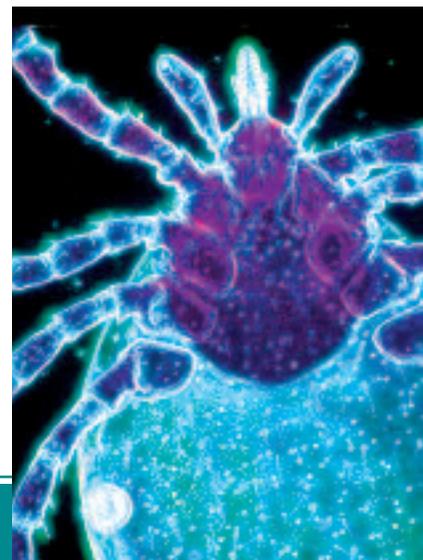


The C6
Lyme
ELISA from
Immunitics®:

- 1 Most Accurate
- 2 Fastest
- 3 Most Economical



The C6 Lyme ELISA from Immunetics® is, quite simply, the most accurate Lyme ELISA available, producing fewer false positives and false negatives than your current screening assay.

In fact, it provides single-test results comparable to the two-tier (ELISA and Western Blot) protocol, the current standard for Lyme serodiagnosis. Now, with the C6 Lyme ELISA, you can provide truly reliable Lyme test results sooner, and with a lower average cost per reported patient result.

1 Most Accurate

Current Lyme ELISA tests are short on specificity. They can generate over 20 percent false positives. This results in either expensive and time-consuming Western Blot confirmatory tests or potential misdiagnosis.

Immunetics' C6 Lyme ELISA is a far more specific assay – demonstrating 98 percent specificity in an average population, a 10-fold improvement over current Whole Cell Sonicate ELISAs.

Also, Immunetics' C6 ELISA is a far more sensitive assay – showing 97 percent sensitivity in comprehensive clinical trials of Lyme patients at every stage of disease. The C6 test correctly detects more patients as positive than other current methods.

And, Immunetics' C6 Lyme ELISA demonstrates superior results across a wide range of patients in all stages of Lyme – from early onset to late stage disseminated infection.

Sensitive at All Stages of Disease

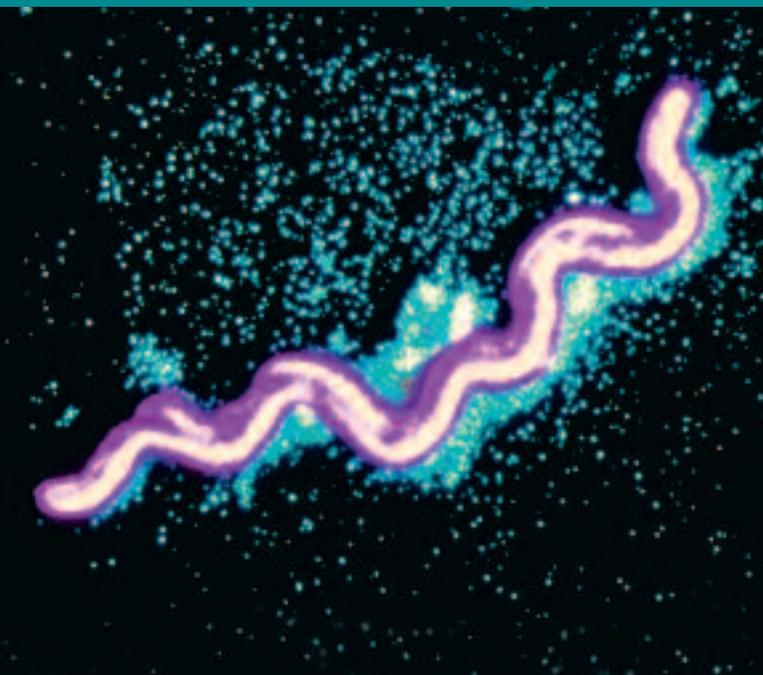
	Months post-onset		
	0-1	>1	>12
C6 Lyme Kit†	100%	93%	98%

Sensitive for All Symptom Groups

	Erythema Migrans	Arthritic	Neuro- logical
C6 Lyme Kit†	96%	99%	96%

† percent sensitivity

This dramatically higher accuracy means superior results and improved patient care.



2

Fastest

The two tier protocol recommends that all positive ELISA results be confirmed by a Western Blot test. However, current ELISA assays produce a large number of false positives, resulting in many time-consuming confirmatory tests which can delay reporting of results. The superior specificity of the C6 Lyme ELISA minimizes false positives, thereby eliminating the majority of confirmatory Western Blots. And, with a turnaround time for the C6 test of only one hour, your Lyme disease testing and reporting is significantly streamlined.

3

Most Economical

Confirmatory Western Blot tests are labor-intensive, expensive, and consume valuable lab and administrative resources. By eliminating 90 percent of false positive ELISA results, the C6 Lyme ELISA eliminates the cost of the unnecessary Western Blot tests. And this significantly reduces the average cost per reportable patient result.

How is this superior performance accomplished?

Immunitics has pioneered the use of the C6 peptide*, a 26-amino acid sequence within the *Borrelia* membrane protein VlsE. This is the first truly specific and sensitive marker for infection with the *Borrelia burgdorferi* spirochete. The C6 peptide sequence is highly antigenic, generating an immune response in nearly all human cases soon after infection, and it is specific to *Borrelia* strains causing Lyme disease. It is not found in other infectious organisms, eliminating cross-reactivity at the source.

U.S. Patents #s 6,475,492; 6,719,983; 6,740,744

Immunitics' C6 test uses a synthetic version of this peptide, which makes possible a highly sensitive, specific and reproducible ELISA for infection with the *B. burgdorferi* spirochete.

Current ELISA tests do not match the specificity or sensitivity of Immunitics' C6 ELISA because they are based on Whole Cell Sonicates (WCS) containing multiple antigens, leading to cross-reactivity and inaccurate or ambiguous results.

Easy to use

Along with superior performance, Immunitics' C6 Lyme ELISA offers a rapid and easy to use protocol. Turnaround time is approximately one hour, and tests can be run on automated ELISA systems or manually.

C6 test kits include:

- ◆ Ready to use reagents
- ◆ 96 well breakaway plate
- ◆ Controls
- ◆ One hour protocol

The C6 Lyme ELISA from Immunitics...

setting a new standard in Lyme test accuracy, and delivering more reliable results sooner and more economically than any other ELISA.



For more information call: 1 800-227-4765 Or login to: www.immunitics.com/c6

Immunetics® C6 *B. burgdorferi* (Lyme) ELISA™ Kit
Cat. No. – DK-E352-096
96 Tests
For In Vitro Diagnostic Use

Intended Use

The Immunetics C6 *B. burgdorferi* (Lyme) ELISA Kit is intended for use in the presumptive detection of IgG and IgM antibodies to *B. burgdorferi* in human serum. The assay should be used only on samples from patients with clinical history, signs or symptoms consistent with *B. burgdorferi* infection. Positive or equivocal results should be supplemented by testing with a standardized Western Blot (second step) method. Positive Western Blot results provide evidence for exposure to or infection with *B. burgdorferi*.

The diagnosis of Lyme disease must be made based on history, signs (such as erythema migrans), symptoms, and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first or second step) should not be used to exclude Lyme disease.



Immunetics®

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