

EVERYTHING YOU NEED TO KNOW ABOUT...

The Laboratory for the Diagnosis of Lyme Disease



**Stony Brook
Medicine**



The Lyme staff pictured above: Karen, Barbara, Mel, Cathy, Shirley, and Sophie.

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).

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

Results: 631-444-3824

Lyme Lab Supervisor

631-444-7965

FAX

631-444-7526

Billing Customer Service:

631-444-4151

Visit our website for downloadable requisition forms, accreditation certificates, shipping requirements, pictures of ticks and release forms.

WWW.STONYBROOKLYMELAB.ORG



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 Serology (ELISA/Screening)

Serum only \$126 CPT Code 86618
CSF only \$126 CPT Code 86618
CSF/Serum pair \$410 CPT Code 86618/82784 (includes immunoglobulin quantitation of Serum and CSF)

Lyme Western Blot (Confirmatory)

Serum only \$270 CPT Code 86617
CSF only \$270 CPT Code 86617

Lyme C-6 (ELISA/Screening)

Serum only \$193 CPT Code 86618

Tick ID \$78 CPT Code 87168 (with written report, free tick ID is no longer available)

Please call our Billing Office at 631-444-4151 to discuss individual insurance coverage or contact your insurance provider. **Please note:** It is a requirement for the patient/guardian to sign the back of the white copy of the requisition form, testing will not begin until this is provided.

Prices are current as of 9/25/17. Prices are subject to change without notice.

We offer volume discounts for ELISA and Western Blot testing if your institution can commit to the required number of specimens per year. Please call for information.

ELISA and Western Blot 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 also available at 631-444-3824 Monday-Friday 7:30 AM-4:30 PM (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 also offer the Lyme C-6 peptide ELISA. This screening assay is a useful adjunct to our "in-house" screening test. An ELISA method based on the use of a synthetic peptide, the C6 peptide, derived from a conserved region of the VlsE protein, has been shown to be sensitive and highly specific to detect B. Burgdorferi antibodies to both U.S. and European Lyme Borreliosis strains (Liang et al., 1999 and 2000). The C6 peptide ELISA has been reported to have 74, 85 and 100% sensitivity with acute, convalescent, and late-phase specimens respectively. Specificity is reported to be 99%. The C-6 assay is not affected by the Lyme vaccine based on the 31 kDa (OSP-A) protein. The C-6 peptide ELISA is FDA approved. All equivocal and positive C-6 samples should be confirmed with the Lyme Western blot assay.

Volume Discounts

Turn-Around-Times

Result Reporting

Methodology



Specimen Requirements, Shipping and Handling



SPECIMEN MINIMUM VOLUMES

LYME DISEASE SEROLOGIES

STONY BROOK ELISA

Serum: 0.5 ml
CSF: 0.5 ml

C-6 ELISA

Serum only: 0.5 ml

CSF AND SERUM PAIRED SEROLOGY (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 LABELED WITH:

1. THE PATIENT'S FULL NAME
2. THE PATIENT'S DATE OF BIRTH OR ANOTHER IDENTIFIER UNIQUE TO THE PATIENT (MEDICAL RECORD #, ID#, ETC.)

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 FIRST/LAST NAME AND DOB.
- 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 WITHIN APPROXIMATELY TWO DAYS.
- 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 LYME DISEASE LABORATORY AT STONY BROOK MEDICINE IS NO LONGER PROVIDING "FREE" TICK IDENTIFICATION SERVICE, THERE IS A FEE ASSOCIATED WITH A TICK REPORT. PLEASE CALL 631-444-3824 IF YOU HAVE ANY QUESTIONS OR NEED FURTHER ASSISTANCE.



QA/QC Procedures

SHIPPING METHODS

OUR LAB UTILIZES **UPS** FOR OUR RETURN SHIPPING. WE SUPPLY, FREE OF CHARGE, POSTAGE PAID, SELF ADDRESSED SHIPPING CONTAINERS AND BOXES WHICH WE CALL "KITS". THE SHIPPING KITS MEET UN AND IATA SHIPPING REGULATIONS. YOU CAN REQUEST KITS BY CALLING 631-444-3824. PLEASE NOTE: **WE DO NOT PAY FOR ANY PICKUP FEE THAT UPS MAY CHARGE IF YOU CALL TO HAVE THE SPECIMEN PICKED UP. THE KIT MUST BE TAKEN TO A UPS PICKUP LOCATION OR GIVEN TO THE UPS DRIVER.** IF YOU HAVE ANY QUESTIONS, PLEASE CALL. 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. PACKAGING MUST BE LABELED "BIOLOGICAL SUBSTANCE CATEGORY B (UN 3373)". PACKAGING DOES NOT REQUIRE BIOHAZARD LABELS. THE LABORATORY IS NOT OPEN TO RECEIVE SHIPMENTS ON THE WEEKEND, PLEASE REFRIDGERATE SAMPLES UNTIL THEY CAN BE SHIPPED TO ARRIVE DURING THE WEEK.

WE SUPPLY KITS TO DOCTORS, LABS, AND MEDICAL INSTITUTIONS. PATIENTS MUST OBTAIN THE KITS THROUGH ONE OF THESE ENTITIES. KITS ARE FOR THE SHIPMENT OF PATIENT SPECIMENS. **WE DO NOT SUPPLY THE BLOOD DRAWING SUPPLIES, ONLY THE SHIPPING CONTAINERS.**

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 ELISA, C6 Peptide 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 4:30 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
The Laboratory for the Diagnosis of Lyme Disease

