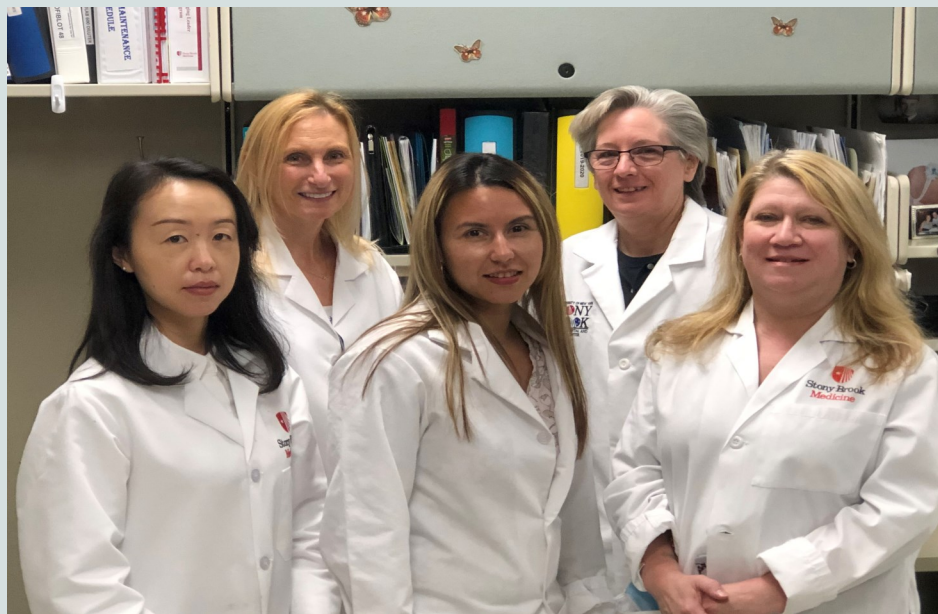


Everything you need to know about...

The Laboratory for the Diagnosis of Lyme Disease



The Lyme staff pictured above: Wen, Cathy, Lina, Karen and Shirley

The Laboratory for the Diagnosis of Lyme Disease was established in 1984 as a division of the Clinical Immunology Laboratory in the Department of Pathology at Stony Brook University School of Medicine. The laboratory gained recognition in the diagnosis of Lyme disease as being one of the select laboratories where accurate laboratory testing for Lyme disease could be obtained. This reputation has resulted in a large number of specimens being received world wide for testing. Despite this large volume, the laboratory takes pride in providing a high level of technical expertise and personal care to its clients. The laboratory is fully licensed and accredited by the NY State Department of Health, JCAHO, and the College of American Pathologists (CAP).

Visit our website for downloadable requisition forms, accreditation certificates, shipping requirements, shipping supplies request form and patient release forms.

WWW.STONYBROOKLYMELAB.ORG

**Stony Brook Medicine
Lyme Disease Laboratory
101 Nicolls Road
Level 3 Room 508
Stony Brook, NY 11794-7300**

**Results: 631-444-3824
Supervisor: 631-444-7965
FAX: 631-444-7526
Billing Customer Service:
631-444-4151**



Certifications

Medicaid- 003-57795-03
Medicare- 33-3039-3
CLIA- 33D0654233
NYSDOH- 23365151M010
CAP- 12559-01
HHS (HCFA)- 33-L047
CDC Interstate- FD 31-1136
NPI#- 1972523348
Outpatient Federal Tax ID #- 113243405



Pricing

Lyme ELISA Stony Brook

Serum	\$135	CPT Code 86618
CSF	\$135	CPT Code 86618
CSF/Serum pair	\$614	CPT Code 86618/82784 (includes immunoglobulin quantitation of Serum and CSF)

Lyme Western Blot Stony Brook (Confirmatory)

Serum	\$289	CPT Code 86617
CSF	\$289	CPT Code 86617

NEW-ZEUS ELISA *B. burgdorferi* VlsE1/pepC10 IgG/IgM reflex beginning 6/1/20

Serum	\$261	CPT Code 86618
-------	-------	----------------

Tick ID	\$83	CPT Code 87168 (free tick ID is no longer available)
---------	------	--

Prices are current as of 1/1/20, prices are subject to change without notice. Please call our Billing Office at 631-444-4151 to discuss individual insurance coverage or contact your insurance provider. Financial Assistance is available at www.stonybrookmedicine.edu/billinginformation or by calling (631) 444-4331.

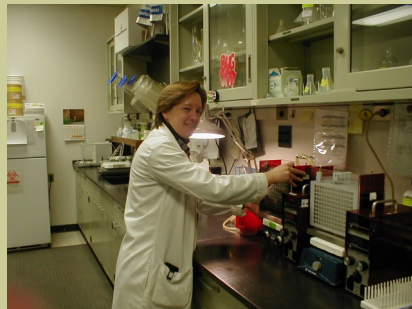
Please note: It is a requirement for the patient/guardian to sign the back of the requisition form, testing will not begin until this is provided.

We offer volume discounts for Lyme Disease testing if your institution can commit to the required number of specimens per year, please call for information.

Results are available within 1-2 days of receipt of specimen. Results are reported with an interpretation by mail. Faxing of results is also available by request, with a follow-up report by mail. Results are available at 631-444-3824 Monday-Friday 8:00 a.m. to 4:30 p.m. (EST).

Our method for performing standard serology testing is an ELISA which has been developed in-house and has been internationally recognized by many prominent researchers in the field of Lyme Disease testing as a reliable and sensitive test. We have worked very closely with the CDC, FDA, and NYSDOH in standardizing the assay. It is a polyvalent assay; i.e. simultaneously detecting IgG, IgA, and IgM (heavy and light chain) anti-Borrelia burgdorferi antibodies. We also offer the qualitative Lyme Western blot assay which is manufactured in-house. Positive bands are reported for both IgM and IgG. We have the ability to report CDC non-specific bands if requested.

We have recently replaced the Immunetics C6 peptide with the ZEUS *B. burgdorferi* VlsE1/pepC10 IgG/IgM Test System. It is intended for the qualitative detection of IgG and IgM class antibodies to VlsE1 and pepC10 antigens from *B. burgdorferi*. The dual antigen combination is ideal for serodiagnosis of Lyme Disease and is proven to be more clinically sensitive than C6 IgG/IgM alone for detecting early acute disease. This test is offered as a reflex only; equivocal and positive test results will be confirmed by Western Blot automatically.



Volume Discounts

Turn-Around-Times Result Reporting

Methodology



Specimen Requirements Shipping and Handling



Deer Tick
Ixodes scapularis



Specimen Minimum Volumes

Lyme Disease Serologies

Stony Brook ELISA

Serum: 0.5 ml
CSF: 0.5 ml

ZEUS VlsE1/pepC10 IgG/IgM ELISA

Serum only: 0.5 ml

CSF/Serum Paired ELISA (Neurologic Lyme)

Serum: 1.0 ml
CSF: 1.0 ml

Western Blot

Serum: 0.5 ml
CSF: 2.0 ml

Sample Tube, Specimen and Shipping Requirements

Specimen Tube Labeling

All sample tubes **MUST** be labelled with:

1. Patient's Full Name
2. Patient's Date of Birth or another identifier unique to the patient (Medical Record #, ID#.)

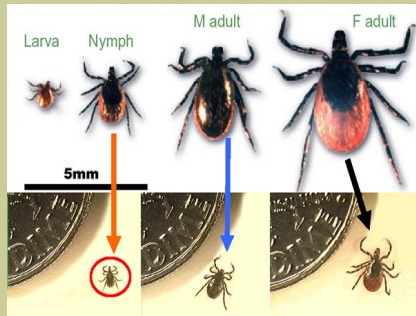
TUBES NOT LABELED ACCORDINGLY WILL NOT BE TESTED NOR WILL THEY BE RETURNED

Specimen Requirements

- Our testing requires serum, cerebral spinal fluid (CSF) or joint fluid.
- All blood tubes must be spun down and the serum separated from the clot before transporting to our lab and labelled with the First/Last name and date of birth.
- When removing the serum sample into a pour-off tube, a screw cap with a leak proof seal is recommended.
- Serum separator (SST) and gold top tubes can be shipped directly once the tube has been centrifuged and the serum has been separated from the clot. Red top tubes are also acceptable but must be spun and the serum portion sent.
- CSF and joint fluids can be sent in any approved sterile specimen tube, preferably with a screw cap.
- Specimens can be shipped at room temperature as long as they arrive in approximately two days. If warm temperatures are anticipated during transport a cold pack or dry ice can be used. We are not open for delivery over the weekend so we suggest you ship within a time frame that will allow the specimen to arrive by Friday.
- Ticks can be shipped in a "ZIP-LOCK" plastic bag in a mailing envelope. Place a small piece of paper towel in the bag for moisture. Add protection to prevent the tick from being crushed if needed. Please note: **The laboratory is no longer able to provide "FREE" Tick Identification, there is a fee associated with a Tick Report and it is considered an orderable test by your physician. Please call 631-444-3824 if you have any further questions regarding tick identification or tick testing locations.**

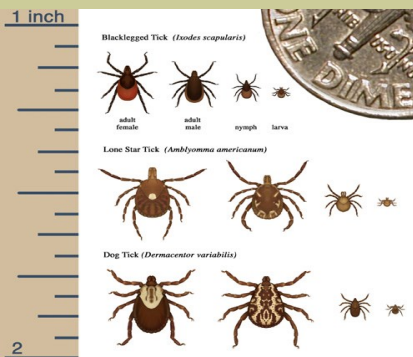


Deer Tick *Ixodes scapularis*



QA/QC Procedures

3 Ticks Common to NYS Area Deer, Lone Star and Dog Tick



Shipping Methods

Our lab utilizes UPS for shipping. We supply free of charge, postage paid, self addressed shipping containers which we call "KITS". The shipping kit meets UN3373 Biological Substance Category B and IATA shipping regulations. Doctor's office's, lab's and hospital's can request kits by calling 631-444-3824. Patients must obtain kits through their health care provider, we can not ship kits directly to the patient. Please note: **We do not pay for any pickup fee that UPS may charge if you call to have a specimen pickup. The kit must be taken to a UPS pickup location or given to the UPS driver during a routine office pickup.** Specimens can be sent by other shipping companies as long as they arrive within approximately two days and are shipped in an approved IATA package and labeled "Biological Substance Category B (UN 3373)". Packaging does not require biohazard labels. The lab is not open over the weekend to receive shipments, please refrigerate samples until they can be shipped to arrive during the week.

Shipping supplies are for the shipment to our laboratory and should not be used for any other shipment. Please note: It does not contain any blood drawing supplies.

Please visit our website at WWW.STONYBROOKLYMELAB.ORG and download our "Shipping Request Form". This form can then be filled out and faxed to 631-444-7526 when your shipping supplies are running low.

QC: Each 96 well ELISA plate that is run contains 15 different controls (with established ranges) representing high positives, low positives, and negatives run in duplicate and on different areas of the plate. All patient samples are run in duplicate and must replicate within 10%. Lot to lot comparisons are performed with known specimens for every lot change of every component of the assays.

QA: Our system performs a delta check on every patient sample when the results are entered. Disparate samples are repeated to confirm results. In addition, all worksheets and instrumentation print outs are reviewed daily by the Section Supervisor.

Proficiency: We presently participate in the CAP proficiency testing program for Lyme Disease testing. This includes the In House ELISA, Zeus and Western Blot test methodologies. We also participate in the CAP Linearity Verification survey, CAP Instrumentation Survey as well as a TICK survey.

I hope that the information provided answers all of your questions. If you should have any further questions or require any additional information please feel free to let me know. I can be reached Monday-Friday 7:30 a.m. to 4:00 p.m. (EST) by calling (631) 444-3824. We are looking forward to serving your laboratory needs for Lyme Disease testing.

Sincerely,

Cathy De Luca

Cathy De Luca MT (ASCP)
Supervisor
Laboratory for the Diagnosis of Lyme Disease

