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

08/25/2021

LABORATORY DIRECTOR

ALAN PESTRONK M.D.

EXPIRATION DATE

08/24/2023

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 until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Monique Spruill
Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

216 certs2_072721

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

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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.

MISSOURI CLIA PROGRAM DEPT OF HEALTH& SR SVCS
BUREAU OF Diagnostic svcs evaluation
PO BOX 570
920 WILDWOOD
JEFFERSON CITY, MO 65102-0570
(573)751-6318

CLIA ID Number: 26D0652044
NEUROMUSCULAR CLINICAL LAB
509 S EUCLID AVE
SAINT LOUIS, MO 63110

COLLEGE of AMERICAN PATHOLOGISTS

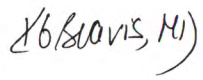
CERTIFICATE OF ACCREDITATION

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

CAP Number: 1923316
AU-ID: 1184628
CLIA Number: 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 2, 2023** 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, Accreditation Committee Chair

Emily Volk, MD, FCAP, President, College of American Pathologists

New York State Department of Health

Clinical Laboratory Permit

PFI: 3499

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, 2022
Expiration Date: June 30, 2023

Subject to Revocation
Permit Not Transferable

POST CONSPICUOUSLY

Serial: LAP 158767

New York State Department of Health

Certificate of Qualification

CQ Code: PESTA1

Alan Pestronk, M.D.
6 Forest Ridge Place
St. Louis MO 63105

has qualified to act as a Laboratory Director in the following categories
in accordance with Article 5, Title V, Section 573 of the Public Health Law.

Diagnostic Immunology

NEW YORK STATE OF OPPORTUNITY. Department of Health

Renewal

Effective Date: December 10, 2022
Expiration Date: December 10, 2024

Subject to Revocation
Certificate Not Transferable

Serial: CQP152207

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 QR CODE TO VERIFY LICENSE
OR VISIT: www.cdph.ca.gov/LFS

EFFECTIVE DATE: 03/07/2022

EXPIRATION DATE: 03/06/2023

LICENSE TYPE:
CLINICAL LABORATORY LICENSE

CLIA ID: 26D0652044

OWNER/S:
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

DIRECTOR/S:
PESTRONK, ALAN

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)*

CERTIFICATE OF DEEMED STATUS

Robert J. Thomas
ROBERT J. THOMAS
BRANCH CHIEF
LABORATORY FIELD SERVICES

LAB CERT 300 (01-2020)

CLINICAL LABORATORY PERMIT

pennsylvania
DEPARTMENT OF HEALTH

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, 2022

DATE EXPIRES: August 15, 2023

AUTHORIZED CATEGORIES/TESTS:

CLINICAL CHEMISTRY
NON-SYPHILIS SEROLOGY
TISSUE PATHOLOGY
Histopathology

Denise Johnson MD, FACOG, FACHE
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. : 20230113-0213A

ISSUED DATE: 01/17/2023

EXPIRATION DATE: 01/17/2024

1. DESCRIPTION OF MATERIAL	HUMAN BLOOD/BLOOD PRODUCTS THAT MAY CONTAIN HEPATITIS A VIRUS, HEPATITIS B VIRUS, AND LENTIVIRUS (HUMAN IMMUNODEFICIENCY VIRUS 1, 2).
2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)	**ROBYN REESE (314) 362-2406** **AUTHORIZED USER: TINA CHISHOLM (314) 362-1639** **AUTHORIZED USER: BECKY PLANT (314) 273-2621** **WASHINGTON UNIVERSITY SCHOOL OF MEDICINE** **509 SOUTH EUCLID AVE** **ST. LOUIS MO 631110**
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	WORLDWIDE
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	MULTIPLE IMPORTATIONS 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

42 CFR 71.54. Permit to Import Biological Agents, Infections Substances, and Vectors
A person may not import into the United States any infectious biological agent, infectious substance, or vector unless: It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.