

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 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.



Monique Spruill

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

194 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:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
GENERAL IMMUNOLOGY (220)	12/02/2009		
ROUTINE CHEMISTRY (310)	04/15/2013		
HISTOPATHOLOGY (610)	11/18/1997		



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.



COLLEGE of AMERICAN
PATHOLOGISTS

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

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
ST OPPORTUNITY.

Department
of Health

Renewal

Effective Date: July 1, 2024

Expiration Date: June 30, 2025

Subject to Revocation

Permit Not Transferable

POST CONSPICUOUSLY

Serial: LAP 188825

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.

Clinical Chemistry

*(limited to neuromuscular
biomarkers)*

Diagnostic Immunology

Amended

Effective Date: February 4, 2025

Expiration Date: December 10, 2026

Subject to Revocation

Certificate Not Transferable

Serial: CQP179690



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: 03/07/2024

EXPIRATION DATE: 03/06/2025

LICENSE TYPE:

CLINICAL LABORATORY LICENSE

CERTIFICATE OF DEEMED STATUS

OWNER/S:

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

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)

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

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

AUTHORIZED CATEGORIES/TESTS:

Name and Director of Laboratory:

CLINICAL CHEMISTRY
NON-SYPHILIS SEROLOGY
TISSUE PATHOLOGY
Histopathology

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, 2024

DATE EXPIRES: August 15, 2025

Debra L. Bogen MD

Debra L. Bogen, MD, FAAP
Acting 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 Regulatory Science and Compliance
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 Regulations, 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. : 20241226-4561A

ISSUED DATE: 01/13/2025

EXPIRATION DATE: 01/13/2026

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)**

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)**

INGE VANDERVORST (322) 416-4250
PPD LABORATORIES
KLEINE KLOOSTERSTRAAT 19
ZAVENTEM 1932 BELGIUM

RITA MARTINS OLOFSSON (467) 304-53041
WIESLAB AB, A SVAR LIFE SCIENCE COMPANY
LUNDAVAGEN 151
MALMO 212 24 SWEDEN

PUVANESWARY KANDIBAN (656) 772-4912
NATIONAL UNIVERSITY HOSPITAL
5 LOWER KENT RIDGE ROAD MB LEVEL 3
SINGAPORE 119074 SINGAPORE

STEVEN BAKER (905) 521-2100
HAMILTON HEALTH
1200 MAIN STREET
HAMILTON ONTARIO L8N 3Z5 CANADA

REKHA DAMJI (403) 770-3285
ALBERTA PRECISION
9-3535 RESEARCH
CALGARY AB T2L 2K8 CANADA

RANDY CARABEO (204) 787-4395
HEALTH SCIENCE CENTRE
820 SHERBROOK ST
WINNEPEG MB R3A 1R9 CANADA

**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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE**

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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

A handwritten signature in blue ink, appearing to read "D. A. Singer". The signature is fluid and cursive, with a long horizontal stroke at the end.

DANIEL A. SINGER, MD, MPH, FACP, DIVISION OF REGULATORY SCIENCE AND COMPLIANCE