LYME DISEASE BIOBANK

A BAY AREA LYME FOUNDATION PROGRAM

Lyme Disease Biobank Applicant Instructions

Overview

The Lyme Disease Biobank (LDB) is a collection of human biological samples to facilitate research in the field of Lyme disease (LD) and other tick-borne infections (TBI). This multiyear initiative launched in 2014, and whole blood, serum, and urine were collected from individuals with suspected acute LD presenting with or without an erythema migrans (EM) or annular rash (cases) and unaffected individuals (LD negative controls from endemic regions). A case report form (CRF) was used to collect information about symptoms, EM (if present), current medications, history of LD and other TBI, medical history, and demographics. Photographs of EM were also taken (if present). Testing was performed, in a blinded fashion, to confirm the presence of *Borrelia burgdorferi*, *Anaplasma phagocytophilum*, *Babesia microti,* and *Borrelia miyamotoi* in the samples by qPCR. Serologic assays (ELISA followed by Western immunoblotting, and C6 peptide analysis) were also performed. Samples are available from ~435 participants enrolled at three sites (East Hampton, NY, Martha's Vineyard, MA, Marshfield, WI). Each participant's donation provides samples for ~50 research projects, with aliquots of whole blood (1 and 2 ml), serum (250 µl), and urine (1 ml). Blinded and deidentified samples are available to qualified investigators through an application process. In order to help determine if LDB samples would be useful for their studies, investigators will have access to information about what types of samples are available prior to applying for sample access.

Application and Review Process

Each potential sample user (herein "applicant") must submit an application that includes a technical proposal, a lay summary of the work, justification for the number of samples being requested, timing and funding of the proposed work, the publication plan, and applicant's CV. Applications can be reviewed without Institutional Review Board (IRB) approval, however IRB approval or exemption from the applicant's IRB is required prior to releasing samples. A checklist will be included to help ensure all sections of the application are complete. The LDB PI will conduct an administrative review to ensure applications are complete and may ask applicants for additional information to clarify or strengthen their application.

Applications will be reviewed by an ad-hoc committee consisting of two individuals with appropriate subject-matter expertise to review the proposal. Committee members will be chosen by the LDB Principal Investigator (LDB PI) from an ad-hoc pool of experts (the LDB Peer

Reviewer Pool) that includes Lyme disease clinical experts, diagnostic experts, immunology experts, pathogen detection experts, and others with appropriate expertise The LDB Board of Directors will approve members of the LDB Reviewer Pool prior to the review of applications. Reviewers are required to sign a *Conflicts of Interest, Confidentiality, and Non-Disclosure Policy* prior to participating in a review. Individuals who have any financial, academic, or other conflict with the applicant or application are required to excuse themselves from reviewing applications and replacement individuals will be selected to serve in substitution. Applicants may request specific reviewers be excluded from participating in the review. Applications will be reviewed in a timely manner (within 45 days) and approvals will be based on technical merit, potential to advance LD (or other TBI) diagnostics, their likelihood to increase knowledge of LD and other TBI, and alignment with LDB goals and objectives. The PI will present applications with competitive scores to the LDB Board of Directors, and the LDB Board of Directors will make the final determination as to which applicants will be approved to receive samples. The PI will notify all applicants of the status of their applications, and comments may be provided to the applicants to help them strengthen their applications for future submissions.

Pricing

Samples will be priced in a cost-recovery model. The pricing schedule is detailed below. Costs for shipping and sample retrieval will be passed on to the investigator.

	Serum (250 ul aliquot)	***Whole blood (1 ml aliquot)***	***Whole blood (2 ml aliquot)***	***Whole blood (5 ml aliquot)***	***Urine (1 ml aliquot)***	***Urine (5 ml aliquot)***
1-150 aliquots	$75	$75	$150	Call for Pricing	$75	Call for Pricing
151-300 aliquots	$60	$60	$120	Call for Pricing	$60	Call for Pricing
301-450 aliquots	$50	$50	$100	Call for Pricing	$50	Call for Pricing

Process for Approved Applicants to Receive Samples

Blinded and deidentified samples will be released upon receipt of an executed Sample and Data Access Agreement that includes a Material Transfer Agreement, full payment (unless otherwise arranged), and a letter indicating that the proposed data analysis plan was approved, granted an exemption, or determined to be non-Human Subjects Research by the applicant's IRB. Once these terms are met, the LDB PI will contact the biorepository to order release of the agreed upon blinded samples to the approved applicant. *Note: Applications can be reviewed without IRB approval, however IRB approval or exemption is required prior to releasing samples or data to approved applicants*.

Approved applicants must abide by the terms in the Lyme Disease Sample and Data Access Agreement, including acknowledging the LDB in any presentations or publications and sharing summary results with the LDB.

Please contact Liz Horn, PhD, MBI, at info@lymbiobank.org with any questions.