research has suggested that the inflammatory response triggered by B. burgdorferi could induce autoantibodies against components of cardiac tissue. We are investigating the presence of autoantibodies against cardiac myosin and other proteins in cardiac tissue to analyze their potential role in tissue damage and heart inflammation.

Conclusion

Through testing multiple antigens from a range of pathogens, the Vibrant Lyme and Co-Infection Microarray Technology has been proven to outperform traditional testing methods like ELISA and blot-based assays in both scope and sensitivity.

Microarray technology optimizes tickborne and co-infection testing without sacrificing accuracy and addresses the inconsistency, lack of reproducibility, and inaccurate results often seen in traditional testing methods.

With such a vast scope of co-infections, testing for Lyme disease and its associated pathogens is critical for accurate diagnosis and determining appropriate treatment for patients. Our diagnostics have undergone multiple rounds of validation to ensure reliability and effectiveness.

This novel microarray technology represents a significant step toward our overarching goal of enhancing tickborne and Lyme testing to deliver the best possible outcomes for patients.

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5. Hari Krishnamurthy, Vasanth Jayaraman, Karthik Krishna et al. A customizable multiplex protein microarray for antibody testing and its application for tick-borne and other infectious diseases. 16 October 2023, PREPRINT (Version 2) available at Research Square [https://doi.org/10.21203/rs.3.rs-3417198/v2]

Regulatory Statement:

The general wellness test intended uses relate to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions. This test has been laboratory developed and its performance characteristics determined by Vibrant America LLC and Vibrant Genomics, a CLIA-certified and CAP-accredited laboratory performing the test. The lab tests referenced have not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

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