

New York State Grants Approval of IGeneX's Newly Developed Lyme ImmunoBlot Tests

Lyme ImmunoBlots (IgM and IgG) represents quantum leap in test performance over the traditional B. burgdorferi Western blots.

PALO ALTO, Calif. -- IGeneX Inc., The Division of Laboratories of the Department of Health of the State of New York has approved IGeneX's newly developed Lyme ImmunoBlots (IgM and IgG), making it immediately available to New York practitioners.

Now, instead of sourcing test antigens from only one or two species of sonicated *Borrelia*, the ImmunoBlot is comprised of specific recombinant antigens from several species of *Borrelia burgdorferi*. The ImmunoBlot therefore detects multiple US and European species of Lyme *Borrelia*, making the P31 epitope confirmation test unnecessary.

To test for all the *Borrelia burgdorferi* species by Western blots, eight individual IgM and eight individual IgG tests are required. Performing 16 Western blots on each patient sample is expensive and impractical, as opposed to just two tests with the Lyme ImmunoBlots.

"The Lyme ImmunoBlot is intentionally more inclusive for *Borrelia burgdorferi* than the currently available Western blots because we now know that other species all cause disease in the US," said Dr. Jyotsna Shah, CEO of IGeneX. "With the increase of international travel in the last 10 years, people can get infected at home, other parts of the US or Europe depending on his or her lifestyle. Thus, it is important to have available a test that can detect the infection irrespective of where it was acquired."

More Comprehensive Detection

The Lyme ImmunoBlot IgM detects the five following recombinant protein groups: P93, P41, P39, P31, and P23. Furthermore, the Lyme ImmunoBlot IgG detects these twelve recombinant protein groups: P93, P66, P58, P45, P41, P39, P34, P31, P30, P28, P23, and P18.

High Accuracy Across the Disease Spectrum

The accuracy of the Lyme ImmunoBlot has been established by exhaustive testing. The sensitivity with well-characterized samples has been shown to be greater than 93% whereas the two-tier testing recommended by CDC has a sensitivity of about 57.6% (Waddell LA et al. *PLoS ONE*. 2016;11(12):e0168613. doi:10.1371/journal.pone.0168613). Additionally, the ImmunoBlots detect the full spectrum of disease: early, active and late-stage disease. This high degree of sensitivity does not come

at the cost of specificity. The specificity of the Lyme immunoblot is equivalent to CDC 2-tier testing (ELISA or IFA followed by Western blots).

New York State Department of Health Approval

The Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health has approved the IGeneX Lyme ImmunoBlot (<https://www.wadsworth.org/igenex-inc-reference-laboratory-12>), making it available to all qualified New York practitioners and their patients. IGeneX works swiftly to ensure that this remarkable test can be utilized immediately.

The Wadsworth Center, a division of New York State Department of Health, is a science-based community committed to protecting and improving the health of New Yorkers through laboratory analysis, investigations, and research, as well as laboratory certification and educational programs. The Center serves a vital role in the New York State Department of Health's efforts to protect and promote the health of New York's citizens.

About IGeneX

For over 25 years, IGeneX has been at the forefront of research and development of diagnostic testing for Lyme disease, Relapsing Fever, and other tick-borne diseases. IGeneX arms its talented scientists with the most cutting-edge technology available to enable them in finding new solutions that challenge the status quo of testing for Lyme and associated tick-borne diseases. This team of experienced, hands-on experts develops these tests in-house using a wider spectrum of relevant proteins and strains that look for and detect more. The mission of IGeneX is to aid practitioners in their diagnosis of tick-borne illnesses by providing the most comprehensive testing possible. Learn more at: www.IGeneX.com

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