



Immunitics[®] Partnering With

DIA MEDIX[®]
A Subsidiary of IVAX Diagnostics, Inc.

Are Proud To Offer...

C6 *B. burgdorferi* (Lyme) ELISA™ Kit

A new standard in accuracy

Immunitics introduces a new *B. burgdorferi* (Lyme) ELISA kit* based on the C6 peptide of the VlsE protein, offering a quantum leap forward in accuracy.

Cat. No. DK-E352-096
For In Vitro Diagnostic Use

Principle

This ELISA is based on the C6 peptide antigen*, a 26 amino acid sequence of the surface protein VlsE. This peptide has been shown to represent the immunodominant portion of VlsE, containing substantially all of the antigenic reactivity of the whole protein. Recent studies have shown that the C6 peptide is a sensitive and specific marker for antibody to *B. burgdorferi sensu lato* and for the serodiagnosis of Lyme disease.

As the C6 antigen represents a defined sequence within the protein, cross-reactivity with antigens found in other organisms is greatly reduced.

*U.S. and foreign patents pending

Features and Benefits

- Accurate
 - Near Western Blot accuracy in an ELISA
- Sensitive
 - More sensitive in detection of antibodies in early and late Lyme disease than competing kits
- Specific
 - Eliminates vast majority of other ELISA's false positives at the screening step
 - Significantly higher specificity than competing ELISAs
- Broadly applicable
 - Detects infection with all strains of *Borrelia* which cause Lyme disease, including European strains *B. garinii* and *B. afzelii*
- Convenient
 - 1 hour turnaround time
 - Breakaway strips for any number of samples
 - Ready-to-use reagents, controls included
- Cost-effective
 - Greatly reduces the number of samples sent for expensive confirmatory testing

Performance Data

The C6 Lyme ELISA kit eliminates the majority of false positive ELISA results, greatly reducing the number of samples requiring supplementary Western Blot testing:

Prospective screening results for 191 patient sera sent for Lyme testing:

	<u>Pos/Eqv</u>	<u>Neg</u>
C6 Lyme kit	2.1%	97.9%
WCS (whole-cell sonicate)ELISA	23.6%	76.4%

Results of re-testing by Lyme Western Blot:
Distribution of 21 Western Blot-negative samples:

	<u>Pos/Eqv</u>	<u>Neg</u>
C6 Lyme kit	2	19
WCS ELISA	21	0

C6 ELISA results match Western Blot results:

		<u>Western Blot</u>	
C6	<u>Pos/Eqv</u>	<u>Pos</u>	<u>Neg</u>
		95%	1.7%
	<u>Neg</u>	1.1%	2.2%

n= 180

Concordance with WB = 97.2%

The C6 Lyme ELISA Kit outperforms a leading competitor's kit in all categories:

Ultraspecific:

	<u>Specificity</u>
C6 Lyme ELISA™	98%
WCS ELISA	94%

Sensitive at all stages of disease:

	<u>Months post-onset</u>		
	0-1	>1	>12
C6 Lyme Kit	100%	93%	98%
WCS ELISA	98%	89%	96%

Sensitive for all symptom groups:

	<u>Erythema Migrans</u>	<u>Arthritic</u>	<u>Neurological</u>
C6 Lyme Kit	96%	99%	96%
WCS ELISA	95%	99%	84%

Non-reactive with Lyme vaccinee sera:

	<u>Pos</u>	<u>Neg</u>
C6 Lyme Kit	0%	100%
WCS ELISA	100%	0%

Products

C6. B. burgdorferi (Lyme) ELISA™
Extra Components for Automation

Catalog#

DK-E352-096
DK-E352-096A

Ordering Information:

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