

### **TEST SPECIFICS**

	NEW! BROAD COVERAGE LYME AB ASSAY	WESTERN BLOT	MOST POPULAR! IMMUNOBLOT
Band Information	No	Yes	Yes
IgM and IgG Info	No	Yes	Yes
Antibody Test	Yes	Yes	Yes
Result Reported	Pos/Neg	Bands for IgM and IgG individually. Pos/Neg CDC and IgX criteria	Bands for IgM and IgG individually. Pos/Neg CDC and IgX criteria
Indeterminate Results	No	Yes	No
Epitope Confirmatory Test Required	No	Yes	No
Speciation	No	No	Yes*
PRICE	\$195 <sup>*†</sup>	\$250 <sup>†</sup>	\$450 <sup>†</sup>

\* Not available for NY patients

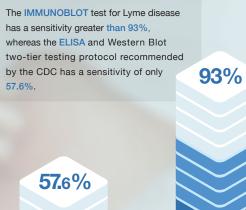
† Before panel discounts

Thousands of patients with Lyme-like symptoms are misdiagnosed, as existing serological tests cannot accurately identify antibodies of all the different strains of Lyme *Borreliae*. Only IGeneX has the technology and experience to overcome these challenges, and only IGeneX has the family of tests to meet the needs of every patient.



# UNPARALLELED LYME DISEASE TESTING

Lyme disease is one of the fastest-growing infectious diseases in the United States. IGeneX has developed several industry-leading tests that measure antibody response to Lyme *Borreliae*, the causative agent of Lyme disease. Our ImmunoBlot test (see right) has a sensitivity rate that is nearly double that of the standard two-tier testing protocol established by the CDC. When used in conjunction with clinical symptoms and patient history, IGeneX tests can better assist physicians in accurately diagnosing patients.



**ELISA**WESTERN BLOT



## **NEW!** BROAD COVERAGE LYME AB ASSAY

- Far broader and more inclusive of Lyme Borreliae species than standard serologies
- Better than two-tier ELISA/WB and two-tier ELISA
- Provides a simple, cost-effective, yes/no result with no complicated interpretation necessary

PRICE: \$195\*†
TEST NUMBER: 601
CPT CODE: 0042U

#### WESTERN BLOT

- A relatively inexpensive method to detect Lyme Borreliae-specific antibodies and to monitor stage of disease
- Specific, which means that most of the time it will be positive only if a person has been truly infected
- Still the best western blot on the market, made with two strains of Bb

PRICE: \$250<sup>†</sup>
TEST NUMBER: 188, 189
CPT CODE: 86617

# MOST POPULAR! IMMUNOBLOT

- 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

PRICE: \$450<sup>†</sup>
TEST NUMBER: 325, 335
CPT CODE: 86618

Better Outcomes Through Better Testing



### PROGRESSION OF LYME DISEASE TESTING

#### APPLYING MODERN DAY TECHNOLOGY TO A COMPLEX DISEASE

CDC criteria for Lyme disease testing has not changed since 1994.

1975 1982-1994 1994 1997 1998 1981-1982 The CDC recognizes Lyme disease Scientist Willy Burgdorfer discovers IGeneX releases an improved Lyme disease first reported in the Two-tier testing protocol of **IGeneX** introduces Lyme town of Old Lyme, CT B. burdorferi, the causative agent from a set of clinical symptoms, as Multiplex PCR ELISA/western blot established western blot made with two strains of Lyme disease the first-generation assays developed by the CDC of Borrelia: B. burgdorferi B31 and to detect B. burgdorferi antibodies B. burgdorferi 297. The standard often lacked accuracy western blot is made with only B. burgdorferi B31.

2008 2007 2005-2006 2003 1998-2002

300k cases of Lyme disease diagnosed in the US

**IGeneX** introduces Epitope test to improve specificity of the Lyme western blot New strains of *Borrelia* discovered in the US: *B.* spielmanii, *B. californiensis*, and *B. texasensis* 

200k cases of Lyme disease diagnosed in the US

New strains of *Borrelia* discovered in Europe: *B. afzelii*, *B. garinii*, and *B. valaisiana* 

2013 2016 2017 2019 2020

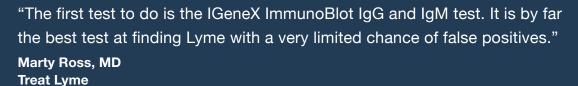
B. miyamotoi, B. americana and B. andersonii are discovered in the US, heightening the urgency for tests to be able to detect multiple or different species of Borrelia

B. mayonii, discovered by the Mayo Clinic, and a B. bissettii-like strain are found in the US

IGeneX begins offering a
Multi-Species Lyme ImmunoBlot
test, which is inclusive of multiple
strains of Borrelia

IGeneX releases a new Lyme test, the Broad Coverage Lyme Ab Assay, that offers the multi-species capability of the ImmunoBlots at a more affordable price. IGeneX continues significant investment in R&D to advance testing across the major tick-borne diseases







"Your patients are not seronegative. You ordered a test that is not picking up additional strains and species of Lyme *Borrelia*."

Joseph Burrascano, MD Southold, NY, USA