

Reporting Title: Lyme Disease C6 Ab, Total

Performing Location: Focus Diagnostics,

Specimen Requirements:

Draw blood in a plain, red-top tube(s). Spin down and separate.
Ship 1 mL of serum refrigerated.

NOTE: Serum gel tube is acceptable, but must pour off into plastic vial.

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	14 days
	Ambient	7 days
	Frozen	30 days

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
Z2016	Lyme Disease C6 Ab Index	Alphanumeric		

CPT Code: 1 × 86618

Reference Values:

REFERENCE RANGE: < or = 0.90

INTERPRETIVE CRITERIA:

< or = 0.90 Antibody Not Detected

0.91 - 1.09 Equivocal; submission of a second specimen (collected 3-4 weeks after initial specimen) suggested if clinically warranted.

> or = 1.10 Antibody Detected

This ELISA detects both IgG and IgM antibodies against the C6 peptide derived from the V1sE protein of *Borrelia burgdorferi*, the causative agent of Lyme disease. IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels tend to rise above background levels about 2 to 3 weeks after infection, and may remain elevated in cases of prolonged disease. The C6 peptide antibody ELISA exhibits sensitivity and specificity values greater than 95% for Lyme disease.

As recommended by the Food and Drug Administration (FDA) Public Health Advisory, July 7, 1997), all samples with positive or equivocal results in the Lyme Disease C6 Antibody EIA (Screening) should be tested by Western Blot/Immunoblot.

Positive or equivocal screening test results should not be interpreted as truly positive until verified as such using a confirmatory assay. [e.g. Lyme Disease Antibodies (IgG, IgM), IBL (serum)]. The screening test and/or immunoblot for Lyme disease antibodies may be falsely negative in early stages of Lyme disease, including the period when erythema migrans is apparent.

Test Performed by: Focus Diagnostics, Inc.
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