

**BREAKTHROUGH LYME DISEASE TEST IS THE “NEXT GENERATION” OF DIAGNOSTICS; CROWD FUNDING CAMPAIGN LAUNCHES TO START CLINICAL STUDY**

PHOENIX, Ariz. (Feb. 27)— A new test for Lyme Disease may prove to be the most accurate tool available for the difficult-to-diagnose disease, giving hope to thousands of undiagnosed and misdiagnosed patients, if funding can be found to move it through clinical study to production.

This new test, called LymeSeq, has been described as the “next generation” of Lyme diagnostics, and is poised to transform the speed and precision of diagnosis over current tests. This test will detect multiple strains of Lyme bacteria, plus all major co-infections and non-Lyme causes of disease like Influenza and *Staph*.

The CDC reports about 300,000 cases of Lyme Disease annually, while others believe the real numbers are much higher due to lack of awareness and reliable testing.

LymeSeq, developed by research scientists at Translational Genomics Research Institute (TGen), has been funded by Focus On Lyme. The test may represent a breakthrough in diagnosis and testing for Lyme disease, which is currently about 50 percent accurate.

After five years shuttling her daughter to doctor visits across the country and intense antibiotic treatments to battle this disease, Focus On Lyme Executive Director Tammy Crawford got in touch with TGen. Knowing the institute’s experience using genetic sequencing to identify pathogens like tuberculosis and *E. coli*, Crawford asked if TGen could do the same for Lyme disease and when they said yes, she founded Focus on Lyme and personally funded the initial research.

The researchers are led by Dr. Paul Keim, the Executive Director of the Pathogen and Microbiome Institute and the Cowden Endowed Chair of Microbiology at Northern Arizona University (NAU), as well as Director of the Pathogen Genomics Division of TGen (TGen North in Flagstaff, Ariz.). Dr. Keim is an internationally recognized expert in DNA-based research methods, a fellow of the American Academy of Microbiology, and a fellow of the American Association for the Advancement of Science.

Crawford says current tests are “akin to a coin toss,” because typical tests for Lyme are insensitive and rely on a serological response. Some patients may test negative because there may not have been time for antibodies to develop; or their immune system may be suppressed; or because the bacteria that causes Lyme has the ability to hide from the body’s immune defenses.

“Together, we’ve developed a test we believe will change the lives of millions. With early detection, we may actually impact even more lives - all the more reason to start human trials as soon as possible,” Crawford said.

LymeSeq works by targeting and amplifying specific regions of the Lyme bacteria’s DNA as well as specific genes in related bacteria. That amplified DNA gets sequenced, then researchers determine the bacterial species present in the sample by searching for the DNA code specific to Lyme or other bacteria, explained Dr. David Engelthaler, Director of Programs and Operations at TGen North, and Director of the Public Health and Translational Genomics Center at the Pathogen and Microbiome Institute.

“LymeSeq has the potential to transform emergency rooms and doctor’s offices world wide, said Holly Ahern, MS, MT (ASCP) and SUNY Adirondack associate professor of microbiology, and a member of the leadership team at Focus on Lyme.

Dr. Richard Horowitz, author of "How Can I Get Better? An Action Plan for Treating Resistant Lyme and Chronic Disease," and presenter at the Focus on Lyme Scientific Conference last week said, “more than ever, we need an accurate test for Lyme disease or chronically ill patients will continue to be mis-diagnosed. Horowitz referenced the National Science Foundation’s identification of Lyme disease as an emerging pandemic threat with global implications for health, economies and human life, citing the current “problematic two-tiered testing scheme,” for which LymeSeq shows promise of being “superior in every way.”

With exciting early signs of high accuracy, the next step is to advance the test into human trials. After seeding the funding with \$75,000 her own money, Crawford formed Focus On Lyme after months of undiagnosed Lyme left her athletic daughter in a wheelchair. A chance encounter on a plane introduced Crawford, desperate for answers, to TGen. Since then, her team of volunteers has raised more than \$301,730 towards a goal of \$500,000 to bring the test to market. BHHS Legacy Foundation recently stepped forward with an additional \$100,000 in grant funding.

“With the development of any new medical advancement, the steps are long, arduous and expensive. But we’ve come so far in such a short period of time, we need your help to get us to the finish line,” Crawford said. “We are all volunteers. Every single penny we raise goes towards the research, we keep nothing back.”

**For more information about Focus On Lyme and the diagnostic test, visit [www.focusonlyme.org](http://www.focusonlyme.org). To donate, visit: [www.focusonlyme.org/donate](http://www.focusonlyme.org/donate)**

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#### **About Focus On Lyme**

Focus On Lyme was formed in 2015 to discover solutions in diagnostics, prevention, treatment and advocacy for Lyme disease sufferers. The best Lyme diagnostic tools that exist today are only 50 percent accurate and for those that are correctly diagnosed, there is not an accurate tool to evaluate the effectiveness of their treatment. Focus On Lyme is striving to provide immediate diagnosis and treatment to Lyme patients worldwide delivering a higher quality of life and minimal long-term effects. Focus on Lyme is currently funding a research project with Translational Genomics Research Institute (TGen) for a diagnostic tool for Lyme showing promise of near 100 percent accuracy in the lab. The test is scheduled to begin human trials in early 2017. If successful, the test would transform the speed and accuracy over current tests, which are “akin to a coin toss,” and could have an impact on millions of lives around the globe.

Focus On Lyme is sponsored by Leadership Children's Foundation, a non-profit organization dedicated to helping children by donating money to causes that help preserve childhood and improve the quality of life for young people across the nation. Funding for our research comes from the generous donations of individuals and organizations, to donate please visit <http://focusonlyme.org/donate/>

For more information, visit: [www.focusonlyme.org](http://www.focusonlyme.org).

**Media Contact:**

Tony Felice  
480-567-6890  
[tony@felicewhitney.com](mailto:tony@felicewhitney.com)