



NANOTRAP LYME ANTIGEN TEST

Thank you for your interest in our test. Before ordering, please read carefully the information below:

• **Sample requirement:**

Collection material: sterile specimen cup for urine collection.
At least 2 cups, containing 80 ml each, morning urine, mid-stream

• **Temperature conditions Nanotrap Lyme Antigen test**

For sample collection at laboratory: Freeze at -20°C after sampling.
For sample collection at home: Patient stores sample at 2-8°C after sampling until shipment on the same day.
Ship in temperature controlled box at 2-8°C with next day delivery service.
Freeze upon arrival in the laboratory.

• **Packaging instructions**

Pack according to IATA P650 / Clearly place UN3373 label on package / if dry-ice is used, label accordingly (UN1845).

I – FILL IN YOUR ADDRESS, INDICATE THE NUMBER OF TESTS YOU WANT TO PURCHASE

Shipping information				
Name :				
Street address :				
ZIP, city :		Country :		
Phone :		Email :		
Date of birth :		Date and hour sample taken :	Gender: F / M	
Your Order				
		Price per test	Number of kits	Total cost
I wish to order :	Nanotrap LA Test	385€ (Including Shipping & VAT)	_____	_____ €
Signature :				

II – INDICATE HOW YOU WANT TO PAY

I pay by Visa/MasterCard and give my credit card information

Name on card:

Card Number : _____

Expiry: _____

I pay by transferring money to the account:

BELFIUS BASILIX scrl
Koningin Paolaplein 8 – 1083 Brussel, Belgium
IBAN: BE91 0682 2382 2776
BIC: GKCCBEBB

You still have to fill in the form and send it back, with your full address. As communication for the transfer/paypal payment, indicate your name as appears on this ordering form.

I make a Paypal payment, on the Paypal account info@proteabiopharma.com

Please note that this test is not subject to reimbursement.

III – SEND BACK THIS FORM

This can be done by email (info@redlabs.be) or by post (R.E.D. Laboratories -Z.1 Researchpark 100- B-1731 Zellik - Belgium)

Frequently Asked Questions:

How was the test developed?

The Nanotrap Lyme Antigen Test was developed at George Mason University, in partnership with Ceres Nanosciences and multiple infectious disease clinics and internal medicine practices. Over 300 patients participated in the clinical trial. Urine samples were collected from every patient and both the current standard of care serological testing and the Nanotrap® LA Test were run for each patient sample and analyzed in conjunction with the physician's report of symptoms and history with Lyme disease. This study has been published in a peer reviewed scientific journal, **Journal of Translational Medicine***.

The study demonstrates the following key findings: **Bb antigen OspA urinary shedding was strongly linked to concurrent active symptoms (e.g. EM rash and arthritis), while resolution of these symptoms after therapy correlated with urinary conversion to OspA negative.**

Pre-treatment, **24/24** newly diagnosed patients with an erythema migrans (EM) rash were positive for urinary OspA, while false positives for asymptomatic patients were **0/117**. Meaning that in the early stage of infection, Nanotrap Lyme Antigen Test approximates **100% sensitivity and specificity** in this study.

Specificity of the urinary OspA test for the clinical symptoms was 40/40. Specificity of the urinary OspA antigen test for later serology outcome was 87.5 % (21 urinary OspA positive/24 serology positive). 41 of 100 patients under surveillance for persistent LB were positive for urinary OspA, indicating possible ongoing infection.

How does this test compare to other tests for Lyme?

The Nanotrap® LA Test is the only direct test for the presence of the Lyme bacterial antigen Bb. The test can be performed with high sensitivity and without the need for invasive sample collection methods such as skin cultures, blood or cerebrospinal fluid draws. The most common test ordered for Lyme disease is the antibody serological test, which is an indirect test, measuring for the body's immune response only, not the presence of the disease itself.

Why test for Outer surface protein A?

The target of the Nanotrap® LA test measurement, *Outer surface protein A (OspA)*, was identified as a valid biomarker for detecting Lyme disease based on the following findings from highly regarded scientific publications:

- OspA is a protein found only on the surface of *Borrelia burgdorferi*,
- OspA antibodies are detectable in patients in early and late stage disease and in antibiotic resistant Lyme (Arthritis Rheum. 1999 42:1809-1812);
- Bb expresses high levels of OspA in the mammalian host in an inflammatory environment;
- OspA has inflammatory properties;
- OspA and surface lipoproteins provide protective shielding against mammalian host innate immunity;
- OspA has been found in Lyme patient urine, cerebrospinal fluid and synovial fluid.

Also, the development team performed the epitope mapping of a sequence in OspA that is common across all species of Lyme disease, including:

Borrelia Burgdorferi, Borrelia garinii, Borrelia afzelii, Borrelia spielmanii, Borrelia bissettii

Furthermore, it was determined that there is 0% overlap with any human protein, proving that the presence of OspA in the human body can only be attributed to infection from Bb.

Where can I get the Nanotrap® LA Test?

Innatoss Laboratories has the exclusive rights in most Western European countries to perform the Nanotrap® LA Test. The test can also be ordered through **R.E.D. Laboratories**. Materials for urine sample collection will be provided by the participating laboratory or by Innatoss Laboratories.

