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2°C-8°C



Σ= tests



cat.#361010-M

LYME DISEASE IgM ANTIBODY TEST SYSTEM

Catalog #361010-M

For Research Use Only

INTENDED USE

The DAI IFA IgM test system is designed for the detection of IgM antibodies directed against *Borrelia burgdorferi* in the sera of patients suspected of having Lyme disease. This test is intended to be used as an aid in the diagnosis of Lyme disease. This device is for **Research Use Only**.

SIGNIFICANCE AND BACKGROUND

Lyme disease is an immune-mediated disorder caused by the tick transmitted spirochete, *Borrelia burgdorferi* (1,2,3). The disease is complex and progresses in three stages (4). Stage 1 usually begins in the summer, 3 to 32 days after exposure to the spirochete. A characteristic inflammatory skin rash, erythema chronicum migrans (ECM), develops at the site of a tick bite. The rash may be accompanied by fatigue, fever, chills, headache, backache, and hyperplasia of lymphoid organs. As the organism spreads throughout the body, multiple skin lesions may develop. Some patients may not develop any Stage 1 symptoms (15). Weeks to months after exposure, some patients (10-18%) develop meningoencephalitis, cranial or peripheral radiculoneuropathy, or myocarditis associated with Stage 2 disease. Symptoms of Stage 2 include severe headache, stiff neck, facial paralysis (Bell's palsy), and migratory musculoskeletal pain. Some patients may develop palpitations, dizziness, or shortness of breath associated with atrioventricular block (6).

Within several weeks to two years after Stage 1, about 60% of patients develop arthritis (Stage 3). Arthritis in large joints may become chronic in some patients (4). During Stage 3 a few patients may develop somnolence, depression, and impaired memory or concentration.

The Lyme disease spirochete is sensitive to antibiotics and early diagnosis and treatment can shorten the duration of Stage 1 and prevent or ameliorate later complications (4,7).

The incidence of Lyme disease is highest during the tick season which lasts from May to August. Lyme disease occurs primarily in three recognized endemic areas. These areas are the East coast from Delaware to Massachusetts; the Western states of California

Nevada, Oregon, and Utah; and the Midwestern states of Wisconsin and Minnesota. The primary tick vectors are *Ixodes dammini* in the northeast and Midwest, and *Ixodes pacificus* in the west. Recently two additional tick vectors; *I. scapularis* and *Amblyomma americanum* have been identified (14).

Clinical recognition of Lyme disease depends heavily on the presence or history of ECM; a unique marker for Lyme disease. In addition to the clinical features associated with Lyme disease, considerable emphasis on epidemiologic and geographical distribution of the pathogen should be a major consideration in arriving at a diagnosis of Lyme disease, especially in the later stages of disease when the organism is difficult to grow or to demonstrate histopathologically (10, 12).

Enzyme-linked immunosorbent (ELISA), and indirect immunofluorescent assays, which measure circulating antibody levels against the infecting spirochete, have been developed for the diagnosis of Lyme disease (8-13). These assays are useful for confirmation of Lyme disease. Assays which detect IgM antibodies are most useful for the diagnosis of Lyme disease during the first several weeks after onset of ECM when IgG antibodies have not reached significant titers (10). Assays which detect IgG specific antibodies are most useful in later stages of the disease when clinical symptoms can mimic other arthritic or neurologic disorders (1,4,8).

PRINCIPLE OF THE ASSAY

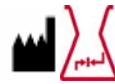
The DAI test system for Lyme disease is designed to detect circulating IgM antibodies to the Lyme disease spirochete in human sera. The test is particularly useful for early stages before IgG antibody titers have developed. The system employs the Lyme disease spirochetes immobilized on a glass slide and fluorescein-labeled anti-human IgM. The test procedure involves two incubation steps:

1. In the first step, human sera are reacted with the spirochetes immobilized on a glass slide. Antibodies in the sera will bind to the spirochetes and remain attached after rinsing.
2. Fluorescein-labeled anti-human IgM added in the second incubation step will bind to the immobilized IgM antibodies causing the spirochetes to fluoresce. After a final wash to remove unbound fluorescein conjugate, the spirochetes are viewed under a fluorescent microscope.

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