VibrantWellness

Tickborne Complete 2.0 Panel

Key Clinical Messages

What is the Tickborne Complete 2.0 Panel?

The Tickborne Complete 2.0 panel is a comprehensive blood test panel that evaluates for the presence of Lyme disease, tickborne relapsing fever, tick-associated co-infections, as well as viral and other opportunistic infections.

The Tickborne Complete 2.0 panel tests all the analytes within the Tickborne 1.0 Complete panel, including comprehensive serology and PCR testing for *Borrelia* family antigens and tickborne relapsing fever and common co-infections from *Babesia*, *Bartonella*, *Ehrlichia*, and *Anaplasma* organisms.

In addition to these analytes, the Tickborne Complete 2.0 panel offers a more extensive exploration of tickborne co-infection exposure, including antigens from *Rickettsia* spp., tickborne encephalitis virus, *Mycoplasma pneumoniae*, and Powassan virus. The Tickborne Complete 2.0 panel also provides a thorough assessment for opportunistic infections, including 24 IgG and IGM antigens from EBV, CMV, West Nile viruses, and more. Lastly, the Tickborne Complete 2.0 panel also includes direct testing of 10 additional analytes with PCR technology.

Why Order the Tickborne Complete 2.0 Panel?

Vibrant America's Tickborne Complete 2.0 panel includes a thorough evaluation for Lyme disease and tick associated co-infections, viruses, and other opportunistic infections that mimic tickborne disease or become symptomatic during infection with infection tickborne disease.

Standard two-tiered testing for Lyme disease has known limitations in detecting early Lyme disease, with sensitivity estimated to be 30-40%.[1]

Standard two-tiered testing also has limitations in disseminated disease, with reported sensitivity varying between 70-100%.1 Furthermore, diverse *Borrelia* and co-infection species in variable geographic regions are often not represented on conventionally available Lyme disease tests.

Due to the sub-optimal sensitivity of conventional testing and diverse species of tickborne illness, many tickborne diseases are diagnosed later in the course of the disease or not diagnosed at all, leaving patients at increased risk of harm.

Vibrant America's Tickborne Complete 2.0 panel utilizes innovative technology, which allows for increased accuracy of testing in early and disseminated Lyme disease, increased reproducibility, and cost-effectiveness of a high number of test analytes within the panel. Through these innovations, the Vibrant Complete 2.0 Test can aid earlier and more comprehensive identification of tickborne illnesses and opportunistic infections.

Which Patients Benefit from This Test?

- Patients with a recent tick bite, fever, flu symptoms, and/or erythema migrans rash.
- Patients who demonstrate musculoskeletal (i.e., migrating joint and or muscle pain), neurological (dizziness, Bell's Palsy, numbness, or tingling, etc.), cardiac, relapsing fever, and/or other Lyme-related symptoms.
- Patients who score high on the Horowitz Multiple Systemic Infectious Disease Syndrome (MSIDS) Questionnaire (available in Vibrant's educational portal).
- Patients who demonstrate symptomatology consistent with tick-related co-infections from *Babesia*, *Bartonella*, *Ehrlichia*, *Anaplasma*, *Rickettsia*, *Mycoplasma pneumoniae*, Powassan virus, and other organisms.
- Patients with symptoms of opportunistic infections such as chronic or reactivated EBV, CMV, Toxoplasma, herpes viruses, or group A strep.
- Patients who have lived in or have traveled to Lyme-endemic regions and have Lyme and/or co-infection-related symptoms.

What Tests Pair Well with the Tickborne Complete 2.0 Panel?

- **Gut Zoomer Test, Candida + IBS Profile** - For aid in diagnosing and treating microbiome dysregulation following antibiotic usage.
- **Wheat Zoomer** – Offers an intestinal permeability panel which can aid in diagnosing leaky gut syndrome that may result from extended antibiotic usage.
- **Mycotoxins Test** – Is it Lyme or mycotoxins, or both? Numerous symptoms overlap between Lyme and Mycotoxin related illnesses. It may be more challenging to resolve tickborne disease when mold and mycotoxin illness is present.
- **Neural Zoomer Plus** – Specific neurological antibodies have been studied to be associated with Lyme diseases, such as Anti-tubulin, Anti-NMDA, Anti-neuron specific enolase, Anti-GM1, anti-dopamine receptor 1, and anti-dopamine receptor 2.
- **Total Immunoglobulins** –Serology testing is based on normal, functional immunoglobulin production. This test assesses the number of immunoglobulins, which is helpful in those with suspected immune function compromise or those undergoing IV IgG therapy.

How Do Patient's Prepare for the Tickborne Complete 2.0 Test?

- **Collection Type:** Available through serum collection or dried blood spot testing.
- **Fasting Required:** No
- **Hydration Restrictions:** None
- **Diet Restrictions:** None
- **Medication Restrictions:** None
- **Dietary Supplement Restrictions:** None

How Were the Tickborne Test Reference Ranges Established?

Reference ranges have been established in adults using a sample cohort comprising 2,000 samples for each antigen tested. The upper 97.5% percentile and upper 99% percentile were calculated for each analyte and set to 10 units and 20 units respectively.

Interpretations - Index values for all analytes are interpreted as follows,

Result	Index Value (units)
Negative	0 - 10
Borderline/Moderate	10.1 - 20
Positive	20.1 - 30

The Vibrant Tickborne Test Algorithm is a helpful resource to aid interpretation of Vibrant Tickborne test results for *Borrelia* infection.

Why Vibrant?

Vibrant Testing Methodology

- **Direct and Indirect Testing:** Vibrant Tickborne Complete 2.0 includes both direct (PCR) and indirect (IgG and IgM) testing for the most comprehensive Lyme and co-infection detection.
- **Enhanced Antibody Testing**
  - **Chemiluminescence Assay:** The chemiluminescence-based assay enables the detection of lower levels of antibodies in comparison to standard ELISA testing.
  - **Immunochip Technology:** Vibrant's Immunochip platform allows for high numbers of test markers yielding comprehensive, cost-effective testing.
  - **Enhanced IgM for Early Detection:** The Tickborne test panels have a novel assay that strips away excess IgG proteins that can interfere with IgM antibody/antigen binding. This technology enhancement improves IgM sensitivity.
  - **Enhanced PCR Testing:** Chip-based multiplex PCR increases sensitivity due to multiple target genes.
    - Enhances sensitivity due to features such as nested amplifications and bead beating for biofilm reduction and to increase organism detection compared to traditional methods.
- **Unparalleled Lyme Disease Test Sensitivity and Specificity**
  - The alternative diagnostic criteria in Vibrant's Tickborne test for Lyme disease yielded 100% sensitivity and 95.2% specificity rates in published research.[2]
    - Vibrant is a leading lab that has completed **all four rounds of CDC sample validation**, including both non-blinded and blinded sample verification.

Vibrant is a CLIA-certified and CAP-accredited lab.

What Markers are Included in the Tickborne Complete 2.0 Panel?

Lyme *Plus* TBRF	Coinfections 1	Coinfections 2	Opportunistic Infections
IgG & IgM	**IgG & IgM**	**IgG & IgM**	**IgG & IgM**
Borrelia burgdorferi VlsE1 *Borrelia burgdorferi* C6 peptide *Borrelia burgdorferi* p18 (DbpB) *Borrelia burgdorferi* p23-25 (OspC) *Borrelia burgdorferi* p28 *Borrelia burgdorferi* p30 *Borrelia burgdorferi* p31 (OspA) *Borrelia burgdorferi* p34 (OspB) *Borrelia burgdorferi* p39 (BmpA) *Borrelia burgdorferi* p41 *Borrelia burgdorferi* p45 *Borrelia burgdorferi* p58 *Borrelia burgdorferi* p66 *Borrelia burgdorferi* p83-93 *Borrelia burgdoferi* B31 WCS *Borrelia burgdoferi* 297 WCS *Borrelia mayonii* *Borrelia afzelii* BmpA *Borrelia afzelii* DbpA *Borrelia afzelii* OspA *Borrelia afzelii* OspC *Borrelia afzelii* p100 *Borrelia garinii* DbpA *Borrelia garinii* OspC *Borrelia bavariensis* DbpA *Borrelia bavariensis* p58 *Borrelia bavariensis* VlsE1 *Borrelia spielmanii* DbpA *Borrelia spielmanii* OspC *Borrelia hermsii* *Borrelia turicatae* *Borrelia miyamotoi* *Borrelia andersonii* *Borrelia maritima* *Borrelia californiensis* *Borrelia bissettiae* *Borrelia lusitaniae* *Borrelia valaisiana* *Borrelia yangtzensis* *Borrelia turcica*	*Babesia microti* IRA *Babesia microti* p32 *Babesia microti* p41 *Babesia microti* WCS *Babesia duncani* *Bartonella henselae* 17 kDa *Bartonella henselae* 26 kDa *Bartonella henselae* SucB *Bartonella elizabethae* *Bartonella vinsonii* *Bartonella quintana* *Anaplasma phagocytophilum* Msp5 *Anaplasma phagocytophilum* Msp2 (p44) *Anaplasma phagocytophilum* OmpA *Ehrlichia chaffeensis*	Coxsackie Virus Powassan Virus Tickborne Encephalitis Virus West Nile Virus *Chlamydophila pneumoniae* *Mycoplasma pneumoniae* *Rickettsia typhi* OmpB *Rickettsia typhi* Surface antigen	Cytomegalovirus EIA Antigen Cytomegalovirus GlyB Cytomegalovirus p150 Cytomegalovirus p28 Cytomegalovirus p52 Cytomegalovirus p65 Cytomegalovirus p38 Epstein Barr Virus EA Antigen Epstein Barr Virus EBNA1 Epstein Barr Virus VCA gp125 Epstein Barr Virus p18 Epstein Barr Virus p23 Parvovirus B19 VLP VP2 Parvovirus B19 VLP VP1/Vp2 Co Capsid *Toxoplasma gondii Crude Extract* *Toxoplasma gondii MIC3* *Toxoplasma gondii p24* *Toxoplasma gondii p29* *Toxoplasma gondii p30* HSV-1 HSV-2 HHV-6 HHV-7 *Streptococcal A*
PCR	**PCR**	**PCR**	**PCR**
Borrelia andersonii *Borrelia maritima* *Borrelia californiensis* *Borrelia bissettiae* *Borrelia lusitaniae* *Borrelia valaisiana* *Borrelia yangtzensis* *Borrelia turcica* *Borrelia burgdorferi* *Borrelia mayonii* *Borrelia afzelii* *Borrelia garinii* *Borrelia bavariensis* *Borrelia spielmanii* *Borrelia hermsii* *Borrelia turicatae* *Borrelia lonestari* *Borrelia miyamotoi*	*Babesia microti* *Babesia duncani* *Bartonella henselae* *Bartonella elizabethae* *Bartonella vinsonii* *Bartonella quintana* HGA: *Anaplasma phagocytophilum* HME: *Ehrlichia chaffeensis*	Coxsackie virus Powassan virus Tickborne Encephalitis Virus West Nile Virus *Chlamydophila pneumoniae* *Mycoplasma pneumoniae* *Rickettsia rickettsii* *Rickettsia typhi*	Parvovirus B19 Toxoplasma gondii

References

1. Moore A, Nelson C, Molins C, Mead P, Schriefer M. Current Guidelines, Common Clinical Pitfalls, and Future Directions for Laboratory Diagnosis of Lyme Disease, United States. Emerg Infect Dis. 2016;22(7):1169-1177. doi:10.3201/eid2207.151694
2. Jayaraman, V., Krishna, K., Yang, Y. et al. An ultra-high-density protein microarray for high throughput single-tier serological detection of Lyme disease. *Sci Rep* **10**, 18085 (2020). https://doi.org/10.1038/s41598-020-75036-2

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