

# LYME IMMUNOBLOTS

## GET FDA CLEARANCE



The Lyme disease IgM and IgG ImmunoBlot tests currently offered at IGeneX as laboratory-developed tests (LDTs) have been converted to test kits. These kits have received clearance from the FDA. Having FDA clearance further validates the Lyme IgM and IgG ImmunoBlots as superior choices for detecting Lyme disease.

### ADVANTAGES OF THE IGENEX IMMUNOBLOT

- ✓ Allows for identification of a broad range of species
- ✓ Detects multiple species in one test
- ✓ Detects the full spectrum of disease: early, active, and late-stage disease
- ✓ Can be made genus and species-specific
- ✓ Avoids the need to visualize glass slides through a microscope
- ✓ Renders Western blot and IFA obsolete



#### **Making an ImmunoBlot**

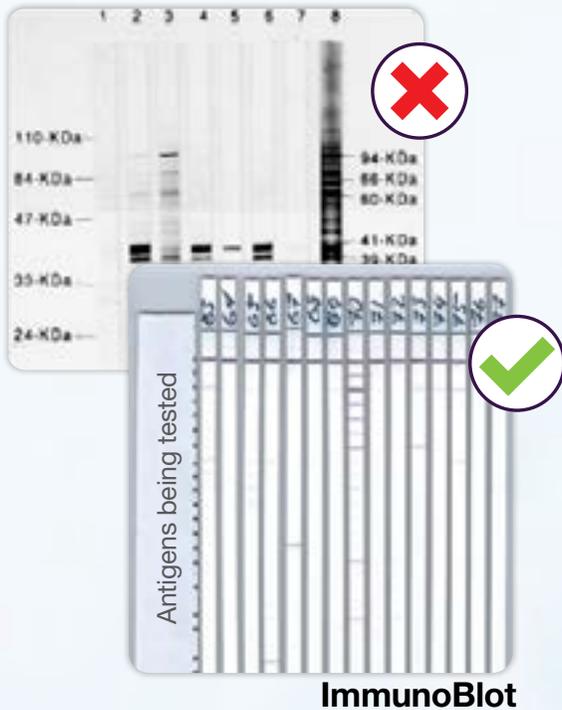
Quantity and location of the antigens are controlled by a printing-like process, improving consistency and specificity.

IGeneX clinical scientists mix a patient's sample with the ImmunoBlot strip to perform the test. A dark purple colored precipitate develops on the antigen-antibody complexes. A sample is considered positive for if two or more bands are present.

## THE DIFFERENCE IS CLEAR

The ImmunoBlot replaces the Western blot. Western blots are blurry, difficult to read, and lead to misdiagnosis. ImmunoBlots are clear, precise, and much easier to interpret.

### Western blot



## FAR BETTER THAN A COIN FLIP

Common Lyme two-tier testing has a sensitivity of just above 50% because it detects only one *Borrelia* species, *B. burgdorferi* B31.

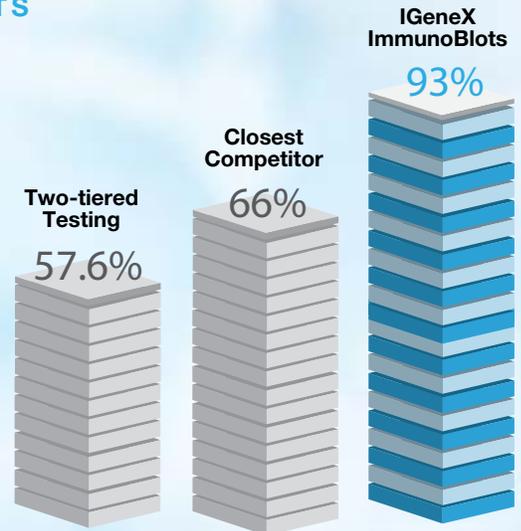
The IGeneX ImmunoBlot detects antibodies to nine different species of *Borrelia*.

### STANDARD TESTS

✓ *B. burgdorferi* B31

### IGENE X IMMUNOBLOT

- ✓ *B. burgdorferi* B31
- ✓ *B. burgdorferi* 297
- ✓ *B. californiensis*
- ✓ *B. mayonii*
- ✓ *B. afzelii*
- ✓ *B. garinii*
- ✓ *B. spielmanii*
- ✓ *B. valaisiana*
- ✓ *B. bissettii*



#### Sources

*The Accuracy of Diagnostic Tests for Lyme Disease in Humans, A Systematic Review and Meta-Analysis of North American Research.* PLoS ONE 11(12): e0168613.  
*Pilot Study of Immunoblots with Recombinant Borrelia burgdorferi Antigens for Laboratory Diagnosis of Lyme Disease.*  
*The Lyme Disease Polymerase Chain Reaction Test Has Low Sensitivity.* Vector Borne Zoonotic Dis.

## IGENE X IMMUNOBLOTS ARE AVAILABLE FOR FOUR DISEASES

### Tick-Borne Relapsing Fever (TBRF) ImmunoBlot

Some of the *Borrelia* that causes TBRF are transmitted by the same ticks that transmit *B. burgdorferi*, the causative agent of Lyme disease. Therefore, it is crucial to test for both TBRF and Lyme. The TBRF ImmunoBlot detects antibodies to species from North America, European and Australian strains. The most common species are *B. miyamotoi*, *B. hermsii*, and *B. turicatae*.

### Babesia ImmunoBlot

Babesia is the most common Lyme disease co-infection, and therefore testing is recommended if testing your patients for Lyme. The IGeneX Babesia ImmunoBlot tests for the Babesia genus and speciates to multiple species of Babesia that infect humans, including *B. microti* and *B. duncani*.

### Bartonella ImmunoBlot

Diagnostic tests for Bartonella, such as IFA, have not been able to detect many of the ever-growing list of species and strains. The Bartonella ImmunoBlots are designed to detect IgM and IgG antibodies to multiple Bartonella species including *B. henselae*, *B. quintana*, *B. elizabethae*, and *B. vinsonii*.

### Lyme ImmunoBlot

The IGeneX Lyme ImmunoBlot detects antibodies to nine different species of *Borrelia*: *B. burgdorferi* B31, *B. burgdorferi* 297, *B. californiensis*, *B. mayonii*, *B. afzelii*, *B. garinii*, *B. spielmanii*, *B. valaisiana*, and *B. bissettii*. By testing for more species than the traditional ELISA and Western blot tests, the ImmunoBlot reduces the risks of false negatives.

CONTACT IGENEX TODAY TO LEARN MORE ABOUT TESTING WITH THE IMMUNOBLOT  
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