Cambridge Biomedical

B. burgdorferi IgG and IgM Antibodies in Serum, Plasma or CSF

Specimen Type	Serum or Plasma	CSF
Specimen Volume	1 mL	1 mL
Collection	Serum: Red top tube with no additives serum gel tube. Plasma: Heparin (sodium or lithium) green top tube. Specimens should be collected under aseptic conditions. Allow blood to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes. Separate serum and freeze immediately.	Lumbar puncture into a sterile tube and freeze immediately.
Minimum Volume	0.25 mL	0.3 mL
Handling	Ship frozen on dry ice.	Ship frozen on dry ice.
Rejection Criteria	Hemolyzed specimens. Lipemic specimens. Specimens outside of listed stability.	Hemolyzed specimens. Specimens that have been heated. Specimens outside of listed stability.
Stability	Frozen for 5 months. Refrigerated for 14 days.	Frozen for 5 months. Refrigerated for 14 days.
Methodology	ELISA	ELISA
Reference Range	IgG: Negative = Index < 0.8. IgM: Negative = Index < 0.8.	IgG: Negative = Index < or = 0.09. IgM: Negative = Index < or = 0.06.
Turnaround Time	Up to 7 business days.	Up to 7 business days.
CPT Code	86618 x 2	86618 x 2

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Clinical Significance	Lyme disease is an illness caused by infection with the spirochete *Borrelia burgdorferi*. Transmission occurs through the bite of ticks from the genus *Ixodes*. The first sign of infection is the development of a circular skin rash known as *erythema migrans* at the site of the bite. This occurs in approximately 70% of patients within a few weeks of the initial infection. General flu-like symptoms including headache, abdominal pain, and fatigue may accompany the rash. Within weeks to months the disease may progress to its secondary stage. Symptoms at this stage include musculoskeletal pain, arthritis, neurological abnormalities, and/or cardiac complications. The tertiary phase of the disease is characterized by chronic arthritic attacks affecting the large joints as well as neuro-cognitive defects. Serological testing for Lyme disease usually consists of testing for the IgM antibody which peaks between three to six weeks after the infection, and may persist throughout the course of the disease and may remain elevated for years after clinical remission. The IgG antibody will rise after the initial IgM peak. Neurologic involvement occurs in up to 40% of symptomatic infections. Late disseminated infection may result in encephalopathy (the most common manifestation of chronic neurologic Lyme disease), encephalomyelitis and polyradiculoneuropathy. In the US, 15% of untreated patients have early neurological complications. The vast majority in this country are cranial neuropathy, in particular facial palsy (may be bilateral). 50 to 75% of individuals with early neuroborreliosis have facial palsy. Intrathecal production of antiborrelial antibodies is typically seen within three to six weeks of infection. The detection of antibodies to *Borrelia burgdorferi* in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier. To account for potential leakage of antibody across the blood-brain barrier, the CSF to serum index must be examined. A CSF to serum index of greater than 1.0 suggests synthesis of antibody in the intrathecal space.
Principle	Enzyme Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum or plasma, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG or IgM conjugated with horseradish peroxidase, which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate Tetramethylbensidine (TMB). If specific antibody to the antigen is present in the patient's serum or plasma, a blue color develops. When the enzymatic reaction is stopped with $1NH_2SO_4$, the contents of the wells turn yellow. The color, which is indicative of the concentration of antibody in the serum or plasma, can be read on a suitable spectrophotometer or ELISA microwell plate reader.