

### WHY PANEL TESTING

The ticks that transmit Lyme disease may also harbor other pathogens, hence there is a need for testing for groups of illnesses. For example, we now know that the TBRF group of Borrelia can cause an illness with symptoms similar to Lyme disease. In addition, more than 30% of patients have mixed infections. We have also found that there are cases in which patients have a positive Lyme IFA or C6 test, are negative by all other Lyme tests, but some may be positive by TBRF testing. Therefore, PCR and ImmunoBlot tests for TBRF have been developed and are now being offered by IGeneX. Lyme and TBRF testing can be ordered as combined Panels for both cost savings and more accurate diagnosis. Some of these panels include both direct and indirect testing.

### **COMPREHENSIVE TESTING**

Comprehensive testing at IGeneX provides patients with multiple options and the best chance at obtaining a defined diagnosis at every stage of infection. The ImmunoBlots, Western Blots, and IFAs are serologic tests, detecting antibodies and the response to an infection. For those who do not produce antibodies or are sero-negative, IGeneX offers PCR, IGXSpot and FISH testing.

Testing for *Borrelia* infections at IGeneX is more complete than available anywhere else. Our in-house developed tests cover a wider spectrum of *B. burgdorferi* species and Tick Borne Relapsing Fever *Borrelia* (TBRF) species which allows us to detect most *Borrelia* causing Lyme and TBRF infections in the United States, Canada, Europe, and Australia.



### **WHY IGENEX**

For over 25 years, IGeneX has been at the forefront of research and development of diagnostic tests for Lyme disease, Relapsing Fever, and other tick-borne diseases. We have a dedicated in-house research and development team of tick-borne disease experts who are committed to developing the most precise and effective diagnostic tests for more relevant species and strains of tick-borne pathogens than any other lab.

In addition, we are hands-on and have developed our in-house testing criteria for Lyme disease and other tick-borne diseases, based on decades of evidence and validation studies. Most labs use Lyme disease testing criteria that were developed in 1994, when much less was known about the disease and its pathogens.

The mission of IGeneX is to aid practitioners in the diagnosis of tick-borne illnesses by providing the most comprehensive testing possible. Ask your doctor about IGeneX or visit igenex.com for more information.

IGeneX Inc.



Ask your doctor about IGeneX or visit **igenex.com** for more information

## LYME DISEASE

# ONE OF THE MOST OFTEN MISDIAGNOSED DISEASES

The resemblance of symptoms to those of other illnesses, as well as the difficulty of detecting the bacteria with most lab tests, makes Lyme disease difficult to diagnose. IGeneX offers the most comprehensive testing solutions.

#### THE SIGNS & SYMPTOMS

Known as the "Great Imitator", Lyme disease, caused by the *Borrelia burgdorferi* group can masquerade as ALS, MS, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Fibromyalgia, Alzheimer's, Parkinson's, Autism, and other illnesses. According to the CDC, there are over 329,000 new cases of Lyme disease every year. However, many more cases go unreported or patients are misdiagnosed because of overlapping symptoms with other ailments.

- Early in the disease: some patients report flu-like symptoms: fever, chills, headache, fatigue, muscle and joint aches, swollen lymph nodes.
- 3 to 30 days after the bite: characteristic red, bulls-eye rash (erythema migrans) may appear.
- Days to months after the bite: migratory pain and/or pain in the tendons, muscles, and bones may occur. Some patients experience heart palpitation/irregular heartbeat, shortness of breath, severe headaches and neck stiffness. Arthritic symptoms, if present, usually affect the large joints like the knees.
- In some cases there are nervous system abnormalities including but not limited to, short-term memory loss, psychiatric symptoms, partial facial paralysis (Bell's palsy), nerve pain and numbness or tingling in the hands or feet.





# BORRELIOSIS TESTS: LYME DISEASE & TICK-BORNE RELAPSING FEVER (TBRF)

Some of the *Borrelia* (e.g. *B. miyamotoî*) that cause Tick-Borne Relapsing Fever (TBRF) are transmitted by the same tick(s) that transmits *B. burgdorferi*, the causative agent of Lyme disease. Both diseases display many similar symptoms, and therefore, when considering Lyme disease testing, it is very important to test for TBRF as well. IGeneX offers comprehensive Borreliosis test panels. The tests below highlight some of the main tests ordered by doctors:

- ImmunoBlot IgG and IgM tests for Lyme and TBRF, visualize specific patient antibodies. Uses pure, recombinant protein antigens to test for the presence of antibodies to Lyme and TBRF.
- **IGXSpot for Lyme** is an Enzyme-Linked ImmunoSpot assay that detects human T cells, reactive to *B. burgdorferi* specific antigens in vitro.
- PCR (Polymerase Chain Reaction) tests for Lyme and TBRF, detect the presence of bacterial DNA in a patient's clinical sample.

### OTHER AVAILABLE TESTS

The ticks that may transmit Borreliosis also carry other diseases, known collectively as co-infections. IGeneX offers testing for most of these co-infections, and is currently the only lab to offer multi-species *Bartonella* Western Blots. Species detected include *B. henselae*, *B. quintana*, *B. elizabethae*, and *B. vinsonii*.

IGeneX provides multiple types of tests for each disease to cover the full spectrum of possible illnesses.

- Borreliosis Tests:
  - Lyme Tests ImmunoBlots, IGXSpot, Western Blots, IFA, Serology, PCR, LDA
  - TBRF Tests ImmunoBlots, IFA, PCR
- Babesia Tests IFA, FISH and PCR.
- Bartonella Tests IGXSpot, Western Blots, IFA, FISH, PCR
- Ehrlichia Tests IFA, PCR
- Rickettsia Tests IFA, PCR
- C. pneumoniae Tests ELISA

Additional tests available include CD57 counts and C6 Peptide.