

TICKBORNE DISEASE



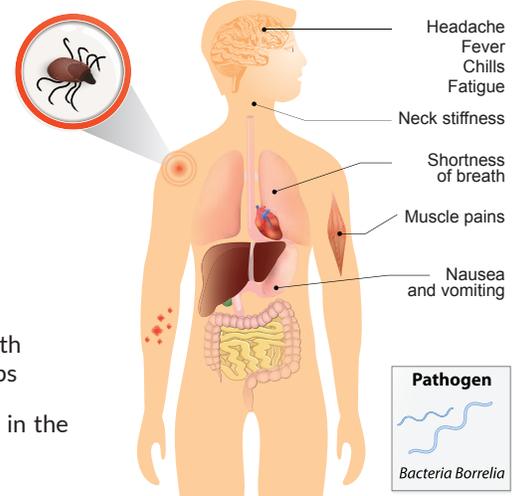
Which Patients Should be Tested for Tickborne Diseases?

Tickborne diseases can be acquired throughout the United States from a variety of ticks, which carry and pass on different microorganisms to humans and animals. Symptoms may be generic and have overlap with other conditions, and therefore, be difficult to associate with a tickborne disease.

Symptoms Associated with Tickborne Diseases Include:

- ❑ Fever and/or chills
- ❑ Headache
- ❑ Bell's palsy
- ❑ Neck stiffness
- ❑ Fatigue
- ❑ Muscle or joint aches/pains
- ❑ GI symptoms: nausea, vomiting, diarrhea
- ❑ Change in cognitive or psychological status
- ❑ Loss of appetite
- ❑ Weight loss
- ❑ Anemia
- ❑ Enlarged, tender lymph nodes
- ❑ Rash
- ❑ Painful abdomen
- ❑ Dizziness or shortness of breath
- ❑ Numbness or weakness in limbs

Tickborne disease symptoms and disease progression can also often be more severe in the elderly and immunocompromised.



Facts About Tickborne Diseases

- ✓ Tickborne diseases have more than doubled in **13 years** and are **77%** of all vector-borne disease reports
- ✓ The most common tickborne diseases (TBDs) in the United States are **Anaplasmosis, Babesiosis, Bartonella infections, Ehrlichiosis, Rickettsiosis, Rocky Mountain spotted fever (RMSF), and Lyme disease**
- ✓ Lyme disease accounts for the **majority (82%)** of all tickborne disease cases
- ✓ From 2004 to 2016, tickborne diseases have risen dramatically:
 - ✓ Anaplasmosis and ehrlichiosis: **5750 cases in 2016, up from 875 in 2004**
 - ✓ Rocky Mountain Spotted Fever: **4269, up from 1713 in 2004**
 - ✓ Babesiosis: **1910, up from 1128 in 2011 (tracking started for the disease in 2011)**
- ✓ Ticks usually need between **24 and 72 hours** to effectively transmit any diseases they are carrying and if found in time on the host, can be removed before they transmit infectious microorganisms to the host

Because many symptoms of tickborne diseases are generic or mimic other conditions, these diseases often go undiagnosed for months, increasing the suffering and disease progression of the patient.



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Clinical Connections to Tickborne Diseases

- Recent research has revealed that the standard two-tier testing recommended by the CDC can lead to false positive or false negative results. Recent studies, in fact, report that the ELISA and Western blot tests can miss up to 60% of well-defined Lyme disease cases.¹ Diagnosis is made even more challenging by the fact that Lyme disease symptoms closely resemble other diseases.
- The Vibrant ImmunoChip** is made from recombinant proteins of several species of *Borrelia burgdorferi*, and not just from B31 used by other Western blot tests.
- The Vibrant **Tickborne Diseases panel** is the first of its kind to be run on a **silicon micro-array platform using chemiluminescence detection** that provides improved sensitivity & specificity.
- Patients often present with a range of non-specific symptoms that may be Lyme, or other conditions that have symptom overlap. Patients with diagnosed Lyme may also experience resurgence of symptoms, which might suggest co-infections. Co-infections are complex and should be included in an initial screen of Lyme and related illnesses.
- Vibrant has the most comprehensive **antibody (indirect)** and **DNA (direct)** test for detection of **Lyme and co-infections**.
- Because standard treatment for tickborne diseases usually involves courses of antibiotics that are prolonged, this can also leave the patient at risk for multiple chronic inflammatory symptoms or conditions due to impact to the microbiome. It is recommended that patients being treated for tickborne diseases undergo regular microbiome screening during antibiotic therapy, such as the **Vibrant Gut Zoomer** or **Vibrant Gut Pathogens tests**.
- The Vibrant Tickborne Diseases panel provides the **earliest identification between different tickborne disease**.



What Does the Vibrant Tickborne Diseases Panel Include?

Vibrant's Tickborne Diseases panel includes two tests:

- Protein microarray antigen and PCR detection of Lyme disease and TBRF
- Protein microarray antigen and PCR detection of co-infections of tickborne diseases (*Anaplasma*, *Babesia*, *Borellia*, *Bartonella*, *Ehrlichia* and *Rickettsia* species)

Lyme + TBRF

Lyme ImmunoChip IgM

Borrelia burgdorferi VlsE1 IgM
Borrelia burgdorferi C6 peptide IgM
Borrelia burgdorferi spp. 18 kDa IgM
Borrelia burgdorferi spp. 23-25 kDa IgM
Borrelia burgdorferi spp. 28 kDa IgM
Borrelia burgdorferi spp. 30 kDa IgM
Borrelia burgdorferi spp. 31 kDa IgM
Borrelia burgdorferi spp. 34 kDa IgM
Borrelia burgdorferi spp. 39 kDa IgM
Borrelia burgdorferi spp. 41 kDa IgM
Borrelia burgdorferi spp. 45 kDa IgM
Borrelia burgdorferi spp. 58 kDa IgM
Borrelia burgdorferi spp. 66 kDa IgM
Borrelia burgdorferi spp. 83-93 kDa IgM

Lyme ImmunoChip IgG

Borrelia burgdorferi VlsE1 IgG
Borrelia burgdorferi C6 peptide IgG
Borrelia burgdorferi spp. 18 kDa IgG
Borrelia burgdorferi spp. 23-25 kDa IgG
Borrelia burgdorferi spp. 28 kDa IgG
Borrelia burgdorferi spp. 30 kDa IgG
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Borrelia burgdorferi spp. 41 kDa IgG
Borrelia burgdorferi spp. 45 kDa IgG
Borrelia burgdorferi spp. 58 kDa IgG
Borrelia burgdorferi spp. 66 kDa IgG
Borrelia burgdorferi spp. 83-93 kDa IgG

Lyme PCR

Borrelia burgdorferi spp.
Borrelia afzelii
Borrelia garinii

TBRF ImmunoChip IgM

Borrelia miyamotoi IgM
Borrelia hermsii IgM
Borrelia turicatae IgM

TBRF ImmunoChip IgG

Borrelia miyamotoi IgG
Borrelia hermsii IgG
Borrelia turicatae IgG

TBRF PCR

Borrelia TBRF spp.
Borrelia lonestari
Borrelia miyamotoi

Coinfections

Babesia ImmunoChip IgM

Babesia microti IRA IgM
Babesia microti p32 IgM
Babesia microti p41 IgM

Babesia ImmunoChip IgG

Babesia microti IRA IgG
Babesia microti p32 IgG
Babesia microti p41 IgG

Babesia PCR

Babesia microti
Babesia duncani

Bartonella ImmunoChip IgM

Bartonella henselae 17 kDa IgM
Bartonella henselae 26 kDa IgM
Bartonella henselae SucB IgM

Bartonella ImmunoChip IgG

Bartonella henselae 17 kDa IgG
Bartonella henselae 26 kDa IgG
Bartonella henselae SucB IgG

Bartonella PCR

Bartonella spp.

HGA ImmunoChip IgM

Anaplasma phagocytophilum Msp5 IgM
Anaplasma phagocytophilum p44 IgM
Anaplasma phagocytophilum Msp5 IgG
Anaplasma phagocytophilum p44 IgG

HME and HGA PCR

Anaplasma phagocytophilum
Ehrlichia chaffeensis
Ehrlichia ewingii

Chlamydomphila pneumoniae

Chlamydomphila pneumoniae IgM
Chlamydomphila pneumoniae IgG

Chlamydomphila pneumoniae

Chlamydomphila pneumoniae

Mycoplasma PCR

Mycoplasma spp.

RMSF PCR

Rickettsia rickettsii

Tularemia PCR

Francisella spp.

Reference:

1. Molins CR, Ashton LV, Wormser GP, Hess AM, Delorey MJ, Mahapatra S, Schriefer ME, Belisle JT. *Development of a Metabolic Biosignature for Detection of Early Lyme Disease*. Clin Infect Dis. 2015 Mar 11.

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. CLIA and CAP certified laboratory performing the test. The test has 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.