IGeneX Inc.

Better Outcomes Through Better Testing

IGeneX is a leading testing lab for Lyme Disease, Tick-Borne Relapsing Fever, Babesiosis, Bartonellosis, Rickettsiosis, and other diseases.

igenex.com

Contact IGeneX today to learn more
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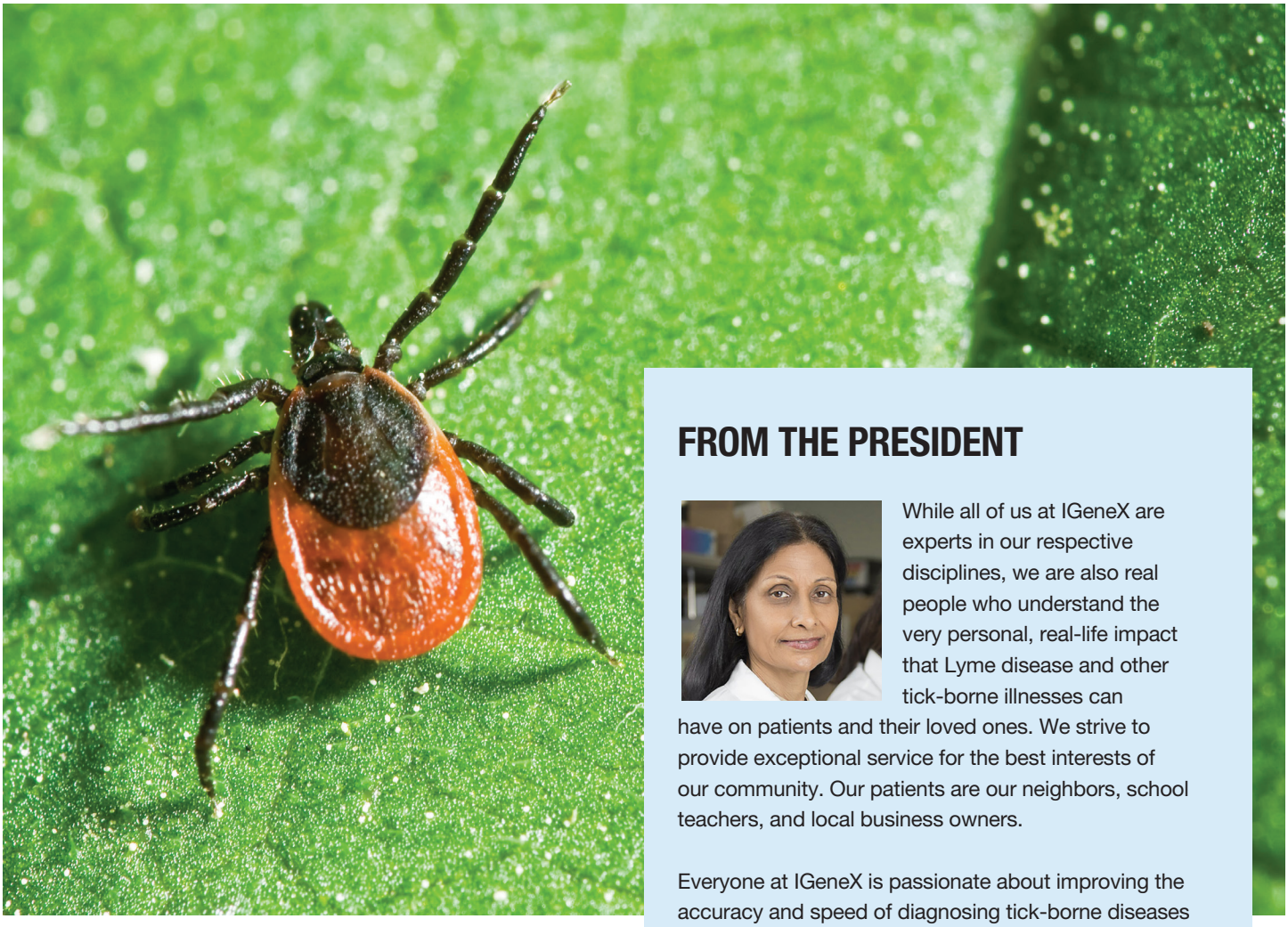


HELPING PATIENTS DIAGNOSE TICK-BORNE ILLNESSES FOR OVER 30 YEARS

For over 30 years, IGeneX has been the global leader in the research and development of tests that accurately detect Lyme disease, Tick-Borne Relapsing Fever, and other tick-borne diseases. Tick-borne illnesses can affect every aspect of life, and without effective diagnosis and treatment, symptoms can often worsen and progress into severe and even life-threatening health issues. And when a patient can't find the cause or a way to get better, their quality of life suffers. At IGeneX, we make it our singular mission to offer best-in-class testing for tick-borne diseases that delivers the most comprehensive and accurate results possible, so patients can find the right treatment path to restore their health and get back to enjoying their lives.

FROM THE PRESIDENT

While all of us at IGeneX are experts in our respective disciplines, we are also real people who understand the very personal, real-life impact that Lyme disease and other tick-borne illnesses can have on patients and their loved ones. We strive to provide exceptional service for the best interests of our community. Our patients are our neighbors, school teachers, and local business owners.

Everyone at IGeneX is passionate about improving the accuracy and speed of diagnosing tick-borne diseases with more precise and advanced testing options, and by training physicians to better understand tick-borne diseases and become literate in all aspects of tick-borne illnesses.

We are now in our fourth decade as a company, and IGeneX is uniquely positioned to remain a leader in the industry. The Lyme IgG ImmunoBlot has recently received clearance from the FDA, marking a major milestone for this technology. Our Broad Coverage Assays bring a new level of affordability and accessibility to IGeneX testing. And recently, after many years of research and development, we introduced culture testing with our new cePCR™ test. Culture testing is the gold standard in testing for tick-borne diseases.

Thanks for giving us an opportunity to serve you, and helping make IGeneX the place to go for quality tick-borne disease testing.

Dr. Jyotsna Shah, PhD
President & Laboratory Director
IGeneX, Inc.

CONTENTS

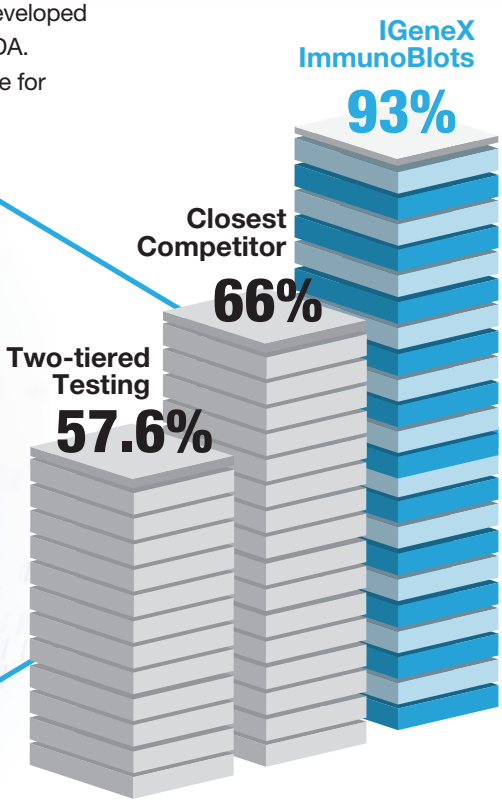
Note: Not all tests are approved in New York state.
Please see the latest IGeneX test requisition form for tests that are approved.

LYME IMMUNOBLOT **GETS** FDA CLEARANCE

The Lyme disease IgG ImmunoBlot test currently offered at IGeneX as a laboratory-developed test (LDT) has been converted to a test kit. This kit has received clearance from the FDA. Having FDA clearance further validates the Lyme IgG ImmunoBlot as a superior choice for detecting Lyme disease.

ADVANTAGES OF THE **IGENEX IMMUNOBLOT**

- ✓ 93% sensitive for Lyme disease
- ✓ Detects early, active, and late-stage disease
- ✓ Clear, precise, and easy to interpret

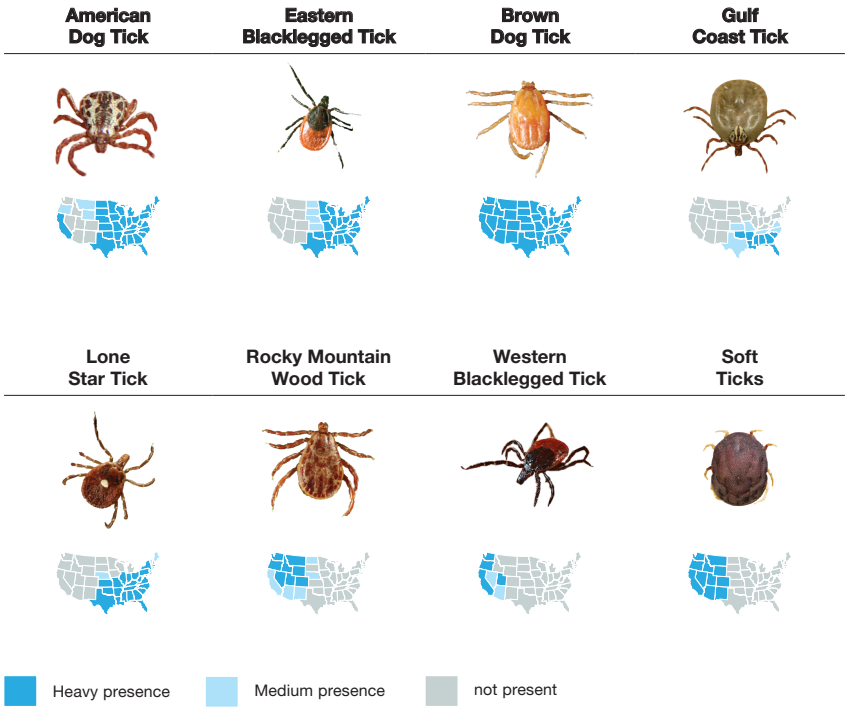


Sources
The Accuracy of Diagnostic Tests for Lyme Disease in Humans (Waddell et al., 2016)
An Ultra-High-Density Protein Microarray for High Throughput Single-Tier Serological Detection of Lyme Disease (Jayaraman et al., 2020)
Pilot Study of Immunoblots with Recombinant Borrelia burgdorferi Antigens for Laboratory Diagnosis of Lyme Disease (Liu et al., 2018)

WHY TEST FOR **TICK-BORNE DISEASES?**

TICKS ARE SPREADING

Ticks are not confined to the Northeast and Upper Midwest. As climate change causes warmer global temperatures, tick endemicity is expanding, making the risk of contracting a tick-borne disease even greater. Ticks have been reported in rural and urban environments, but are most often found in grassy or wooded areas and are typically most active from spring through fall. Ticks come in many different varieties that not only look different, but also can transmit different types of diseases to both people and animals.



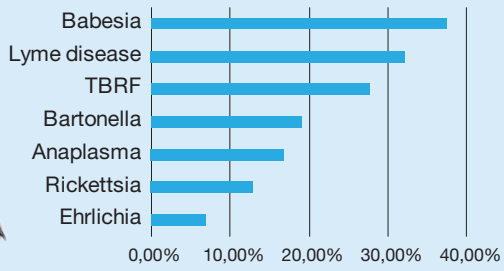
IT'S MORE THAN JUST LYME DISEASE

Lyme disease is the most widespread and well known tick-borne disease, infecting roughly 500,000 people per year. However, other TBDs, commonly referred to as co-infections, are spreading as well. One such co-infection, called Babesia, is transmitted by the same blacklegged ticks as Lyme, and might actually be more widespread than Lyme.

An IGeneX study of 10,000 patients revealed that 37.3% were positive for Babesia, and 32.1% for Lyme disease. But because Lyme is more widely reported than Babesia, and Lyme figures include TBRF (both diseases are caused by *Borrelia)*, Lyme is generally considered more widespread than Babesia.

PETS CAN PASS ALONG TICK-BORNE DISEASES

A large percentage of homeowners own at least one dog or cat. But these cuddly creatures are not so cute if they transmit tick-borne diseases. Dogs may contract a TBD through contact with lice, ticks, mites, and fleas. They can pass it to humans directly through a bite, but usually it's by shedding the disease-carrying ticks throughout the house. Cats can pass on disease directly through a scratch, commonly called Cat Scratch Disease.



Source: 2024 IGeneX study of 10,000 patients from various states.

CURRENT TESTING IS TOO INSENSITIVE, LEADING TO A LIFETIME OF PAIN AND SUFFERING FOR MANY PATIENTS

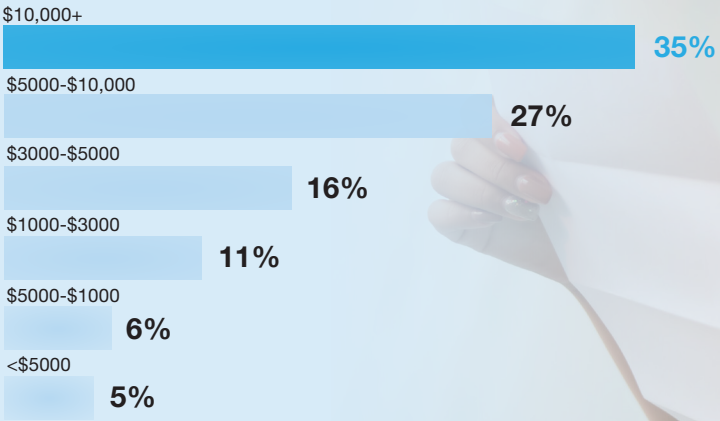
LYME TESTS ARE A COIN FLIP

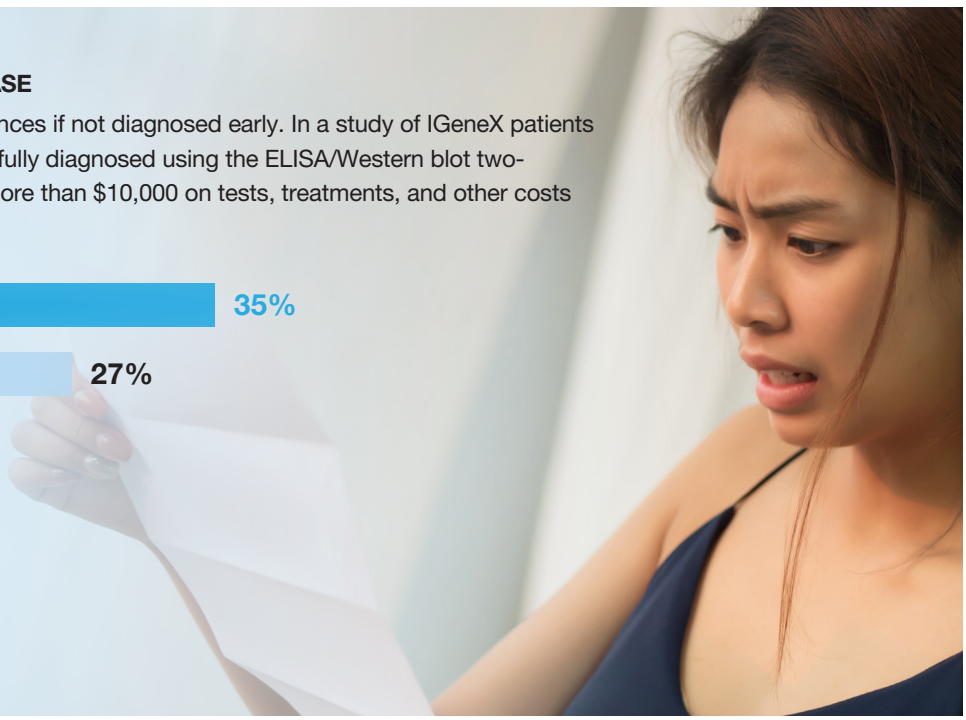
Common Lyme two-tier testing, consisting of an ELISA then Western blot, has a sensitivity just above 50% because they detect only one Borrelia species, *B. burgdorferi B31*.

In no other testing, from cancer to HIV, would this be acceptable.

STAGGERING COST OF LYME DISEASE

Patients risk serious financial consequences if not diagnosed early. In a study of IGeneX patients from 2022- 2024, 76% were unsuccessfully diagnosed using the ELISA/Western blot two-step protocol. In addition, 35% spent more than $10,000 on tests, treatments, and other costs associated with their disease.





TICK-BORNE DISEASE SYMPTOMS OFTEN OVERLAP

Tick-borne diseases are challenging to diagnose because of the wide range of non-specific symptoms they can present. This makes testing important.

LYME DISEASE

Lyme disease is the most well-known tick-borne illness and one of the fastest growing infectious diseases in the United States, infecting 500,000 people annually.

EARLY STAGE

- Gradual onset of initial (viral-like) symptoms-making it difficult to pinpoint when the infection began
- Fever, chills, headache, fatigue, muscle and joint aches, and swollen lymph nodes
- Slow response to treatment, with an initial symptom flare ("Herxheimer-like reaction")
- Erythema migrans (EM) rash in 25% to 50% of cases
- Expands gradually over a period of days
- Takes on "bull's-eye" appearance
- May feel warm to the touch but is rarely painful
- May appear on any area of the body

LATE STAGE

- Severe headaches and neck stiffness ("Lyme shrug").
- Migratory: first a knee will hurt, then an elbow or shoulder, and later headaches.
- Bell's palsy (loss of muscle tone or droop on one or both sides of the face)
- Irregular heart beat (Lyme Carditis)
- Episodes of dizziness or shortness of breath
- Inflammation of the brain (Encephalitis) and spinal cord
- Problems with short-term memory
- Afternoon fevers and tiredness

BABESIOSIS

Babesiosis is transmitted to humans through the bite of an infected tick, but unlike other tick-borne diseases, it is caused by microscopic parasites that infect red blood cells. This makes it similar to malaria.

- Rapid onset of high fever, severe headaches, sweats and fatigue, thus it is easy to know when infection began.
- Headaches can be severe - dull, global (described like the head is in a vise)
- Air hunger, need to sigh and take a deep breath; dry cough without apparent reason
- Fatigue is prominent, does not clear with rest, and is made worse with exercise
- Mental dullness and slowing of reactions
- Dizziness - more like a tippy feeling, and not vertigo or purely orthostasis
- Symptoms cycle rapidly, with flares every four to six days
- Hypercoagulation is often associated with Babesia infections
- Makes Lyme symptoms worse and Lyme treatments less effective
- Babesia parasites infect red blood cells, and can cause hemolytic anemia (from the destruction of red blood cells)
- Babesiosis can be a severe, life-threatening disease, particularly in people who:
  - Do not have a spleen
  - Have a weak immune system for other reasons (such as cancer, lymphoma, or AIDS)
  - Have other serious health conditions (such as liver or kidney disease) or are elderly

BARTONELLOSIS

Bartonellosis is primarily associated with fleas, lice, and ticks. Several species of Bartonella cause serious diseases in humans, such as Cat scratch disease (CSD), endocarditis, trench fever, and Carrion's disease.

- Gradual onset of initial illness
- Central Nervous System (CNS) symptoms are out of proportion to the musculoskeletal ones
- Signs of CNS irritability can include muscle twitches, tremors, insomnia, seizures, agitation, anxiety, severe mood swings, outbursts and antisocial behavior
- GI involvement may present as gastritis or abdominal pain (mesenteric adenitis)
- May have papular or linear red rashes (like stretch marks that do not always follow skin planes), especially in those with GI involvement
- Sore soles, especially in the morning
- Tender sub-cutaneous nodules along the extremities, especially outer thigh, shins, and triceps
- Occasional lymphadenopathy
- Morning fevers, usually around 99 degrees; occasionally light sweats are noted.
- Elevated vascular endothelial growth factor (VEGF) occurs in a minority, but the degree of elevation correlates with activity of the infection and may be used to monitor treatment
- Rapid response to treatment changes - often symptoms improve within days after antibiotics are begun, but relapses occur also within days if medication is withdrawn early

TICK-BORNE RELAPSING FEVER (TBRF)

It looks like Lyme, behaves like Lyme, but it's not Lyme. Is it TBRF? Some of the Borrelia that cause TBRF are transmitted by the same ticks that transmit *B. burgdorferi*, the causative agent of Lyme disease.

- Recurring bouts of fever, each lasting about 3 days. The fever then goes away for about 1 week before returning.
- Very high fever (up to 106.7°F) is possible, making patients delirious, agitated, tachycardic and tachypneic
- Drenching sweats and a rapid decrease in body temperature with patients may become transiently hypotensive
- Headaches, muscle pain, joint pain, chills, vomiting, and abdominal pain
- Presence greater among pregnant women
- In more extreme cases, TBRF can cause death, especially in childbearing mothers and neonatal infants

RICKETTSIOSIS

Rickettsiosis is classified by two main biogroups: the spotted fever group and the typhus group. The most serious and commonly reported spotted fever group in the United States is Rocky Mountain spotted fever (RMSF).

- A dark scab at the site of tick bite, known as an eschar
- Fever, headache, rash, muscle aches, exhaustion
- Nausea, vomiting and a hacking cough may also develop
- Abdominal pain
- Inflammation of the airways (pneumonitis) and pneumonia
- Heart damage
- Anemia
- Severe low blood pressure

EHRLICHIOSIS / ANAPLASMOSIS

Ehrlichiosis and Anaplasmosis are caused by intracellular bacteria belonging to the family *Anaplasmataceae*. In general, Anaplasmosis leads to milder disease than Ehrlichiosis.

- Symptoms begin about 12 days after a tick bite
- Fever, chills, muscle aches, weakness, nausea and/or vomiting, cough, and malaise
- A rash may develop on the torso, arms, and legs with Ehrlichiosis, but is uncommon in people with Anaplasmosis
- Headaches are sharp, knife-like, and often behind the eyes
- Muscle pain, not joint pain, mild or severe
- Low WBC, low platelet count, and elevated liver enzymes
- Rarely see diffuse vasculitic rash, including palms and soles
- Symptoms of both infections are more severe in people with a weakened immune system
- May cause blood clotting, failure of several organs, seizures, and coma

Progression of Tick-Borne Disease Testing at IGeneX

APPLYING MODERN-DAY TECHNOLOGY
TO COMPLEX INFECTIOUS DISEASES FOR OVER 30 YEARS

LYME DISEASE

1975

Lyme disease, the most widespread tick-borne disease, first reported in the town of Old Lyme, CT.

1982-1990

The CDC recognizes Lyme disease from a set of clinical symptoms, as the first-generation tests often lacked accuracy.

1991

IGeneX is founded.

RICKETTSIOSIS

2006

Lyme IFA screen test launched by IGeneX.

2007

IGeneX introduces the following tests: Epitope test to improve specificity of the Lyme Western blot, *Rickettsia* PCR, *Babesia duncani* IFA.

2010

IGeneX introduces the following tests: CD57, *Bartonella* FISH.

2012

C. pneumoniae ELISA test launched by IGeneX.

TBRF

2016

TBRF Multi-Species Western blot test launched by IGeneX.

2017

IGeneX introduces the following tests: Multi-Species Lyme ImmunoBlot IgM/IgG tests, which are inclusive of multiple strains of *Borrelia: B. burgdorferi B31, B. burgdorferi 297, B. californiensis, B. mayonii, B. afzelii, B. garinii, B. spielmanii,* and *B. valaisiana;* Multi-Species TBRF ImmunoBlot IgM/IgG tests, which are inclusive of multiple strains of *Borrelia: B. hermsii, B. miyamotoi,* and *B. turicatae;* Lyme IgXSpot tests.

2019

IGeneX introduces multi-species serological tests with high sensitivity and specificity at an affordable price: Broad Coverage Lyme Ab Assay, Broad Coverage TBRF Ab Assay.

1994

Two-tier testing protocol of ELISA/Western Blot established by the CDC. IGeneX introduces Lyme Serology IgG/IgM and Western blot tests.

BABESIOSIS

1996

Babesia microti IFA test launched by IGeneX.

EHRLICHIOSIS & ANAPLASMOSIS

1997

IGeneX releases an improved Western blot made with two strains of Borrelia: *B. burgdorferi B31* and *B. burgdorferi 297*. (The standard Western blot is made with only *B. burgdorferi B31*.) IGeneX introduces Ehrlichia IFA and Anaplasma IFA tests.

1998

IGeneX introduces the following tests: Lyme Multiplex PCR, *Babesia* PCR, *Babesia* FISH.

2001

IGeneX introduces the following tests: *Ehrlichia* PCR, *Anaplasma* PCR, LDA tests.

BARTONELLOSIS

2002

IGeneX introduces the following tests: *Bartonella henselae* PCR, *Bartonella henselae* IFA.

2021

IGeneX introduces Bartonella Multi-Species ImmunoBlots that detect *Bartonella spp.* and four species: *B. henselae, B. elizabethae, B. vinsonii,* and *B. quintana*

2023

IGeneX introduces the following tests: *Babesia* Multi-Species ImmunoBlots, Culture Enhanced PCR (cePCR), Lyme Screen Immunoassay IgM/IgG

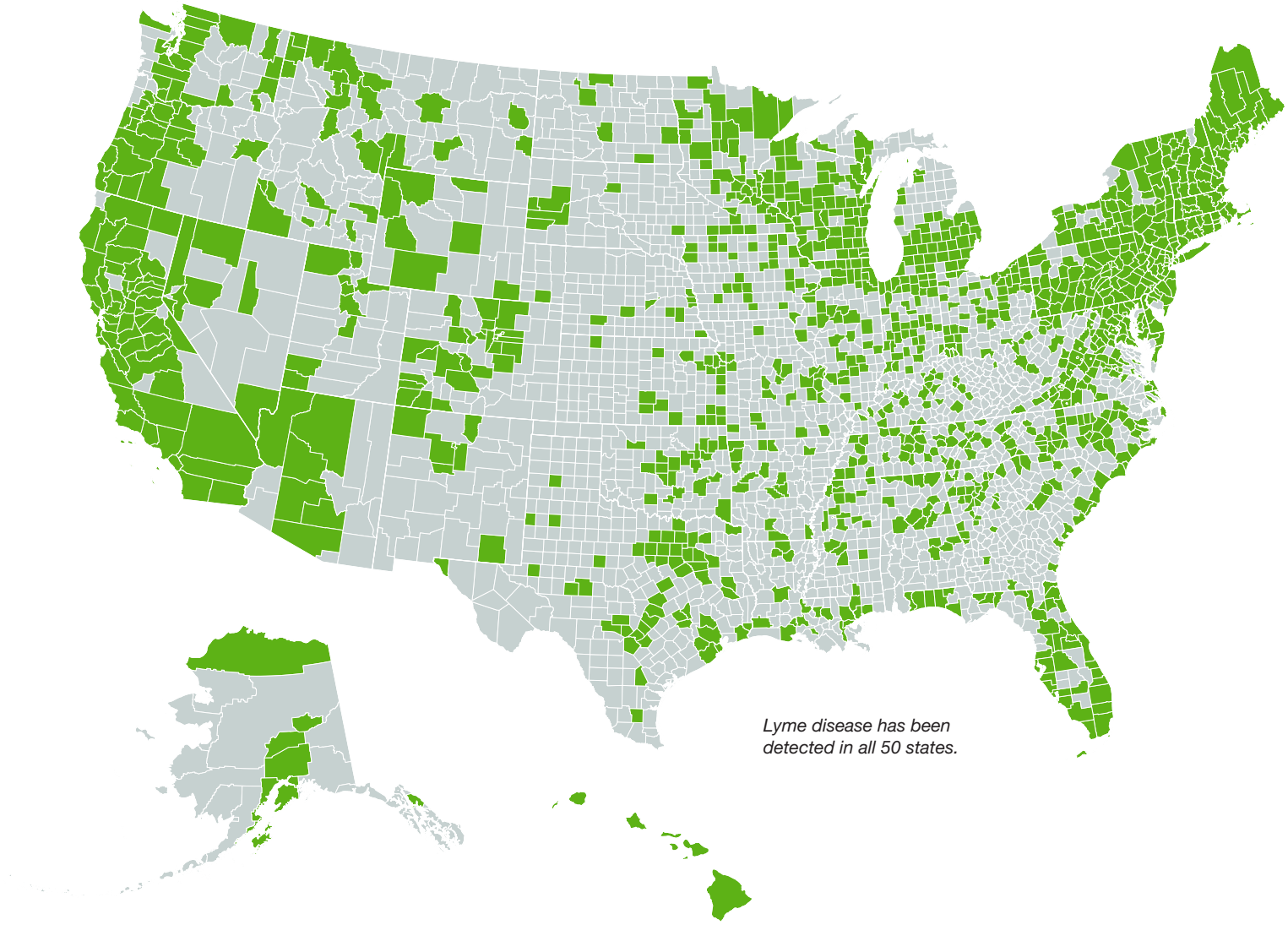
2025

FDA clearance: The Lyme disease IgG ImmunoBlot test currently offered at IGeneX has been converted to a test kit. This kit has received clearance from the FDA.

LYME DISEASE

Lyme disease is the most well-known tick-borne illness and one of the fastest growing infectious diseases in the United States. According to the Centers for Disease Control and Prevention (CDC), around 500,000 people are diagnosed with Lyme disease annually in the US, although the number is thought to be much higher. It is caused by Lyme *Borreliae* bacteria carried by ticks.

Generally, Lyme disease is diagnosed by a two-tiered testing approach involving an ELISA followed by a Western blot test. Unfortunately, the sensitivity of these commercially available tests is poor. IGeneX has developed several Lyme tests that provide higher sensitivity to detect and speciate more *Borreliae*. When used in conjunction with clinical symptoms and patient history, these tests can better assist physicians in accurately diagnosing patients.



Lyme disease has been detected in all 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR LYME DISEASE	
✓ Multi-Species ImmunoBlots	✓ LSA
✓ PCR	✓ Serology (screen)
✓ Broad Coverage Assay	✓ cePCR
✓ IgXSpot	

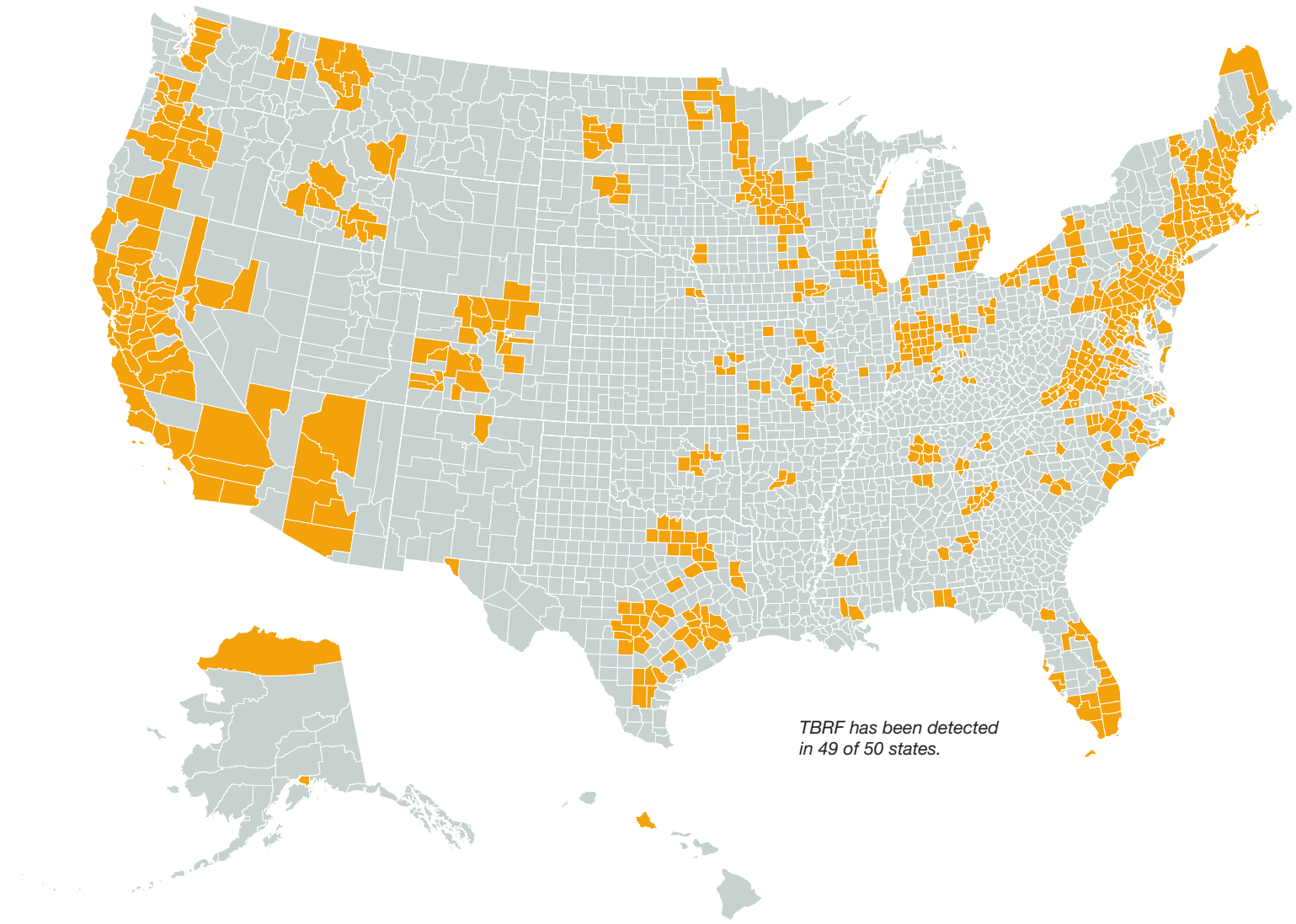
TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
LYME MULTI-SPECIES IMMUNOBLOTS (IGM/IGG)			
#325 Lyme ImmunoBlot IgM **#335** Lyme ImmunoBlot IgG	The IgM and IgG ImmunoBlots (IB) are qualitative immunoassays in which antibodies are visualized. They are used to determine whether pathogen-specific antibodies are present in patient serum or plasma. These tests are generally more sensitive and specific than the Western blot, ELISA and IFA tests. **Principle** IB strips are prepared from recombinant proteins of interest. The recombinant proteins are applied to a membrane and cut into strips. **Immunoblotting** Patient serum or plasma is incubated with the IB strip. If specific antibodies to pathogen antigens are present, they will bind to the corresponding antigen bands. After washing off the unbound serum, the strip is incubated with alkaline phosphate-conjugated goat anti-human antibody. Bound antibodies react with BCIP/NBT, a chromogenic substrate. A dark purple precipitate develops on the antigen-antibody complexes. Bands are visualized and scored for intensities relative to the controls.	**IgM (IGeneX Criteria)** **Positive**: If two or more of the following bands are present: 23, 31, 34, 39 and 41 kDa. **Negative**: Any other profile. **IgM (CDC Criteria)** **Positive**: If two or more of the following bands are present: 23, 39 and 41kDa. **Negative**: Any other profile. **IgG (IGeneX Criteria)** **Positive:** If two or more of the following bands are present: 23, 31, 34, 39, 41 and 93 kDa. **Negative:** Any other profile. **IgG (CDC Criteria)** **Positive:** If five or more of the following bands are present: 18, 23, 28, 30, 39, 41, 45, 58, 66, and 93kDa. **Negative:** Any other profile. **Limitation:** Bands 31 and 34 kDa are present in Lyme vaccinated patients. Viral antibodies may cross react with the 93 kDa antigen.	Improved sensitivity because it includes Lyme *Borreliae*-specific antigens from multiple strains and species. Improved specificity because pure proteins are sprayed at specific positions on the blot. Superior at all stages of Lyme disease. ImmunoBlots can be positive whereas ELISA and IFA tests can be negative at early and late stages when antibody levels are very low. No need for a reflex test or confirmatory epitope test.
LYME IGXSPOT			
#300 Lyme IgXSpot	The IgXSpot is an enzyme-linked immunospot assay that detects human T-cells reactive to *Borrelia*/pathogen-specific antigens invitro. It is well documented that both humoral and cellular immune responses develop in *Borrelia*/pathogen infection. The cellular immune response develops much earlier than humoral response in most patients who are infected with *Borrelia* species. In some patients, sero-conversion from cellular to humoral response does not occur or occurs much later in the disease. In some patients with a chronic form of the disease, the humoral response is poor. Therefore, the IgXSpot test is recommended for detection of very early and/or late *Borrelia*/pathogen infection and in seronegative patient's whole blood samples. **Principle** ELISPOT is a widely used method for detecting and monitoring cellular immune responses to specific antigens. The IgXSpot assay allows visualization of the secretory product(s) of individual activated or responding cells to *Borrelia*-specific antigens. Each spot that develops in the assay represents a single reactive cell.	**Positive:** > or = 3 SFU **Negative:** < or = 2 SFU **Sample Viability cut-off:** > 70% **SFU:** Spot Forming Unit Represents a reactive cell to *B. burgdorferi* antigen(s).	Detects specific T-cell responses soon after infection, when antibodies are not detectable, or late in the disease when the levels of antibodies are low. When combined with Lyme ImmunoBlot tests, provides information on the full spectrum of a patient's immune response to infection and stage of disease. Enables doctors to monitor disease progression and treatment. Especially useful for seronegative patients. They can be diagnosed with a *Borrelia* infection without antibody (IgM/IgG) production.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
LYME MULTIPLEX PCR			
#453 Lyme Multiplex PCR: Serum **#456** Lyme Multiplex PCR: Whole Blood **#450** Lyme Multiplex PCR: Urine **#455** Lyme Multiplex PCR: Urine (Pooled) **#459** Lyme Multiplex PCR: CSF **#462** Lyme Multiplex PCR: Miscellaneous	The Lyme Multiplex PCR test detects *Borrelia burgdorferi* specific DNA sequences from Osp A plasmid and flagellin genomic genes. **Principle** The multiplex PCR-based diagnostic test is performed directly on the clinical specimen in a three-step assay. The steps are as follows: **Selection hybridization:** Specifically removes the "common PCR inhibitors" from the clinical sample while simultaneously selecting and purifying the DNA fragment of interest. This procedure also concentrates the fragment of interest, thereby improving sensitivity. **PCR amplification:** The purified pathogen DNA fragment of interest is PCR-amplified with pathogen-specific primers. This sequence "hybridizes" or binds specifically to pathogen DNA of interest under predetermined PCR conditions. Therefore, only pathogen-specific DNA is amplified. **Detection of amplified products:** The PCR-amplified products are transferred and bound to a nitrocellulose membrane. They are then hybridized with pathogen-specific probes. Only samples that have pathogen-specific DNA hybridize to the probes and give a blue-purple color dot on the membrane.	**Genomic** **Positive:** *B. burgdorferi* DNA detected. **Negative:** *B. burgdorferi* DNA not detected in the sample analyzed. **Plasmid** **Positive:** *B. burgdorferi* DNA detected. **Negative:** *B. burgdorferi* DNA not detected in the sample analyzed. Sample is considered positive if either genomic or plasmid is positive.	Facilitates earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Therefore, PCRs are useful for seronegative patients as well. The assay can be performed on any type of sample: whole blood, serum, urine, tissue, breast milk, cerebral spinal fluid, synovial fluid, and ticks. PCRs are detecting the DNA of the bacteria itself. Therefore, a positive result is definitive. Detects DNA to other Lyme *Borreliae*: *B. afzelii*, *B. andersonii*, *B. garinii, B. mayonii,* and more.
BROAD COVERAGE LYME AB ASSAY			
#601 Broad Coverage Lyme Ab Assay	The Lyme Broad Coverage Antibody (BCA) Assay is a qualitative test designed to detect IgM and IgG antibodies to Lyme *Borreliae* group-specific antigens in human serum. The sensitivity of the Lyme BCA Assay is 90%, and the specificity is 97%. **Principle** The test detects IgM and IgG antibodies to the Lyme *Borreliae* group, and should be used in conjunction with patient clinical symptoms and history. **Limitation** For specific protein or band information, ImmunoBlot IgM or IgG tests should be ordered to provide more information and possible speciation of the *Borrelia*.	**Positive:** Lyme *Borreliae* antigens detected **Negative:** Lyme *Borreliae* antigens not detected	Far broader and more inclusive of Lyme *Borreliae* species than standard serologies. Detects antibodies to Lyme *Borreliae* species from North American, European, Asian, and Australian strains. Better than two-tier ELISA/WB and two-tier ELISA. Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
LYME SCREEN IMMUNOASSAY			
#605 Lyme Screen Immunoassay IgM **#606** Lyme Screen Immunoassay IgG Not generally recommended as a standalone test.	The Lyme Screen Immunoassay is a qualitative test designed to detect IgM and IgG antibodies to Lyme *Borreliae* group-specific antigens in human serum. The sensitivity of the Lyme BCA Assay is 84%, and the specificity is 94%. **Principle** The test detects IgM and IgG antibodies to the Lyme *Borreliae* group, and should be used in conjunction with patient clinical symptoms and history. **Limitation** For specific protein or band information, ImmunoBlot IgM or IgG tests should be ordered to provide more information and possible speciation of the *Borrelia*.	**Positive:** Lyme *Borreliae* antigens detected **Negative:** Lyme *Borreliae* antigens not detected	Far broader and more inclusive of Lyme *Borreliae* species than standard serologies. Detects antibodies to Lyme *Borreliae* species from North American, European, Asian, and Australian strains. Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary. Satisfies two-tier testing recommended by the CDC.
SEROLOGY - LYME IGG/IGM, LYME IGM SEROLOGY			
#183 Lyme Serology IgG/IgM **#195** Lyme Serology IgM Not generally recommended as a standalone test.	The IgG/IgM Serology test is an enzyme linked immunoassay which indicates the presence of IgG and IgM antibodies to *B. burgdorferi*. The IgG antibody often persists long after symptoms have disappeared. The presence of antibodies indicates exposure, not active disease. A positive or equivocal test must be confirmed by both IgG and IgM ImmunoBlot tests. The Lyme IgM antibody assay is another serologic test in ELISA format, and it detects the presence of IgM antibodies to *B. burgdorferi* after exposure to an infected tick. Because IgM antibodies appear early in response to infection, this test may be positive two to six weeks after exposure. The level of IgM rapidly declines over time. A positive or equivocal IgM antibody test must be confirmed by an IgM ImmunoBlot.	**IgG/IgM** **Positive:** ≥ 1.2 **Equivocal:** ≥ 1.0 to < 1.2 **Negative:** < 1.0 **IgM** **Positive:** ≥ 1.2 (Confirmatory assays recommended) **Equivocal:** ≥ 0.8 to < 1.2 (Retesting in two to four weeks recommended). **Negative:** < 0.8 (Indicates IgM antibodies to *B. burgdorferi* not detected).	Inexpensive An option for initial screening. However, ImmunoBlots are highly recommended in conjunction with these tests.
LYME cePCR (CULTURE ENHANCED)			
#1100C Lyme cePCR	The Lyme cePCR test detects *Borrelia burgdorferi* specific DNA sequences from Osp A plasmid and flagellin genomic genes, in clinical specimens. **Principle** In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.	**Genomic** **Positive:** *B. burgdorferi* DNA detected. **Negative:** *B. burgdorferi* DNA not detected. **Plasmid** **Positive:** *B. burgdorferi* DNA detected. **Negative:** *B. burgdorferi* DNA not detected. Sample is considered positive if either genomic or plasmid is positive.	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. Highly Specific - The only 100% specific method for identification of a tick-borne disease.

TICK-BORNE RELAPSING FEVER (TBRF)

Looks like Lyme, behaves like Lyme, but it's not Lyme. Is it TBRF? New data confirms detection of thousands of cases of TBRF across the U.S. Some of the *Borrelia* that cause TBRF are transmitted by the same ticks that transmit Lyme *Borreliae*, the causative agents of Lyme disease. Moreover, both Lyme and TBRF sufferers display many similar symptoms, often leading to misdiagnosis. Therefore, it is important to test for both Lyme and TBRF.



TBRF has been detected in 49 of 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR TBRF

- Multi-Species ImmunoBlots
- Broad Coverage Assay
- PCR
- cePCR

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
TBRF IMMUNOBLOTS (IGM/IGG)			
#345 TBRF ImmunoBlot IgM **#355** TBRF ImmunoBlot IgG	TBRF ImmunoBlots are very sensitive indicators of exposure to TBRF *Borrelia*. The ImmunoBlot IgM may be positive as early as 2 weeks after a tick bite. This test will usually remain positive for six to eight weeks after initial exposure, and can remain positive for a very long time. The IgG ImmunoBlot can present as early as 6 to 8 weeks after infection. The TBRF ImmunoBlot IgG is a sensitive indicator of exposure to *B. miyamotoi, B. hermsii, B. turicatae* and other strains of TBRF *Borrelia*. For best results, the IgM ImmunoBlot and IgG ImmunoBlot should be run together. **Principle** IB strips are prepared from recombinant proteins of interest. The recombinant proteins are applied to a membrane and cut into strips. **Immunoblotting** The patient sample is incubated with the IB strip. If antibodies are present, they will bind to the corresponding antigen bands. After washing, the strip is incubated with alkaline phosphate-conjugated goat anti-human antibody. Bound antibodies react with BCIP/NBT, a chromogenic substrate. A dark purple precipitate develops on the antigen-antibody complexes. Bands are scored for intensities relative to the positive and negative controls.	**IgM** **Positive**: If two TBRF *Borrelia* specific bands are present. **Indeterminate:** If one TBRF *Borrelia* specific IgM band is present. **IgG** **Positive**: If two TBRF *Borrelia* specific bands are present. **Indeterminate:** If one TBRF *Borrelia* specific IgG band is present.	Improved sensitivity because it includes TBRF *Borreliae*-specific antigens from multiple strains and species. Improved specificity because pure proteins are sprayed at specific positions on the blot. Superior at all stages of TBRF disease. Possible speciation of the individual *Borrelia* strains.
TBRF PCR			
#556 TBRF PCR: Whole Blood **#573** TBRF PCR: Serum **#559** TBRF PCR: Urine **#562** TBRF PCR: Urine (pooled) **#565** TBRF PCR: CSF **#568** TBRF PCR: Miscellaneous	The Relapsing Fever (RF) *Borrelia* group real-time PCR Assay is designed for qualitative detection of RF *Borrelia* group DNA in clinical samples. The RF group includes *B. miyamotoi*, *B. hermsii*, *B. coriaceae*, *B. lonestari* and *B. anserine*, etc. The assay detects RF *Borrelia* group genomic DNA and *B. miyamotoi* specific DNA. For diagnostic purposes, PCR results should be used in conjunction with other data available to the physician. **Principle** The multiplex PCR-based diagnostic test is performed directly on the clinical specimen in a three-step assay. The steps are as follows: **Selection hybridization step** Removes the “common PCR inhibitors” from the clinical sample while simultaneously selecting and purifying the DNA fragment of interest. This procedure also concentrates the fragment, thereby improving sensitivity. **PCR amplification** The purified pathogen DNA fragment of interest is PCR-amplified with pathogen-specific primers. This sequence “hybridizes” or binds specifically to pathogen DNA of interest under predetermined PCR conditions. Therefore, only pathogen-specific DNA is amplified. **Detection of amplified products** The PCR-amplified products are transferred and bound to a nitrocellulose membrane. The membrane-bound, PCR-amplified products are hybridized with pathogen-specific probes. Only samples that have pathogen-specific DNA hybridize to the probes and give a blue-purple color dot on the membrane.	RF *Borrelia* Genus (detects RF *Borrelia* species including *B. hermsii, B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae, B. turcica,* and *B. recurrentis*) **Positive:** RF *Borrelia* DNA was detected. **Negative:** RF *Borrelia* DNA was not detected in the sample analyzed. RF *Borrelia* Subgroup Species (detects *B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae and B. recurrentis*) **Positive:** RF *Borrelia* species DNA was detected. **Negative:** RF *Borrelia* species DNA was not detected in the sample analyzed.	Ability to test multiple sample types using PCRs, including urine, tissue, breast milk, cerebral spinal fluid, in addition to blood. Especially useful for seronegative patients. PCRs are detecting the DNA of the bacteria itself. Therefore, a positive result is definitive. Enables accurate identification of biochemically unusual strains of pathogen. Facilitates much earlier detection of the microorganism because the assay is independent of the host’s immune response schedule. Therefore, PCRs are useful for seronegative patients as well. Allows monitoring of the efficacy of an antibiotic regimen.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BROAD COVERAGE TBRF BORRELIA AB ASSAY			
#602 Broad Coverage TBRF Borrelia Ab Assay	The TBRF Broad Coverage Antibody Assay (BCA) is a qualitative test designed to detect IgM and IgG antibodies to TBRF *Borreliae* group-specific antigens in human serum. A positive test suggests exposure to the TBRF *Borreliae* group, and should be used in conjunction with patient clinical symptoms and history. It is a simple and cost-effective test, which gives either a positive or negative result. **Principle** Detects IgM and IgG antibodies to the TBRF *Borreliae* group, and a positive test suggests exposure to the TBRF *Borreliae* group, and should be used in conjunction with patient clinical symptoms and history. For specific protein or band information, an ImmunoBlot IgM or IgG test should be ordered to provide more information and possible speciation of the *Borrelia*.	**Positive:** TBRF *Borreliae* group-specific antigens detected. **Negative:** TBRF *Borreliae* group-specific antigens not detected. The sensitivity of the TBRF *Borrelia* BCA Assay is greater than 90%, and the specificity is greater than 94%.	Far broader and more inclusive of TBRF *Borreliae* (including, but not limited to, *B. miyamotoi*) species than standard serologies. Detects antibodies to TBRF *Borrelia* species from North American, European, Asian and Australian strains. Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary.
RFB & BBSL CEPCR (CULTURE ENHANCED)			
#1200C RFB & Bbsl cePCR	The RFB & Bbsl cePCR test detects RF *Borrelia* group DNA in clinical samples. The RF group includes *B. miyamotoi*, *B. hermsii*, *B. coriaceae*, *B. lonestari* and *B. anserine*, etc. The assay detects RF *Borrelia* group genomic DNA and *B. miyamotoi* specific DNA. **Principle** In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.	RF *Borrelia* Genus (detects RF *Borrelia* species including *B. hermsii, B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae, B. turcica,* and *B. recurrentis*) **Positive:** RF *Borrelia* DNA was detected. **Negative:** RF *Borrelia* DNA was not detected in the sample analyzed. RF Borrelia Subgroup Species (detects *B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae* and *B. recurrentis*) **Positive:** RF *Borrelia* species DNA was detected. **Negative:** RF *Borrelia* species DNA was not detected in the sample analyzed.	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. Highly Specific - The only 100% specific method for identification of a tick-borne disease.

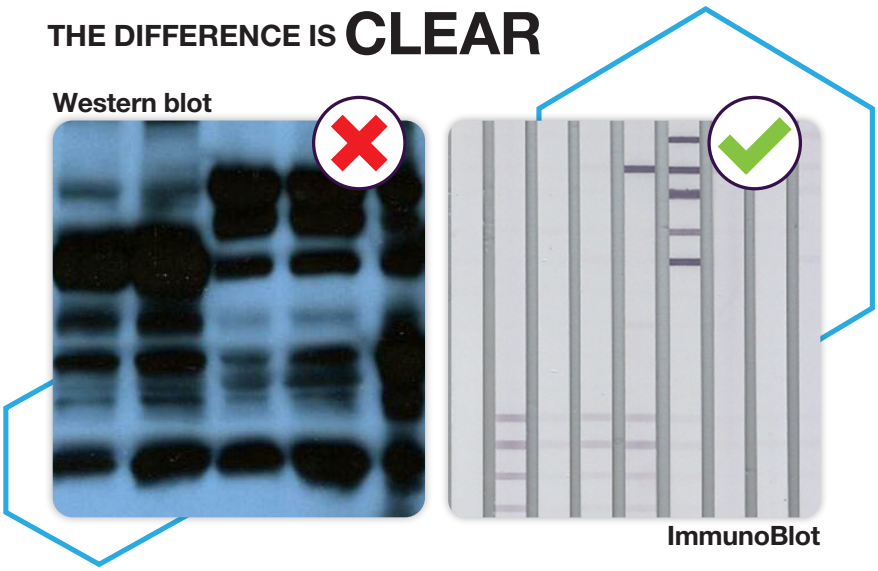
OUT WITH THE OLD. **IN WITH THE NEW.**

THE IGENEX IMMUNOBLOT REPLACES THE WESTERN BLOT

The Western blot technique for detecting antibodies to tick-borne diseases was introduced in the late 1970s. Technological advancements over the past 50 years have lead to tests that go beyond what can be accompilshed with the Western blot. The most significant advancement has been the introduction of the iGenex ImmunoBlot. The IGenex ImmunoBlot has two key differentiators. First, it looks for multiple pathogenes, instead of one with the Western blot. And second, it uses reconbinant proteins instead of proteins from natural sources, leading to a more specific test.

THE DIFFERENCE IS **CLEAR**

Western blot



ImmunoBlot

Western blots are blurry, difficult to read, and lead to misdiagnosis.
IGeneX ImmunoBlots are clear, precise, and much easier to interpret.

IGENEX IMMUNOBLOT IS BETTER MADE

Follow the science. The IGeneX ImmunoBlot uses recombinant proteins instead of proteins from natural sources. Recombinant DNA technology provides a more efficient method to obtain large amounts of proteins. Additionally, by using recombinant technology, IGeneX scientists are able to create DNA sequences that would not naturally exist under normal circumstances, leading to more sensitive and specific tests.

ADVANTAGES OF THE IGENEX **IMMUNOBLOT** OVER THE WESTERN BLOT

- ✓ Requires only one test to detect multiple species. Western blotting would require multiple tests.
- ✓ Uses specifically created recombinant proteins and not proteins from cultures
- ✓ Produces consistent bands that are easier to interpret
- ✓ Detects the full spectrum of disease: early, active, and late-stage
- ✓ Does not require a confirmation test.

ISOLATE THE GENES

Pure genes are stored and ready to be cloned by iGenex researchers.

1

EXPRESS THE GENES

The genes of interest are put into a host cell and expressed as a new protein. This is the so-called “recombinant protein.”

2

PURIFY THE PROTEINS

The protein of interest is isolated and purified, and the non-proteinaceous materials are removed.

3

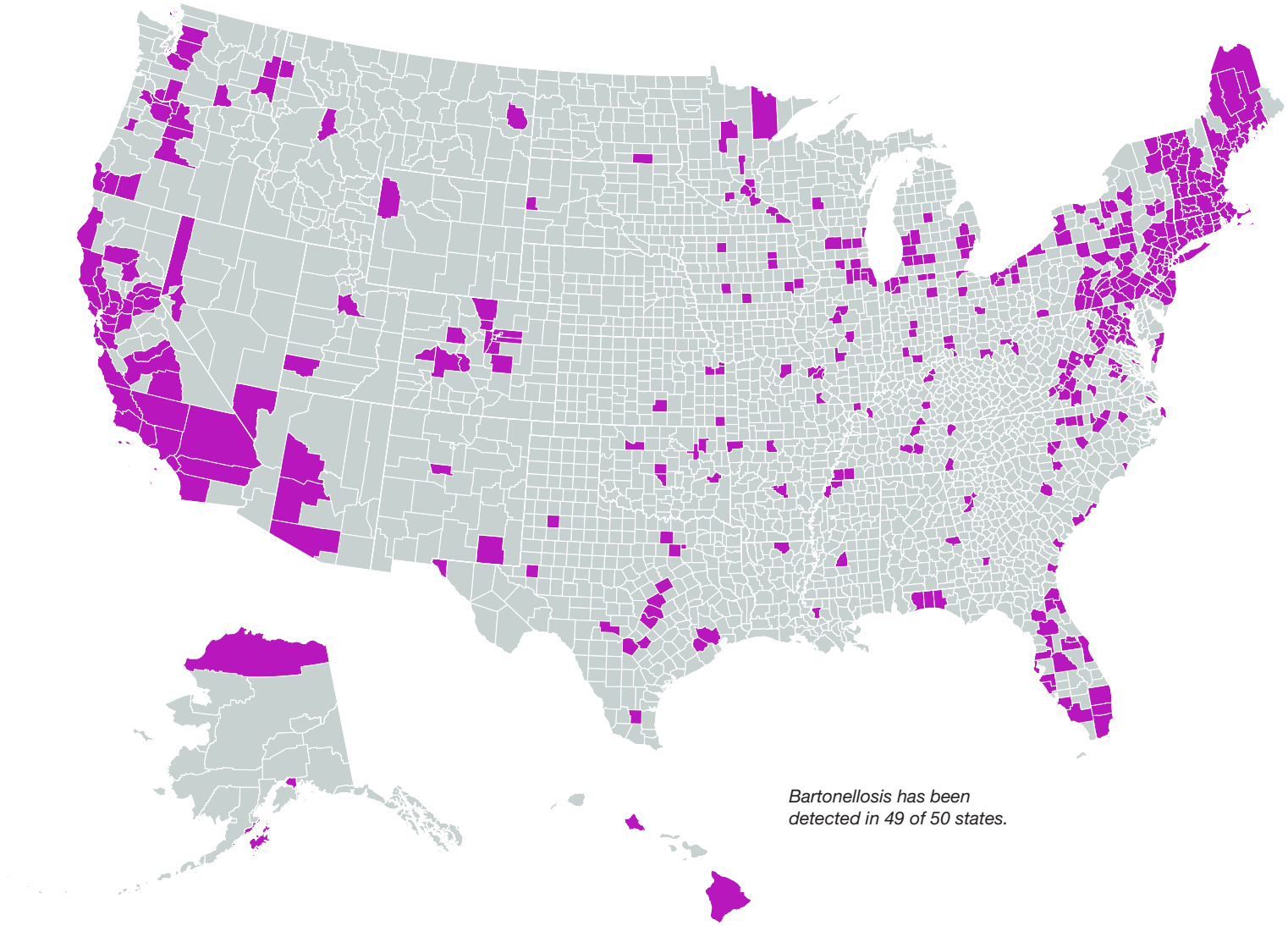
SPRAY THE PROTEINS

The purified recombinant proteins are sprayed in precise amounts onto specific locations on a membrane strip.

4

BARTONELLOSIS

Bartonellosis is primarily associated with fleas, lice, and ticks. Several species of Bartonella cause serious diseases in humans, such as Cat Scratch Disease (CSD), endocarditis, trench fever, and Carrion's disease. The symptoms of Bartonellosis can vary from mild to severe, and usually begin 5 to 14 days after infection. Common symptoms include fever, headaches, fatigue, poor appetite, brain fog, muscle pain, and swollen glands around the head, neck and arms. The diagnosis for Bartonellosis should be considered in patients bitten by a tick or flea or scratched by small animals and are experiencing any of the symptoms typical of Bartonellosis infections, even mild ones.



Bartonellosis has been detected in 49 of 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR BARTONELLOSIS	
✓ Multi-Species ImmunoBlots	✓ IFA
✓ PCR	✓ FISH
✓ IgXSpot	✓ cePCR
✓ Broad Coverage Assay	

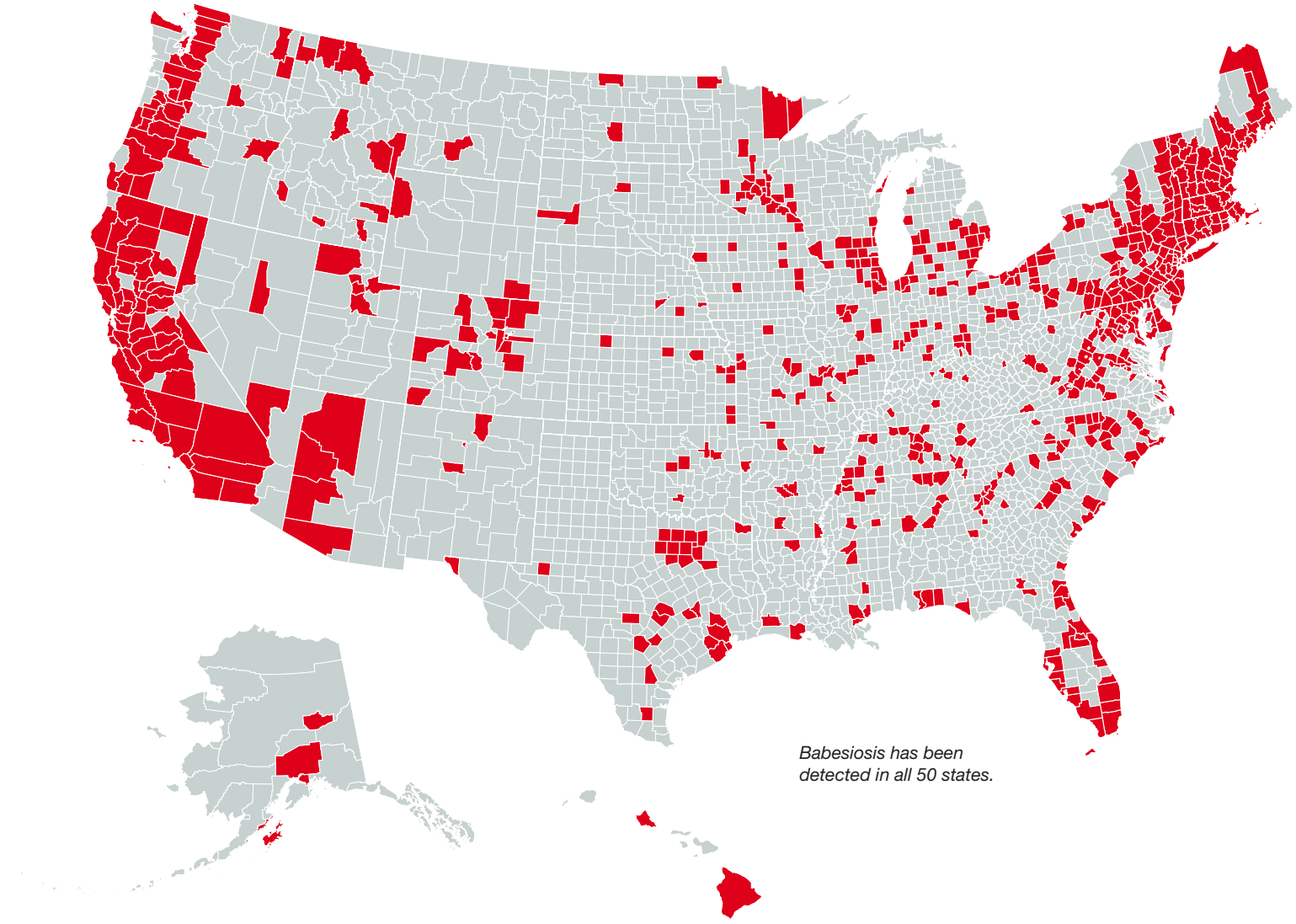
TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BARTONELLA MULTI-SPECIES IMMUNOBLOTS (IGM/IGG)			
#374 Bartonella ImmunoBlot IgM **#384** Bartonella ImmunoBlot IgG	The Bartonella ImmunoBlots are designed to detect IgM/IgG antibodies to Bartonella species including *Bartonella henselae, B. quintana, B. elizabethae* and *B. vinsonii* antigens in serum of patient suspected of having Bartonella infection. For diagnostic purposes, the Bartonella ImmunoBlot test results should be used in conjunction with clinical symptoms and other evidence available to the diagnosing practitioner. **Principle** ImmunoBlotting is a form of testing that uses pure, recombinant proteins sprayed in precise amounts at specific positions on the test strips to dramatically increase accuracy, and has long been considered the gold standard in infectious disease testing due to its superior sensitivity and specificity. These tests effectively replace traditional tests such as ELISA and the Western blot. **Performance Characteristics** Sensitivity: 15 samples were positive for Bartonella and validated with PCR. All 15 samples were positive by either ImmunoBlot IgM and/or IgG. Specificity: Based on a study performed on 34 well-characterized samples, of which 10 samples were negative for Bartonella and positive for antibodies to other tick-borne pathogens, the specificity of the Bartonella ImmunoBlot test is 100%.	The Bartonella IgM and IgG ImmunoBlot detects specific antibodies in human serum to *B. elizabethae, B. vinsonii, B. henselae,* and *B. quintana*. **Positive:** Presence of 2 or more specific antibodies to *Bartonella* antigen(s) detected. If positive, species is determined. **Indeterminate:** Presence of one specific antibody to *Bartonella* antigen detected. **Negative:** No specific antibody to *Bartonella* antigen(s) detected.	*Bartonella* IgM/IgG ImmunoBlot test has very high sensitivity and specificity for detecting *Bartonella* specific antibodies in patient's serum and speciating *Bartonella* positive samples to *B. henselae*, *B. quintana*, *B. elizabethae* and *B. vinsonii*. Thus it is a very useful diagnostic tool for *Bartonella* infection. The result can be reported in 5 business days unlike culture that can take months. No other test like it on the market
BARTONELLA FISH			
#289 Bartonella FISH	The *Bartonella* FISH assay is designed for qualitative detection of ribosomal RNA of bacteria belonging to the Genus *Bartonella*. *Bartonella* are rod-shaped, gram-negative bacteria. The FISH test provides a significant increase in specificity over standard gram stain for the presence of *Bartonella* in a whole blood smear. A positive result indicates the presence of bacterium from the Genus *Bartonella*, including *B. berkhoffii*, *B. henselae*, *B. elizabethae*, *B. quintana*, *B. vinsonii* and more. The presence of an organism is an indication of the presence of disease. A positive result can aid in diagnosis during the course of the disease. **Principle** Hybridization directly on a thin blood smear with a fluorescein-labeled *Bartonella* specific probe, followed by identification of *Bartonella* on a blood smear by viewing under a fluorescent microscope.	**Positive:** Fluorescing rod-shaped bodies detected in the smear. **Negative:** Fluorescing rod-shaped bodies not detected in the smear.	Detects active infection Detects a broad range of species of *Bartonella*

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BARTONELLA IGXSPOT			
#350 Bartonella IgXSpot	The *Bartonella* IgXSpot test is an Enzyme-Linked ImmunoSpot (ELISPOT) assay that detect human T cells reactive to *Bartonella* specific antigens in vitro. Detects specific T cell responses soon after *Bartonella* infection, when antibodies to the organisms are not detectable or late in the disease when the levels of antibodies are very low. ELISPOT is a widely used method for detecting and monitoring cellular immune response to specific antigens. The IgXSpot assay allows visualization of the secretory product(s) of individual activated or responding T cells to *Bartonella* specific antigens, which include *B. henselae*, *B. quintana*, *B. elizabethae* and *B. vinsonii*. Each spot that develops in the assay represents a single reactive cell. When combined with Western blot tests, the *Bartonella* IgXSpot provides information on the full spectrum of a patient's immune response to infection and stage of disease, and is especially useful for seronegative patients. For diagnostic purposes, the *Bartonella* IgXSpot test results should be used in conjunction with clinical symptoms and other evidence available to the diagnosing physician.	**Positive:** > or = 3 SFU **Negative:** < or = 2 SFU **Sample Viability cut-off:** > 70% **SFU:** Spot Forming Unit Represents a reactive cell to *B. burgdorferi* antigen(s).	Detects specific T-cell responses soon after infection, when antibodies are not detectable, or late in the disease when the levels of antibodies are low. When combined with Bartonella ImmunoBlot tests, provides information on the full spectrum of a patient's immune response to infection and stage of disease. Enables doctors to monitor disease progression and treatment. Especially useful for seronegative patients. They can be diagnosed with a *Bartonella* infection without antibody (IgM/IgG) production.
BARTONELLA PCR			
#280 Bartonella PCR: Whole Blood **#281** *B. henselae* PCR: CSF **#282** Bartonella PCR: Urine	The *Bartonella henselae* Polymerase Chain Reaction (PCR) test is an assay that detects *B. henselae*-specific DNA in whole blood, urine or cerebral spinal fluid (CSF). The combination of the following three steps imparts a very high specificity and sensitivity to the test: 1. Hybridization/selection 2. Amplification of *Bartonella*-specific DNA 3. Detection of *Bartonella*-specific amplified DNA fragments **Principle** *B. henselae* ribosomal DNA (rDNA) fragments are hybrid-selected by probes, followed by PCR amplification of selected *B. henselae* rDNA. PCR products are confirmed by *B. henselae*-specific probes in a southern blot assay. The primers and probes used for the selection of *B. henselae* rDNA fragments are designed from published small subunit ribosomal RNA sequences.	**Positive:** *B. henselae* rDNA detected. **Negative:** *B. henselae* rDNA not detected in the sample analyzed.	Enables accurate identification of biochemically unusual strains of pathogen. Facilitates much earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Therefore, PCRs are useful for seronegative patients as well. Allows monitoring of the efficacy of an antibiotic regime. PCRs are detecting the DNA of the bacteria itself. Therefore, a positive result is definitive.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BARTONELLA HENSELAE IGM AND IGG IFA			
#285 B. henselae IgM & IgG IFA	The *B. henselae* Immunofluorescence Assay (IFA) is used to detect antibodies to *B. henselae* in human serum. Infections with *B. henselae* have been associated with Cat Scratch Disease, bacillary angiomatosis, peliosis hepatis, and bacteremia. Titers rise during the first two-to-four weeks of illness and decline over the next six-to-12 months. In patients with previously high titers, the presence of only IgG titer of less than 160 may indicate a resolving infection. If the IFA is negative but the clinical symptoms are present, PCR testing is suggested. *B. henselae* is most often transmitted to humans by cats. Recently, it has been suggested that *B. henselae* can also be present in the same species of tick that transmits pathogens causing Lyme disease, Babesiosis, and Ehrlichiosis. Therefore, patients with positive titers should also be tested for the other tick-borne diseases.	**IgM** < 20 Negative 20 May or may not indicate active infection ≥ 40 Indicates active infection **IgG** < 40 Negative ≥ 40 to < 160 May or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection. ≥ 160 Indicates active infection	Indirect testing, and therefore useful when the pathogens are hiding, but eliciting an immune response. Active infection may be indicated when either IgM only, IgM and IgG, or IgG (≥ 160) antibodies are present. Specific for *Bartonella hensalae*
BARTONELLA CEPCR (CULTURE ENHANCED)			
#1300C Bartonella cePCR	The Bartonella cePCR test detects *B. henselae*-specific DNA in whole blood and/or cerebral spinal fluid (CSF). **Principle** In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.	**Positive:** *B. henselae* rDNA detected. **Negative:** *B. henselae* rDNA not detected	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. Highly Specific - The only 100% specific method for identification of a tick-borne disease.
BROAD COVERAGE BARTONELLA AB ASSAY			
#611 Broad Coverage Bartonella Ab Assay	The Bartonella Broad Coverage Antibody Assay (BCA) is a qualitative test designed to detect IgM and IgG antibodies to Bartonella group-specific antigens in human serum. A positive test suggests exposure to the Bartonella group, and should be used in conjunction with patient clinical symptoms and history. The BCA Assay is a simple and cost-effective test, which gives either a positive or negative result.	**Positive:** Bartonella group-specific antigens detected. **Negative:** Bartonella group-specific antigens not detected.	Far broader and more inclusive of Bartonella species than standard serologies. Detects antibodies to Bartonella species from North American, European, Asian and Australian strains. Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary.

BABESIOSIS

Babesiosis is transmitted to humans through the bite of an infected tick, but unlike other tick-borne diseases, it is caused by microscopic parasites that infect red blood cells. This makes it similar to malaria. The severity of infection is dependent on the species of Babesia and the immune status of the patient. Most patients will experience flu-like symptoms, high fevers and chills, fatigue, malaise, muscle pain, headaches, myalgia, nausea, and shortness of breath.



Babesiosis has been detected in all 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR BABESIOSIS.

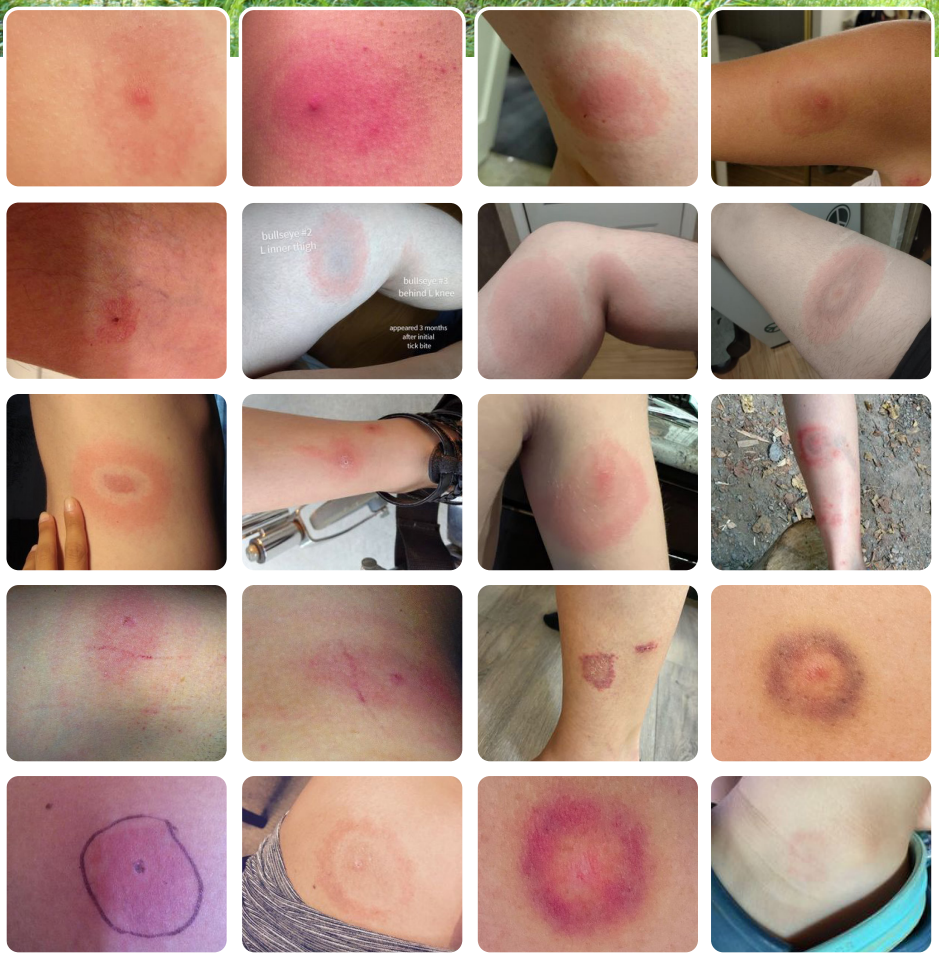
Multi-Species ImmunoBlots	PCR
FISH	cePCR
IFA	Broad Coverage Assay

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BABESIA MULTI-SPECIES IMMUNOBLOTS (IGM/IGG)			
#900 Babesia ImmunoBlot IgM **#905** Babesia ImmunoBlot IgG	The Babesia ImmunoBlots are designed to detect IgM/IgG antibodies to the Babesia Genus and Babesia species including *B. microti* and *B. duncani* antigens in serum of patient suspected of having Babesia infection. For diagnostic purposes, the Babesia ImmunoBlot test results should be used in conjunction with clinical symptoms and other evidence available to the diagnosing practitioner. **Principle** ImmunoBlotting is a form of testing that uses multiple pure, recombinant proteins sprayed in precise amounts at specific positions on the test strips to dramatically increase accuracy, and has long been considered the gold standard in infectious disease testing due to its superior sensitivity and specificity. These tests effectively replace traditional tests such as IFA and the Western blot. Until recently, diagnostic tests for Babesia have been grossly insensitive and have not been able to detect many of the ever-growing list of species and strains. The new IGeneX ImmunoBlots overcome these obstacles with the ability to detect antibodies to the Babesia Genus and Babesia species including *B. microti* and *B. duncani*.	**IgM** Positive: Presence of 2 or more Babesia specific proteins. Negative: Presence of only 1 or no Babesia specific protein. **IgG** Positive: Presence of 2 or more Babesia specific proteins. Negative: Presence of only 1 or no Babesia specific protein.	Uses specifically created recombinant proteins and not proteins from cultures. Unlike IFA, can detect multiple species in one test. Detects the full spectrum of disease: early, active and late-stage. Detects Babesia genus and speciates to *B. microti* and *B. duncani.* Replaces the IFA. Avoids the error prone process of visualizing slides through a microscope.
BABESIA FISH			
#640 Babesia FISH	The *Babesia* FISH assay is designed for qualitative detection of ribosomal RNA of *Babesia* parasites directly in a blood smear. The test's highest degree of specificity is provided by nucleic acid probes, which bind to RNA sequences of the *Babesia*. This test detects all species of *Babesia*. **Principle** The FISH assay is based on two fundamental principles: Hybridization directly on a thin blood smear with a fluorescein-labeled *Babesia* specific probe; identification of *Babesia* parasites on a blood smear by viewing with a fluorescent microscope. The FISH assay provides a significant increase in sensitivity and specificity over standard Giemsa-stained smears for the presence of intraerythrocytic parasites (piroplasts) in RBCs. The parasites exist as a ring and/or merozoite forms. A positive sample must show fluorescing rings in at least two RBCs. A negative sample must show no fluorescence within the RBCs.	**Positive:** *Babesia* specific rRNA detected. A positive sample must show fluorescing rings inside at least two RBCs. **Negative:** Babesia specific rRNA not detected. A negative sample must show no fluorescence within RBCs. A single negative FISH test result does not exclude the possibility of *Babesia* infection.	Detects active infection. Detects a broad range of species of *Babesia*.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
BABESIA MICROTI AND BABESIA DUNCANI IFA (IGM/IGG)			
#200 B. microti IgM & IgG IFA **#720** B. duncani IgM & IgG IFA	The *Babesia* Immunofluorescence Assay (IFA) is designed to detect human IgM and IgG antibodies to *Babesia* antigens in human serum. Titers rise during the first two-to-four weeks of illness and then decline over the next six-to-12 months. In patients with previously high titers, an IgG titer of less than 160 may indicate a resolving infection. If the IFA is negative but clinical symptoms are present, PCR and/or FISH testing are suggested. *Babesia* is carried by the same species of ticks that cause Ehrlichiosis, Bartonellosis, and Lyme disease. Therefore, patients with positive titers should also be tested for other tick-borne diseases.	**IgM** < 20 Negative 20 May or may not indicate active infection. ≥ 40 Indicates active infection. **IgG** < 40 Negative ≥ 40 to < 160 May or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection. ≥ 160 Indicates active infection.	Indirect testing, and therefore useful when the pathogens are hiding, but eliciting an immune response. Active infection may be indicated when either IgM only, IgM and IgG, or IgG (≥ 160) antibodies are present.
BABESIA PCR			
#663 Babesia PCR: Whole Blood **#665** Babesia PCR: Urine	The Babesia microti/duncani PCR screen is an assay that detects Babesia DNA in whole blood and speciates to *B. microti* and *B. duncani*. The combination of the following three steps imparts a very high specificity and sensitivity to the test: 1. Hybridization/Selection 2. Amplification of Babesia-specific DNA 3. Detection of Babesia-specific amplified DNA fragments.	*B. microti*: Positive: *B. microti* specific DNA detected. Negative: *B. microti* specific DNA not detected in the sample analyzed. *B. duncani*: Positive: *B. duncani* specific DNA detected Negative: *B. duncani* specific DNA not detected.	Enables accurate identification of unusual strains of pathogen. Facilitates earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Allows monitoring of the efficacy of an antibiotic regime. Higly specific.
BABESIA CEPCR			
#1300C Babesia cePCR	The Babesia cePCR test detects Babesia DNA in whole blood and speciates to *B. microti* and *B. duncani*. Principle In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.	*B. microti*: Positive: *B. microti* specific DNA detected. Negative: *B. microti* specific DNA not detected in the sample analyzed. *B. duncani*: Positive: *B. duncani* specific DNA detected Negative: *B. duncani* specific DNA not detected.	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. The only 100% specific method for identification of a tick-borne disease.
BROAD COVERAGE BABESIA AB ASSAY			
#609 Broad Coverage Babesia Ab Assay	The Babesia Broad Coverage Antibody Assay (BCA) is a qualitative test designed to detect IgM and IgG antibodies to Babesia group-specific antigens in human serum. A positive test suggests exposure to the Babesia group, and should be used in conjunction with patient clinical symptoms and history. The BCA Assay is a simple and cost-effective test, which gives either a positive or negative result.	**Positive:** Babesia group-specific antigens detected. **Negative:** Babesia group-specific antigens not detected.	Far broader and more inclusive of Babesia species than standard serologies. Detects antibodies to Babesia species from North American, European, Asian and Australian strains. Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary.

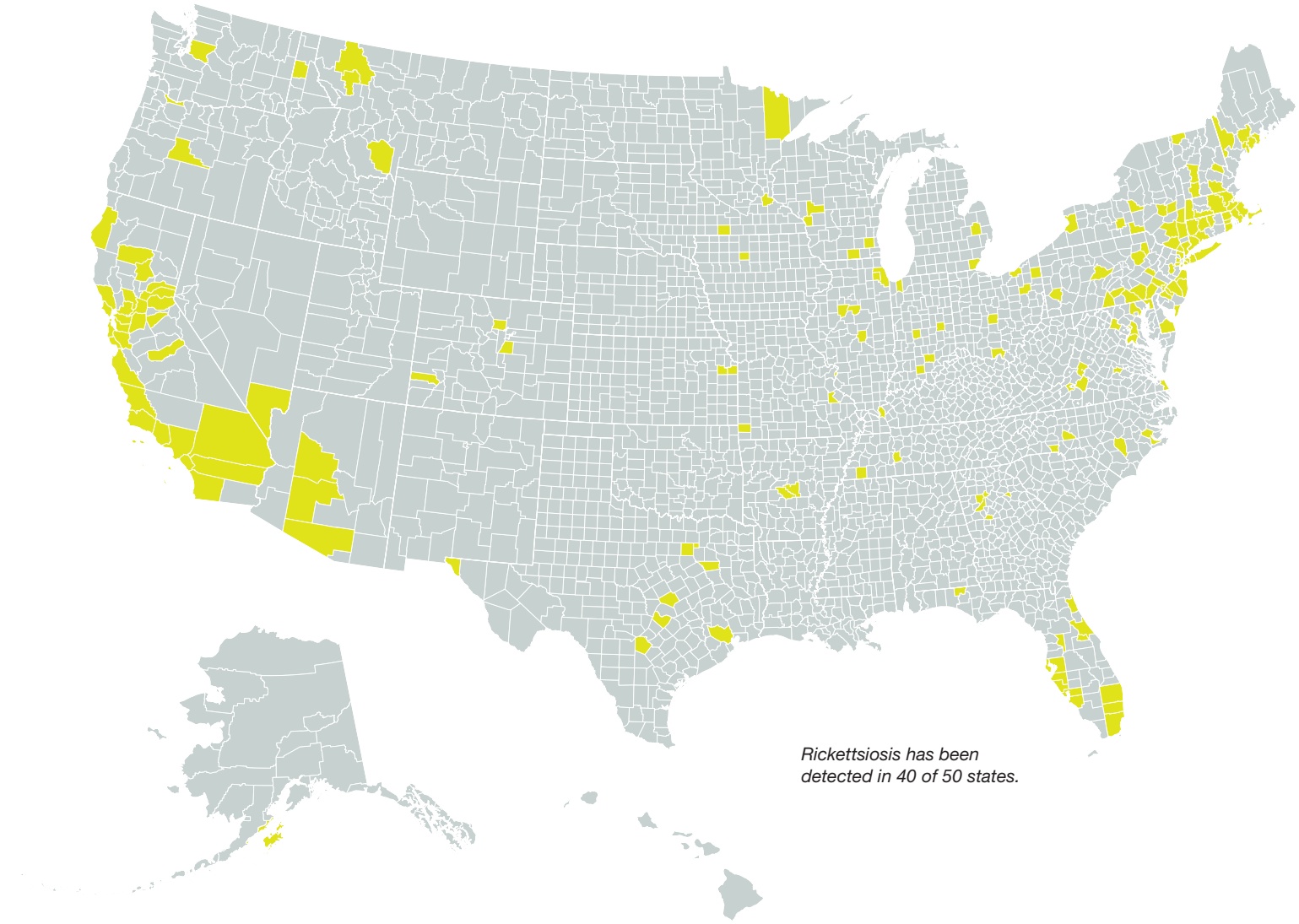
IDENTIFYING TICK BITES

Erythema migrans, or the “bulls-eye” rash, is a fairly common symptom that occurs in people who have been bitten by a tick. However, not all tick bites will result in a rash, and not all tick bite rashes look the same. Below are images from real IGeneX patients who were bitten by a tick.



RICKETTSIOSIS

Rickettsiosis is classified by two main biogroups: the spotted fever group and the typhus group. The symptoms include fever, headache, rash, nausea, vomiting, abdominal pain, myalgia, respiratory concerns, chills, and loss of appetite. Rickettsiosis is very difficult to diagnose based on symptoms alone, as the symptoms are non-specific and common to several other illnesses. Therefore, without laboratory testing, doctors are rarely able to correctly identify Rickettsiosis.



Rickettsiosis has been detected in 40 of 50 states.

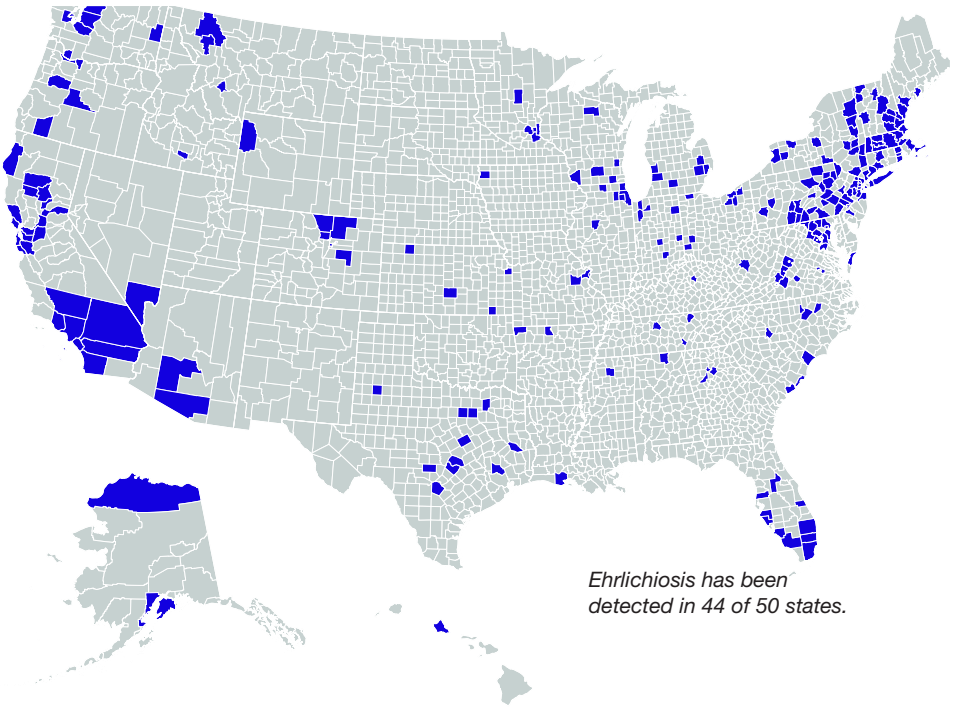
IGENEX OFFERS THE FOLLOWING TESTS FOR BABESIOSIS.

- PCR
- cePCR
- IFA

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
RICKETTSIA RICKETTSII & RICKETTSIA TYPHI IGG IFA			
#965 R. rickettsii & R. typhi IgG IFA	The *Rickettsia* Immunofluorescent Assay (IFA) is designed to detect *Rickettsia*-specific antibodies in human serum. For diagnostic purposes, IFA test results should be used in conjunction with other data available to the diagnosing physician. The *Rickettsia* IFA is used to detect antibodies to *Rickettsia* species in human serum. These species include *R. ricketsii* and *R. typhi*, known to cause Rocky Mountain Spotted Fever and Murine Typhus, respectively. Titers rise during the first two-to-four weeks of illness and decline over the next six-to-12 months. In patients with previously high titers, titers of less than 160 may indicate a resolving infection. If the IFA result is negative but the clinical symptoms are present, PCR testing is suggested.	**IgM** < 20 Negative 20 May or may not indicate active infection. ≥ 40 Indicates active infection. **IgG** < 40 Negative 40 to < 160 May or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection. ≥ 160 Indicates active infection.	Indirect testing, and therefore useful when the pathogens are hiding, but eliciting an immune response. Active infection may be indicated when either IgM only, IgM and IgG, or IgG (≥ 160) antibodies are present.
RICKETTSIA PCR			
#970 Rickettsia PCR Panel: Urine **#986** Rickettsia PCR Panel: CSF **#998** Rickettsia PCR Panel: Whole Blood	The polymerase chain reaction (PCR)-based diagnostic assay for detection of *Rickettsia* from blood is highly specific to *R. rickettsii* and *R. felis/typhi* DNAs. The combination of the following three steps imparts a very high specificity and sensitivity to the test: 1. Hybridization/selection 2. Amplification of *Rickettsia*-specific DNA 3. Detection of *Rickettsia*-specific amplified DNA fragments **Principle** The *Rickettsia* species PCR test is an assay that detects *Rickettsia* species-specific DNA in clinical samples. *Rickettsia* 17 kDa antigen gene fragments are hybrid-selected by probes, followed by PCR amplification of the selected DNA fragment. PCR products are tested with *Rickettsia*-specific probes (*R. rickettsii* and *R. felis/typhi*) by southern blot assays. The primers and probes used for the selection of a *Rickettsia* gene fragment encoding the 17 kDa antigen DNA fragments are designed from published sequences.	**Positive:** *Rickettsia* specific DNA detected. **Negative:** *Rickettsia* specific DNA not detected in the sample analyzed. **Limitations** This test should only be performed in conjunction with southern blot assays. Results should be interpreted in conjunction with other laboratory and clinical findings. Test results can only help the physician in confirming a clinical diagnosis.	Enables accurate identification of biochemically unusual strains of pathogen. Facilitates much earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Therefore, PCRs are useful for seronegative patients as well. Allows monitoring of the efficacy of an antibiotic regime. PCRs detect the DNA of the bacteria itself. Therefore, a positive result is definitive.
RICKETTSIA CEPCR (CULTURE ENHANCED)			
#1600C Rickettsia cePCR	The Rickettsia cePCR test for detection of *Rickettsia* from blood is highly specific to *R. rickettsii* and *R. felis/typhi* DNAs. **Principle** In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.	**Positive:** *Rickettsia* specific DNA detected. **Negative:** *Rickettsia* specific DNA not detected. **Limitations** This test should only be performed in conjunction with southern blot assays. Results should be interpreted in conjunction with other laboratory and clinical findings.	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. Highly Specific - The only 100% specific method for identification of a tick-borne disease.

EHRLICHIOSIS

Ehrlichia bacteria are spread to people primarily through the bite of infected ticks including the lone star tick and the blacklegged tick. People with Ehrlichiosis will often have fever, chills, headache, muscle aches, and sometimes upset stomach. The signs and symptoms of Ehrlichiosis usually appear within a week or two of a tick bite. If treated quickly with appropriate antibiotics, Ehrlichiosis generally improves within a few days.

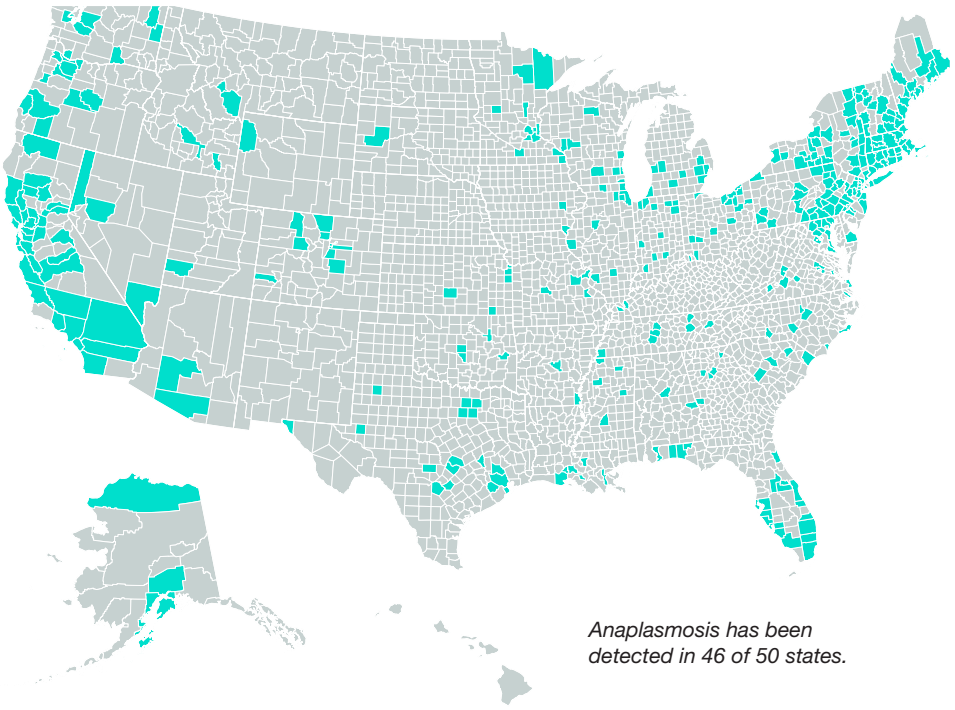


Ehrlichiosis has been detected in 44 of 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR EHRLICHIOSIS	
✓ PCR	✓ cePCR
✓ IFA	

ANAPLASMOSIS

Anaplasma bacteria are spread by tick bites primarily from the blacklegged tick (*Ixodes scapularis*) and the western blacklegged tick (*Ixodes pacificus*). People with Anaplasmosis will often have fever, headache, chills, and muscle aches. It's an uncommon illness that can affect people of all ages, and happens most often in the Spring and Summer months. In general, Anaplasmosis leads to milder disease than Ehrlichiosis, even though the two are similar.



Anaplasmosis has been detected in 46 of 50 states.

IGENEX OFFERS THE FOLLOWING TESTS FOR ANAPLASMOSIS	
✓ PCR	✓ cePCR
✓ IFA	

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
HME - EHRLICHIA CHAFFEENSIS IFA (IGM/IGG)			
#203 HME (Ehrlichia chaffeensis) IgM & IgG IFA	The *Ehrlichia chaffeensis* (HME) IFA is designed to detect human IgG and IgM antibodies to HME antigens in human serum. For diagnostic purposes, HME IFA test results should be used in conjunction with other information available to the diagnosing physician. **Principle** Titers rise during the first two-to-four weeks of illness and decline over the next six-to-12 months. In patients with previously high titers, the presence of only IgG titer of less than 160 may indicate a resolving infection. If the IFA result is negative, but the clinical symptoms of HME infection are present, PCR testing is suggested. *E. chaffeensis* is carried by the same ticks that have also been known to cause Babesiosis, Bartonellosis and Lyme disease. Patients with positive titers should also be tested for other tick-borne diseases.	**IgM** < 20 Negative 20 May or may not indicate active infection. ≥ 40 Indicates active infection. **IgG** < 40 Negative ≥ 40 to < 160 May or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection. ≥ 160 Indicates active infection.	Indirect testing, and therefore useful when the pathogens are hiding or not active. Active infection may be indicated when either IgM only, IgM and IgG, or IgG (≥ 160) antibodies are present. Note: A negative HME IFA test result does not exclude the possibility of chaffeensis infection. Cross-reactions can occur among the *Rickettsiaceae*, including: *Rickettsia*, *Ehrlichia* and *Anaplasma*. Results should be interpreted in conjunction with other laboratory and clinical findings.
HME - EHRLICHIA CHAFFEENSIS PCR			
#750 HME (Ehrlichia chaffeensis) PCR: Serum **#770** HME (Ehrlichia chaffeensis) PCR: Whole Blood **#780** HME (Ehrlichia chaffeensis) PCR: Urine	The polymerase chain reaction (PCR)-based diagnostic assays are highly specific to *Ehrlichia chaffeensis* (HME) DNAs. The combination of the following three steps imparts a very high specificity and sensitivity to the test: 1. Hybridization/selection 2. Amplification of *Ehrlichia*-specific DNA 3. Detection of *Ehrlichia*-specific amplified DNA fragments **Principle** The *Ehrlichia chaffeensis* (HME) PCR test detects *E. chaffeensis* ribosomal DNA (rDNA) fragments in patient samples. The rDNA fragments are hybrid-selected by probes, followed by PCR amplification of the selected fragments using specific primers. PCR products are then confirmed with *E. chaffeensis*-specific probes by southern blot assay.	**Positive:** *E. chaffeensis* rDNA detected. **Negative:** *E. chaffeensis* rDNA not detected in the sample analyzed.	Enables accurate identification of biochemically unusual strains of pathogen. Facilitates much earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Therefore, PCRs are useful for seronegative patients as well. Allows monitoring of the efficacy of an antibiotic regime. PCRs detect the DNA of the bacteria itself. Therefore, a positive result is definitive.
EHRLICHIA CEPCR (CULTURE ENHANCED)			
#1500C Ehrlichia & Anaplasma cePCR	The Ehrlichia cePCR test is highly specific to *Ehrlichia chaffeensis* (HME) rDNA and *Anaplasma phagocytophilum* (HGA) rDNA fragments in the patient specimens.	**Positive:** *E. chaffeensis* or *A. phagocytophilum* rDNA detected. **Negative:** *E. chaffeensis, A. phagocytophilum* or rDNA not detected.	Provides much higher sensitivity than standard PCR testing. Effective for patients without an EM rash who have not yet seroconverted. Highly Specific - The only 100% specific method for identification of a tick-borne disease.

TESTS OFFERED	TEST METHODOLOGIES	TEST INTERPRETATIONS	ADVANTAGES
HGA - ANAPLASMA PHAGOCYTOPHILUM IFA (IGM/IGG)			
#206 HGA (Anaplasma phagocytophilum) IgM & IgG IFA	The *Anaplasma phagocytophilum* (HGA) IFA is designed to detect human IgG and IgM antibodies to HGA antigens in human serum. For diagnostic purposes, HGA IFA test results should be used in conjunction with other information available to the diagnosing physician. **Principle** The *Anaplasma phagocytophilum* (HGA) IFA is used to detect antibodies to *Anaplasma phagocytophilum* in human serum. Titers rise during the first two-to-four weeks of illness and decline over the next six-to-12 months. In patients with previously high titers, the presence of only IgG titer of less than 160 may indicate a resolving infection. If the IFA result is negative but the clinical symptoms of HME or HGA infection are present, PCR testing is suggested. *E. chaffeensis* and *A. phagocytophilum* are carried by the same ticks that have also been known to cause Babesiosis, Bartonellosis and Lyme disease. Patients with positive titers should also be tested for other tick-borne diseases. A negative HGA IFA test result does not exclude the possibility of phagocytophilum infection. Cross-reactions can occur among the *Rickettsiaceae*, including: *Rickettsia*, *Ehrlichia* and *Anaplasma*. Results should be interpreted in conjunction with other laboratory and clinical findings.	**IgM** < 20 Negative 20 May or may not indicate active infection. ≥ 40 Indicates active infection. **IgG** < 40 Negative 40 to < 160 May or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection. ≥ 160 Indicates active infection.	Indirect testing, and therefore useful when the pathogens are hiding or not active. Active infection may be indicated when either IgM only, IgM and IgG, or IgG (≥ 160) antibodies are present.
HGA - ANAPLASMA PHAGOCYTOPHILUM PCR			
#755 HGA (Anaplasma phagocytophilum) PCR: Serum **#775** HGA (Anaplasma phagocytophilum) PCR: Whole Blood **#785** HGA (Anaplasma phagocytophilum) PCR: Urine	The polymerase chain reaction (PCR)-based diagnostic assays are highly specific to *Anaplasma phagocytophilum* (HGA) DNAs. The combination of the following three steps imparts a very high specificity and sensitivity to the test: 1. Hybridization/selection 2. Amplification of *Anaplasma*-specific DNA 3. Detection of *Anaplasma*-specific amplified DNA fragments **Principle** The HGA (Human Granulocytic Anaplasmosis) PCR test detects *Anaplasma phagocytophilum* rDNA fragments in the patient specimens. The *A. phagocytophilum* rDNA fragments are hybrid-selected by probes, followed by PCR amplification of the selected fragments using Anaplasma specific primers. *A. phagocytophilum* specific PCR products are then detected with probes in a dot-blot assay.	**Positive:** *A. phagocytophilum* rDNA detected. **Negative:** *A. phagocytophilum* rDNA not detected in the sample analyzed.	Enables accurate identification of biochemically unusual strains of pathogen. Facilitates much earlier detection of the microorganism because the assay is independent of the host's immune response schedule. Therefore, PCRs are useful for seronegative patients as well. Allows monitoring of the efficacy of an antibiotic regime. PCRs detect the DNA of the bacteria itself. Therefore, a positive result is definitive.

TEST PANELS

IGeneX offers panels for Borreliosis, all Tick-Borne Diseases, and Co-infections. Panels are a combination of individual tests that are tailored to meet the needs of the referring healthcare practitioner. They also offer a significant price discount for patients.

TICK-BORNE DISEASE TEST PANELS

PANEL CODE	NAME
TBD4IBL	**TICK BORNE DISEASE PANEL 4IBL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG
TBD5IBL	**TICK BORNE DISEASE PANEL 5IBL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Babesia FISH · Bartonella FISH
TBD6IBL	**TICK BORNE DISEASE PANEL 6IBL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Babesia FISH · Bartonella FISH · Lyme Multiplex PCR – Serum & Whole Blood · TBRF PCR – Serum & Whole Blood
TBD7	**TICK BORNE DISEASE PANEL 7** · Lyme Multiplex PCR – Urine · TBRF PCR – Urine · Babesia PCR - Urine · Bartonella PCR – Urine · HME (Ehrlichia chaffeensis) PCR – Urine · HGA (Anaplasma phagocytophilum) PCR – Urine · Rickettsia PCR Panel – Urine

PANEL CODE	NAME
TBD8BL	**TICK BORNE DISEASE PANEL 8BL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Babesia FISH
TBD9BL	**TICK BORNE DISEASE PANEL 9BL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Lyme Multiplex PCR – Serum & Whole Blood
TBD-10BL	**TICK BORNE DISEASE PANEL 10BL** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Lyme Multiplex PCR – Serum & Whole Blood · Babesia FISH · Lyme Multiplex PCR – Serum & Whole Blood · TBRF Multiplex PCR – Serum & Whole Blood · PCR-Whole Blood: Babesia, B. henselae, HME, HGA, Rickettsia (Only R. rickettsii will be reported for NY residents in Rickettsia PCR)

PANEL CODE	NAME
TBD11L	**TICK BORNE DISEASE PANEL 11L** · Lyme Screen Immunoassay IgG/IgM · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Lyme ImmunoBlot IgM/IgG · TBRF ImmunoBlot IgM/IgG · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Babesia FISH · Bartonella FISH · Lyme Multiplex PCR – Serum & Whole Blood · TBRF PCR – Serum & Whole Blood · Babesia PCR – Whole Blood · B. henselae PCR – Whole Blood · HME PCR – Whole Blood · HMA PCR – Whole Blood · Rickettsia PCR – Whole Blood

INDIVIDUAL DISEASE PANELS

(PANELS FOR EACH INDIVIDUAL DISEASE)

IINDIVIDUAL DISEASE TEST PANELS

PANEL CODE	NAME
IB1L	**LYME IMMUNOBLOT PANEL 1** · Lyme Screen Immunoassay IgG/IgM · Lyme ImmunoBlot IgM/IgG
IB2	**LYME IMMUNOBLOT PANEL 2** · Lyme ImmunoBlot IgM/IgG · Lyme Multiplex PCR – Serum · Lyme Multiplex PCR – Whole Blood
IB3L	**LYME IMMUNOBLOT PANEL 3** · Lyme Screen Immunoassay IgG/IgM · Lyme ImmunoBlot IgM/IgG · Lyme Multiplex PCR – Whole Blood
IB4	**LYME IMMUNOBLOT PANEL 4** · Lyme ImmunoBlot IgM/IgG · Lyme Multiplex PCR – Serum · Lyme Multiplex PCR – Whole Blood · Test #300: Lyme IgXSpot
LPCR1	**LYME MULTIPLEX PCR PANEL 1** · Lyme Multiplex PCR – Serum · Lyme Multiplex PCR – Whole Blood

PANEL CODE	NAME
TBRF1	**TBRF PANEL 1** · TBRF ImmunoBlot IgM/IgG · TBRF PCR – Serum · TBRF PCR – Whole Blood
TBRF2	**TBRF PANEL 2** · TBRF PCR – Serum · TBRF PCR – Whole Blood
BAB2B	· **BABESIA PANEL 2** · Babesia ImmunoBlot IgM/IgG · Babesia PCR · Babesia FISH
BART2I	**BARTONELLA PANEL 2I** · Test #350: Bartonella IgXSpot · Bartonella ImmunoBlot IgM & IgG
BART3I	**BARTONELLA PANEL 3I** · Test #350: Bartonella IgXSpot · Bartonella ImmunoBlot IgM & IgG · B. henselae PCR · Bartonella FISH

PANEL CODE	NAME
BART4I	**BARTONELLA PANEL 4I** · Bartonella ImmunoBlot IgM & IgG · B. henselae PCR · Bartonella FISH
EP1	**EHRLICHIOSIS PANEL 1** · IFA (IgM & IgG): E. chaffeensis (HME), A. phagocytophilum (HGA) · PCR-Whole Blood: E. chaffeensis (HME), A. phagocytophilum (HGA)
RP1	**RICKETTSIOSIS PANEL 1** · Rickettsia rickettsii/typhi IFA IgG, Rickettsia PCR (Only R. rickettsii will be reported for NY residents in Rickettsia PCR)

CEPCR TEST PANELS (CULTURE ENHANCED PCR) PANELS

(CULTURE PANELS INCLUDE A TWO-WEEK CULTURE WITH A REAL TIME PCR TEST)

BORRELIOSIS TEST PANELS

PANEL CODE	NAME
CEBOR	**BORRELIOSIS cePCR TEST PANEL** · Culture cePCR: Lyme, RFB & Bbsl

PANEL CODE	NAME
CECOI	**CO-INFECTION cePCR TEST PANEL** · Culture cePCR: Babesia, Bartonella, Ehrlichia and Anaplasma, Rickettsia

PANEL CODE	NAME
CETBD	**TBD cePCR TEST PANEL** · Culture cePCR: Lyme, RFB & Bbsl, Babesia, Bartonella, Ehrlichia and Anaplasma, Rickettsia

CO-INFECTION PANELS

(COMBINES BABESIOSIS, HME, HGA, BARTONELLOSIS, & RICKETTSIOSIS TESTING)

CO-INFECTION TEST PANELS

PANEL CODE	NAME
CP5	**CO-INFECTION PANEL 5** · B. microti IgM & IgG IFA · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · Bartonella henselae IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Babesia FISH
CP7IB	**CO-INFECTION PANEL 7IB** · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG
CP8IB	**CO-INFECTION PANEL 8IB** · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · Bartonella ImmunoBlot IgM/IgG · Babesia ImmunoBlot IgM/IgG · Babesia FISH · Bartonella FISH
CP10	**CO-INFECTION PANEL 10** · HME (Ehrlichia chaffeensis) IgM & IgG IFA · HGA (Anaplasma phagocytophilum) IgM & IgG IFA · R. rickettsii & R. typhi IgG IFA · B. microti IFA · B. henselae IFA · Babesia PCR – Whole Blood · Bartonella PCR – Whole Blood · HME PCR – Whole Blood · HMA PCR – Whole Blood · Rickettsia PCR – Whole Blood · Babesia FISH
CP11	**CO-INFECTION PANEL 11** · Babesia PCR – Whole Blood · Bartonella PCR – Whole Blood · HME PCR – Whole Blood · HMA PCR – Whole Blood · Rickettsia PCR – Whole Blood

BORRELIOSIS PANELS

(COMBINES LYME & TBRF TESTING)

BORRELIOSIS TEST PANELS

PANEL CODE	NAME
LTP1L	**LYME/TBRF PANEL 1** · Lyme Screen Immunoassay IgG/IgM · Lyme ImmunoBlot IgM · Lyme ImmunoBlot IgG · TBRF ImmunoBlot IgM · TBRF ImmunoBlot IgG
LTP2L	**LYME/TBRF PANEL 2** · Lyme Screen Immunoassay IgG/IgM · Lyme ImmunoBlot IgM · Lyme ImmunoBlot IgG · Lyme Multiplex PCR – Serum · Lyme Multiplex PCR – Whole Blood · TBRF ImmunoBlot IgM · TBRF ImmunoBlot IgG
LTP3L	**LYME/TBRF PANEL 3** · Lyme Screen Immunoassay IgG/IgM · Lyme ImmunoBlot IgM · Lyme ImmunoBlot IgG · Lyme Multiplex PCR – Serum · Lyme Multiplex PCR – Whole Blood · TBRF ImmunoBlot IgM · TBRF ImmunoBlot IgG · TBRF PCR – Serum · TBRF PCR – Whole Blood

IgX cePCR™
Culture Enhanced PCR Testing

CULTURE TESTING NOW AVAILABLE!

Introducing culture-enhanced PCR testing for the definitive detection of tick-borne diseases.

Culture testing is widely considered to be the “gold standard” for diagnosis of tick-borne illnesses. For years, tick-borne disease cultures were too expensive and tedious to be practical for laboratory use. Until now. After many years of development, IGeneX is pleased to introduce cePCR™ (Culture Enhanced PCR) for all of the major tick-borne illnesses. IGeneX is currently the only lab that can culture all of the major tick-borne diseases.

Advantages of Culture-Enhanced PCR (cePCR)

- Provides much higher sensitivity than standard PCR testing
- The only 100% specific method for identification of a tick-borne disease
- Screens for seven tick-borne diseases in one test: Lyme disease, Tick-Borne Relapsing Fever, Bartonella, Babesia, Anaplasma, Ehrlichia, and Rickettsia
- Obtaining cultures before antibiotic use improves the chances of identifying the offending microorganism, which improves patient care

How cePCR Works?

In culturing, a clinical sample from the body (e.g. blood) is incubated in media. During this incubation period, micro-organisms in the sample grow and multiply. The sample is then tested by PCR to identify the pathogens.

Step 1

An aliquot of whole blood is placed into a proprietary culture media.

Step 2

The culture media is incubated for several days.

Step 3

PCR tests are performed on the cultured samples.

cePCR Validation Studies

During the development of cePCR, IGeneX performed two validation studies that verified the accuracy of the test.

1 Real-time PCR followed by sequencing

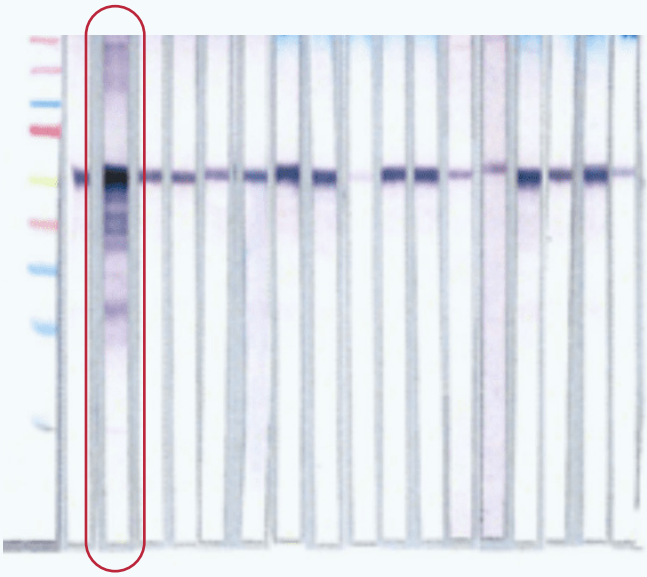
IGeneX cultured 1200 samples for two weeks. 57 samples were positive, spread across six diseases listed below. The samples were then sent for DNA sequencing to confirm the species. Some of the species that were detected, such as *A. platys*, are rarely found in the US, and likely would not be detected with traditional PCR.

Total Samples Tested (1200) – 57 Samples Positive

	Positive	Species (based on sequence analysis)	
Lyme Borreliae	23	17	*B. burgdorferi*
		2	*B. garinii*
		4	*B. mayonii*
Relapsing Fever Borreliae	5	4	*B. miyamotoi*
		1	*B. miyamotoi*
Babesia	20	12	*B. microti*
		7	*B. duncani*
		1	*Babesia sp.*
Bartonella	7	5	*B. henselae*
		1	*B. elizabethae*
		1	*B. tribocrum*
Anaplasma	2	1	*A. phagocytophilum*
		1	*A. platys*
Samples	**57**		**4.75%**

2 Reverse Western blotting using pathogen-specific antibodies

IGeneX cultured patients' blood for 16 weeks and prepared Western blots from the culture pellets. The blots were tested against antibodies to four tick-borne disease groups: Lyme disease, Tick-Borne Relapsing Fever, Babesia, and Bartonella. The blot below clearly shows the detection of a pathogen.



Available cePCR Test Panels

Borreliosis cePCR Test Panel
Includes two-week culture, plus real-time PCR for Lyme and TBRF.

Co-infection cePCR Test Panel
Includes two-week culture, plus real-time PCR for Babesia, Bartonella, HME, HGA, and Rickettsia.

Tick-Borne Disease cePCR Test Panel
Includes two-week culture, plus real-time PCR for Lyme, TBRF, Babesia, Bartonella, HME, HGA, and Rickettsia.

IGENEX BROAD COVERAGE SCREENING ASSAYS

NOW AVAILABLE FROM HOME!

INTRODUCING AcuDart

Tick-borne disease testing from the comfort of home.

AcuDart Tick-Borne Disease Test Panel

Lyme disease | Bartonellosis | Babesiosis
Tick-Borne Relapsing Fever

- SUPERIOR ACCURACY
- NO DOCTOR VISIT REQUIRED
- COMPLETED AT HOME
- SIMPLE FINGER PRICK BLOOD DRAW

The AcuDart tests are the equivalent of the IGeneX Broad Coverage Ab Assays.

Same as IGeneX test #601

Broad Coverage Lyme Ab Assay

Same as IGeneX test #602

Broad Coverage TBRF Borrelia Ab Assay

Same as IGeneX test #609

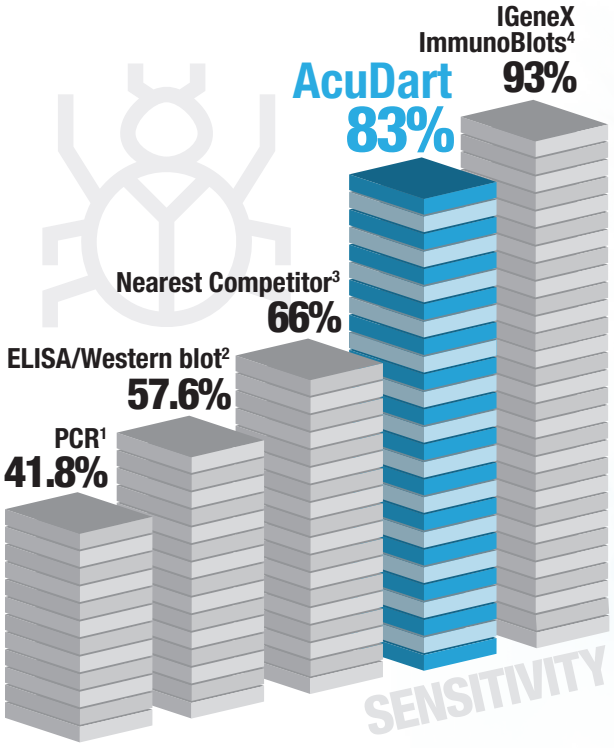
Broad Coverage Babesia Ab Assay

Same as IGeneX test #611

Broad Coverage Bartonella Ab Assay

ACUDART STANDS TALL

The AcuDart Lyme disease test has a sensitivity of just above 80%, which is considerably higher than PCR, the ELISA/Western blot two-tier protocol, and tests from specialty labs.



Sources

1. The Lyme Disease Polymerase Chain Reaction Test Has Low Sensitivity (Nigrovic et al., 2020)
2. The Accuracy of Diagnostic Tests for Lyme Disease in Humans (Waddell et al., 2016)
3. An Ultra-High-Density Protein Microarray for High Throughput Single-Tier Serological Detection of Lyme Disease (Jayaraman et al., 2020)
4. Pilot Study of Immunoblots with Recombinant Borrelia burgdorferi Antigens for Laboratory Diagnosis of Lyme Disease (Liu et al., 2018)

ACUDART VS. IGENEX IMMUNOBLOTS

	ACUDART	IGENEX IMMUNOBLOTS
Detects multiple species	✓	✓
More inclusive than standard serologies	✓	✓
Better than two-tier ELISA/WB	✓	✓
Uses recombinant proteins	✓	✓
Detects all stages of disease	✓	✓
Provides species-specific information	✗	✓
Reports IgM and IgG antibodies	✗	✓
Includes band information	✗	✓

STOCK YOUR OFFICE WITH ACUDART KITS.
BUY IN BULK AND SAVE 15%!

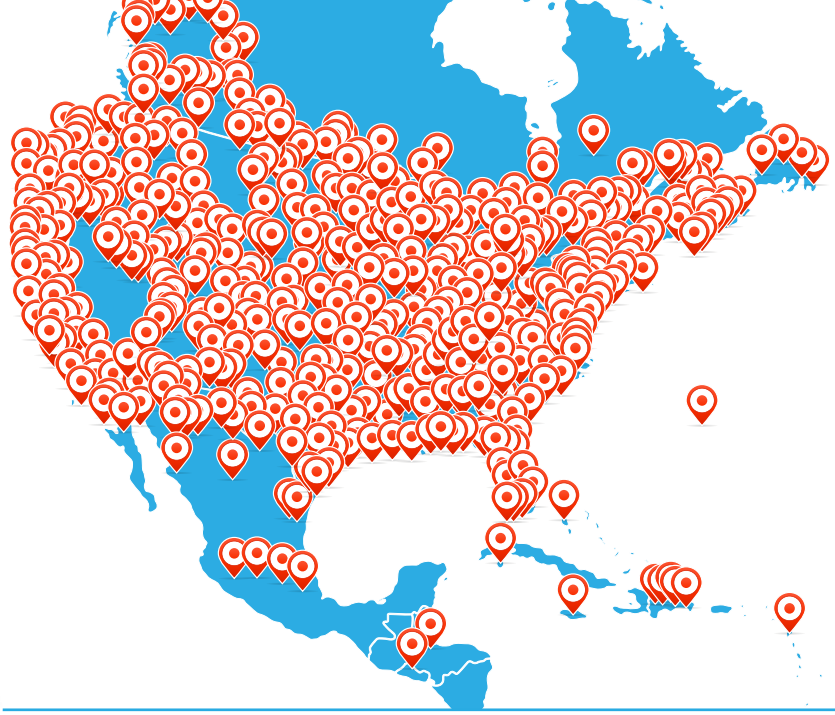
For more information on AcuDart tests, please visit **acudarthealth.com**

IGeneX Inc. AcuDart™

WHY IGENEX?

TRUSTED BY DOCTORS

IGeneX is at the forefront of research and development of diagnostic testing for Lyme disease and other infectious diseases. The company's expansive molecular and immunological test menu, technical expertise, and patient-first approach have made them the choice of many healthcare providers. Over 10,000 doctors across North America put their trust in IGeneX to deliver timely, reliable results.



LOVED BY PATIENTS

Patient health is the #1 priority for IGeneX. Since 1991, IGeneX has tested thousands of patients across all of the major tick-borne illnesses. Many of these patients have spent years of their life, and staggering amounts of money, trying to get the right diagnosis before coming to IGeneX. Our goal is to provide the most accurate and complete detection, early in the patient's journey.

THE MOST COMPREHENSIVE TESTING

No other lab can do what IGeneX can do. IGeneX provides multiple direct and indirect tests for each of the major tick-borne diseases. Multi-Species ImmunoBlots, LSA, IgXSpot, BCA and IFA are indirect tests, and measure the immune system's response to an infection. PCR, cePCR and FISH are direct tests, which identify the pathogen.

AVAILABLE IGENEX TESTS

DISEASE	TESTS
Lyme disease	Multi-Species ImmunoBlots, Serology, IgXSpot, LSA, PCR, BCA, cePCR
TBRF	Multi-Species ImmunoBlots, PCR, BCA, cePCR
Bartonellosis	Multi-Species ImmunoBlots, IgXSpot, IFA, FISH, PCR, cePCR
Babesiosis	Multi-Species ImmunoBlots, IFA, FISH, PCR, cePCR
Rickettsiosis	IFA, PCR, cePCR
Ehrlichiosis	IFA, PCR, cePCR
Anaplasmosis	IFA, PCR, cePCR

FULLY LICENSED

IGeneX is certified by CLIA to perform high-complexity tests in all 50 states. IGeneX also holds licenses and permits for individual states that require separate state licensures. Including New York. This demonstrates that IGeneX meets the quality of standards at state and federal levels.

Clinical Laboratory Improvements Amedments

New York

Get started with IGeneX

Getting started ordering from IGeneX could not be easier. In fact, there is no need to even contact IGeneX to set up an account. An account will be created for you automatically when you order your first test.

HOW IT WORKS

Step 1
ORDER COLLECTION KITS

Physicians can order any of the IGeneX collection kits (Blood kits are used in more than 90% of tests) in bulk, free of charge, to distribute to their patients by calling 1-800-832-3200 or visiting igenex.com.

Step 2
COMPLETE PAPERWORK

The kits will include a Test Requisition Form (TRF) that you'll need to complete with your patient.

Step 3
DRAW SPECIMEN & SHIP

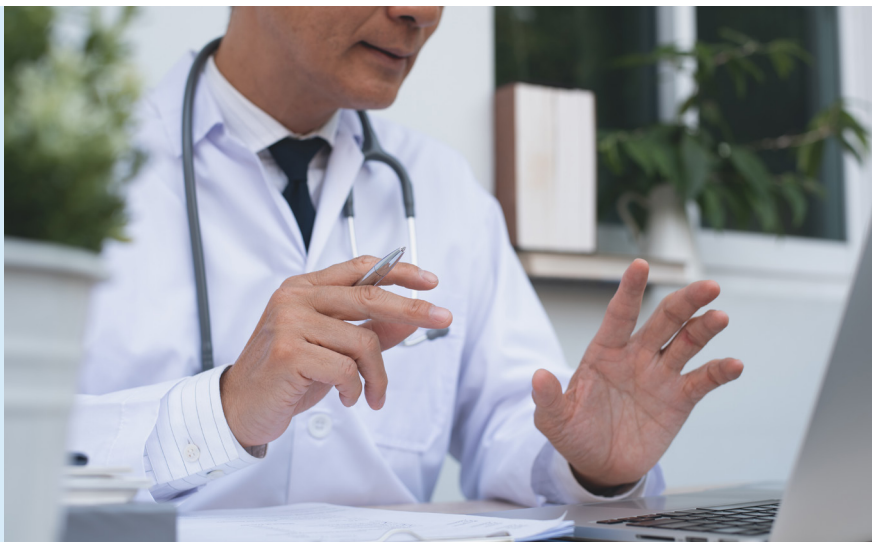
Have your patients take the kit and all completed contents to a blood draw site. A prepaid FedEx shipping label is included with the kit for returning to IGeneX.

Step 4
GET RESULTS

Once your patient's kit is received, IGeneX will conduct the appropriate tests. Completed test results will be sent directly to you, and also be accessible in the Physician Portal.

IGENEX PHYSICIAN PORTAL

Do you want instant access to patient results? The IGeneX physician portal is a great HIPAA-compliant online resource that provides physicians access to real-time clinical information on their patients. This easy, free, and convenient web-based platform provides physicians with the information they need to deliver superior care to patients.



Better
Outcomes
Through
Better
Testing

TO LEARN MORE
CONTACT IGENEX

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