CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

NEUROMUSCULAR CLINICAL LAB 509 S EUCLID AVE SAINT LOUIS, MO 63110

CLIA ID NUMBER 26D0652044

EFFECTIVE DATE

08/25/2023

EXPIRATION DATE

08/24/2025

LABORATORY DIRECTOR

ALAN PESTRONK M.D.

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid antil the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



ue Spruill, Director

Division of Clinical Laboratory Improvement & Quality

Quality & Safety Oversight Group Center for Clinical Standards and Quality

certs2_072523

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE) **EFFECTIVE DATE**

GENERAL IMMUNOLOGY (220) 12/02/2009 **ROUTINE CHEMISTRY (310)** 04/15/2013 HISTOPATHOLOGY (610) 11/18/1997



LAB CERTIFICATION (CODE)

EFFECTIVE DATE



FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



CERTIFICATE OF ACCREDITATION

Washington University
Neuromuscular Clinical Lab
Saint Louis, Missouri
Alan Pestronk, MD

CAP#: 1923316 CLIA#: 26D0652044

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **October 02, 2025** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Kathleen G. Beavis, MD Chair, Accreditation Committee

26 SLOVIS, MI

Emily E.Volk, MD President, College of American Pathologists

New York State Department of Health

PFI: 3499

Clinical Laboratory Permit

CLIA: 26D0652044

Neuromuscular Clinical Laboratory IWJ Building Rm 404 509 S Euclid Ave Box 8111 St Louis MO 63110

Director: Alan Pestronk, M.D. Owner: Washington University School of Medicine

is hereby authorized to perform laboratory procedures at the above location in the following categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This permit shall become void upon a change in the director, owner or location of the laboratory, and an application for a new permit shall be made to the Department.

Diagnostic Immunology
Diagnostic Services Serology

Renewal

Effective Date: July 1, 2024 Expiration Date: June 30, 2025 Subject to Revocation Permit Not Transferable

New York State Department of Health

Certificate of Qualification OCOMO PERTAI

Alan Pestronk, M. 6 Forest Ridge Plac

has qualified to act as a Laboratory Director in the following outroperies in accordance with Article 5. Talls V. Sacrico STS of the Public Block Load

Diagnostic Immonstagy

Effective Date: December 10, 2024 Expiration Date: December 10, 2026 Subject to Revocation Certificate Not Transferable



CLINICAL AND PUBLIC HEALTH LABORATORY LICENSE



In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address.

NEUROMUSCULAR CLINICAL LABORATORY

509 S EUCLID AVE. ST. LOUIS, MO 63110



STATE ID: CDS-00800679
SCAN OR CODE TO VERIFY LICENSE
OR VISIT: www.cdph.ca.gov/LFS

EFFECTIVE DATE: 03/07/2024 EXPIRATION DATE: 03/06/2025

OWNER/S:

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

LICENSE TYPE:

CLINICAL LABORATORY LICENSE CERTIFICATE OF DEEMED STATUS

DIRECTOR/S:

ALAN PESTRONK MD

DISPLAY: State law requires that the clinical laboratory license shall be conspicuously posted in the clinical laboratory.

CHANGE OF LABORATORY NAME, DIRECTOR, OWNER AND/OR ADDRESS:

State law requires that the laboratory owner and/or the director notify this office within 30 days of any change in ownership, name, location, or laboratory directors. If this office is not notified, your license may be revoked 30 days after major Owner and/or Director change. If your license is revoked, you must cease engaging in clinical laboratory practice and apply for a new laboratory license. To make these changes or to submit a new application, visit our website: https://www.cdph.ca.gov/LFS (Go to Laboratory Facilities)

> BRANCH CHIEF LABORATORY FIELD SERVICES



Pursuant to the act of September 26, 1951, P.L. 1539 as amended, a Permit to operate a Clinical Laboratory is hereby granted to:

Laboratory Identification Number: 37448

Name and Director of Laboratory:

NEUROMUSCULAR CLINICAL LABORATORY ALAN PESTRONK, M.D. 509 S EUCLID AVE SAINT LOUIS, MO 63110

Owner:

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

ISSUE DATE: August 15, 2023

DATE EXPIRES: August 15, 2024

AUTHORIZED CATEGORIES/TESTS:

CLINICAL CHEMISTRY NON-SYPHILIS SEROLOGY TISSUE PATHOLOGY

Histopathology

Debra L. Bogu MD

Debra L. Bogen, MD, FAAP Secretary of Health

DISPLAY THIS CERTIFICATE PROMINENTLY

This permit is subject to revocation, suspension, or limitation for violation of the Act or the Regulations promulgated thereunder.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop H21-7 Atlanta, GA 30329

Telephone: 404-718-2077; 404-488-7100 (after hours) Email: importpermit@cdc.gov



Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulators, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

PHS PERMIT NO.: 20240103-0036A ISSUED DATE: 01/10/2024 EXPIRATION DATE: 01/10/2025

1. DESCRIPTION OF MATERIAL

BLOOD/BLOOD PRODUCTS FROM HUMANS THAT MAY CONTAIN: HEPATITIS A VIRUS; HEPATITIS B VIRUS; LENTIVIRUS (HUMAN IMMUNODEFICIENCY VIRUS 1, 2)

2. PERMITTEE

(NAME, ORGANIZATION, ADDRESS AND CONTACT

INFORMATION)

ACT

ROBYN REESE (314) 362-2406

AUTHORIZED USER: TINA CHISHOLM (314) 362-1639 AUTHORIZED USER: BECKY PLANT (314) 273-2621 AUTHORIZED USER: DAVID MACIAK (314) 273-9727

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE 509 SOUTH EUCLID AVE

3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)

WORLDWIDE

4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE

MULTIPLE IMPORTATIONS

ST. LOUIS MO 631110

A. RECORD OF EACH IMPORTATION SHALL BE MAINTAINED ON PERMANENT FILE BY PERMITTEE

B. USDA/APHIS MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ANIMALS, MATERIALS EXPOSED TO ANIMAL PRODUCTS/BYPRODUCTS, AND AGENTS THAT ARE INFECTIOUS TO ANIMALS OR PLANTS.U.S.FISH AND WILDLIFE SERVICE MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ENDANGERED ANIMALS.

5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED

PACKAGING MUST CONFORM TO 49 CFR SECTIONS 171-180.

WORK WITH THE AGENT(S) DESCRIBED SHALL BE RESTRICTED TO AREAS AND CONDITIONS MEETING REQUIREMENTS IN THE CDC/ NIH PUBLICATION "BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES.

AS THE PERMITTEE, YOUR FACILITY WILL BE SUBJECT TO INSPECTION AT SOME TIME IN THE FUTURE TO CONFIRM THAT THE IMPORTERS BIOSAFETY MEASURES ARE COMMENSURATE WITH THE HAZARD POSED BY THE ITEMS TO BE IMPORTED AND THE LEVEL OF RISK GIVEN ITS INTENDED USE.

THE CONDITIONS FOR IMPORTATION AND CONTINUED POSSESSION LISTED ON THE CDC PERMIT REMAIN IN EFFECT UNTIL THE IMPORTER IS NO LONGER IN POSSESSION OF THE IMPORTED MATERIAL.

ALL MATERIAL IS FOR LABORATORY USE ONLY - NOT FOR USE IN THE PRODUCTION OF BIOLOGICS FOR HUMANS OR ANIMALS.

6.SIGNATURE OF ISSUING OFFICER

Samuel S. Edwin

SAMUEL S. EDWIN, PH.D. DIRECTOR, DIVISION OF SELECT AGENTS AND TOXINS