

A revolutionary test that utilizes direct detection to confirm the presence of *Borrelia* infection, indicating presence of Lyme disease in patients.

Confirms current infection by detecting OspA antigen in easy-to-collect urine samples.

What is Lyme *Borrelia*?

Borrelia burgdorferi is the primary species responsible for infection in North America. Lyme *Borrelia* is the bacteria that causes Lyme disease, a tick-borne illness.

How Can Someone Be Exposed?

Humans and animals can be exposed to *Borrelia* bacteria if they have lived in or traveled to Lyme-endemic areas. Exposure can occur both outdoors and indoors through contact with ticks, or through working with or living alongside animals that have been exposed to ticks. The primary vector for transmission is the bite of an infected blacklegged tick (deer tick).

When infected ticks detach from their host, such as deer or other animals, they may be unknowingly picked up by humans or their companion pets, potentially becoming the next host for the infected tick. This can lead to the transmission of *Borrelia* and the subsequent development of Lyme disease.

Why Test for Lyme *Borrelia*?

Lyme borreliosis infection can present many ways after exposure, and can cause both acute and chronic illness. It can be clinically diagnosed by a healthcare provider based on a patient's medical history, current symptoms, and exposure risk. Laboratory test results are used to confirm or support diagnosis and can also be used post-treatment to monitor therapeutic interventions. The good news is that Lyme Disease is treatable and preventable, especially when detected early.

What Patients Might Benefit From the Lyme *Borrelia* Direct Detect Profile?

Patients presenting with flu-like symptoms, with or without Erythema migrans (EM) rash, and have lived or traveled to an area where Lyme disease is endemic.

Patients with chronic illness not improving, and past/present exposure to ticks, even with past treatment of Lyme, or Post-Treatment Lyme Disease Syndrome (PTLDS)

Acute Symptoms

Fatigue 76%
Headache 70%
Rash <70%
Fever 60%
Sweats 60%
Chills 60%
Muscle Pain 54%
Joint Pain 48%
Neck Pain 46%
Sleep Issues 41%



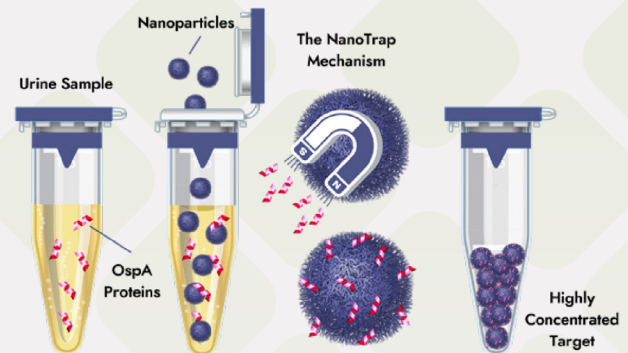
Chronic Symptoms

Fatigue 79%
Joint Pain 70%
Muscle Pain 69%
Other Pain 66%
Sleep Issues 66%
Cognitive 66%
Neuropathy 61%
Depression 62%
Headache 50%
Heart Related 31%

Methodology: Nanotrap® Direct

How the test works:

From a urine sample, Nanotrap® enrichment is performed for direct detection of Outer surface protein A (OspA) to allow us to detect *Borrelia* up to 10x.



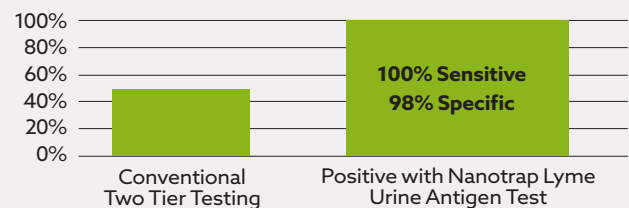
The Nanotrap® test targets the OspA protein, which can be found on the surface of *Borrelia Burgdorferi* as well as European and Asian strains of *Borrelia*.

Discover the Power of MosaicDX's Lyme *Borrelia* Direct Detect Profile

This urine-based test provides more sensitive direct detection for Lyme *Borrelia* infection at all stages of Lyme disease than standard methods.

- Identifies positive cases missed by conventional Two-Tiered Testing (TTT)
- Reduces concern for false positive results by direct detection of OspA antigen
- Confirms presence of pathogen with easy to collect urine samples

Lyme Antigen in Acute Patients¹



- Up to 2x more sensitive than conventional antibody testing
- Confirms cases missed by antibody testing
- Easy at-home or in-office urine sample collection

Some Patients Never Develop Lyme Disease Antibodies

Dysregulated antibody response is a hallmark of *Borrelia burgdorferi* infection. Antibody titers can persist for years in some Lyme disease patients, while in others they may never develop at all. More sensitive and reliable direct detection with the Lyme Nanotrap® Urine Antigen Test supports confirmation of infection at all stages of disease.

How the Test Works

The Lyme *Borrelia* Direct Detect Nanotrap® urine antigen test provides more reliable confirmation of active *Borrelia burgdorferi* infection. Capture and concentration of Outer surface protein A in urine is reported as detected or not detected. Clinical utility data documented **100% sensitivity and 98% specificity** in 24/24 patients with EM rash.

Data

Acute: Published data shows the Nanotrap® Antigen Test is very effective for confirmation of early stage Lyme borreliosis in patients with EM rashes (24/24).

Chronic: In a study of 100 symptomatic patients with a history of Lyme disease diagnosis and treatment—but negative serology—41% still had detectable OspA in their urine, helping providers discern if the pathogen still needed treatment.

Galaxy validation data (unpublished) shows it is able to detect pathogen presence in patients with negative TTT results. Further research is needed to confirm clinical utility for other presentations of Lyme borreliosis, including Lyme arthritis, Lyme carditis, and neuroborreliosis.

Combinations and Complementary Test Recommendations

Ticks and other vectors can transmit multiple infections—not just Lyme disease. To help prioritize treatment, providers should consider additional Lyme and Co-infection tests to identify which pathogens are currently present.

Combining the Tickborne BBB Direct Detect dPCR with the Lyme *Borrelia* Nanotrap® urine antigen test for Lyme provides optimal coverage for the top flea and tick-borne infections at the genus level.

Lyme *Borrelia* (Nanotrap) Direct Detect assesses the current presence of Lyme *Borrelia* infection in urine. Concentrations of Lyme *Borrelia* are so low in the blood that a blood draw is unlikely to capture the pathogen in the test tube.

Tickborne BBB Direct Detect includes genus level testing for *Borrelia*, *Babesia* and *Bartonella*. An advantage of genus level testing is that providers no longer have to guess which species to test for. Genus level testing will include all species associated with each pathogen.



Scan QR code now
to learn more about
our Lyme *Borrelia*
Direct Detect



To learn more please visit Mosaicdx.com

Find references at MosaicDX.com/Test/Lyme-Coinfections

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