Nelson Labs®
A Sotera Health company

Certifications:

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CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 16 March 2021
Certificate Number: AT-1382

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Nathan Conder nconder@nelsonlabs.com
Robert Thoreson rthoreson@nelsonlabs.com
www.nelsonlabs.com 801-290-7500

TESTING

Valid to: **March 16, 2021** Certificate Number: **AT-1382**

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Agar Overlay	STP0031 based on ANSI/AAMI/ISO 10993-1,5,12 USP <87>, USP<1031>	Medical Devices, Raw Materials	ISO Class 5 Hoods Microscope Incubators
Antimicrobial Preservative Effectiveness	STP0131 based on USP <51>, STP0132 based on USP <51> and EP 5.1.3	Antimicrobial Preservatives	Incubators
Bacterial Endotoxins	STP0046 based on USP <85>, USP<161>, USP<797>, AAMI ST72, EP 2.6.14, ASTM D7102-04, BS EN 455-3	Medical Devices, Drugs	Microplate Reader
Bacterial Filtration Efficiency (BFE) Viral Filtration Efficiency (VFE)	STP0004 and STP0007 based on ASTM F2101, EN14683, ASTM F2100	Medical & Surgical Face Masks	Andersen Sampler
Viral Penetration and Whole Glove Viral Barrier Testing	STP0062, STP0174, and STP00198 based on ASTM F1671, AAMI PB70, ISO16604, and NFPA 1999	Textiles, Gloves	ISO Class 5 Hoods Incubators
Bioburden	STP0036 based on ISO 11737-1	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Radiation Sterilization Validations and Dose Audits	STP0050 based on ISO 11737-2, 11137-01 and -02, AAMI TIR 17, 35, 37. STP0051 based on ISO 11737-01 and -02, 11137-01 and -02, AAMI TIR 17, 33, 37. STP0195 based on ISO 11137-2 and AAMI TIR 40. STP0044 based on ISO11137-01 and -02, AAMI TIR 33, 35	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicators (Population verification, Process Challenge Device (PCD) Preparation, BI Sterility)	STP0045, STP0079, and SOP0180 based on USP<55>, ISO 11138-1 to -4, ISO 11135-1 to -2, ISO 11138-7 ISO 14937, ISO 17665-2, AAMI TIR 13, 14, 16, BS EN 550	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubator
Cleaning, Disinfection, Sterilization Including the following sub-analyses (separately accredited): • Hemoglobin • Protein • Carbohydrates • MEM elution • TOC • Bioburden	Template 122, STP0129, STP0194 and Template 202 based on AAMI TIR 12, 30, ASTM E1837, ISO17664, ISO 15883 STP0086 and STP0202 based on ANSI/AAMI ST79, AAMITIR12, ANSI/AAMI/ISO 17665, USP <1211> STP0152 based on AAMI TIR 12, USP<1211>, ANSI/AAMI/ ISO 11135-1 STP0159, Template 124, and Template 194 based on ISO 17664, ANSI/AAMI ST79, ANSI/AAMI ST77, ANSI/AAMI/ISO 11135, AAMI TIR30	Medical Devices, Reusable Devices	Washer/Disinfectors Sterilizers (Steam, EO, VHP) UV/VIS Spectrophotometer
Container Closure Integrity (Bacterial Ingress)	STP0164 based on PDA TR 27 and FDA Guidance for Industry: Container and Closure Integrity Testing	Packaging Materials for Medical Device & Pharmaceutical	Pressure/Vacuum Vessel Incubators

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Hemolysis	STP0093 based on ANSI/AAMI/ISO 10993-1,4,12 and ASTM F756-08	Medical Devices, Raw Materials	Spectrophotometer Incubators
MEM Elution	STP0032 based on ANSI/AAMI/ ISO 10993-1,5,12 USP <87>, USP<1031>	Medical Devices, Raw Materials	ISO Class 5 Hoods Microscope Incubators
Bacterial Reverse Mutation Assay (Ames Test)	STP0097 and STP0098 based on ISO 10993-1,3,12,33 OECD 471	Medical Devices, Raw Materials	Incubators, Automated Plate Counter
Chromosome Aberration Assay	STP0101 and STP0102 based on ISO 10993-1,3,12,33 OECD 473	Medical Devices, Raw Materials	ISO Class 5 Hoods, Microscope, Incubators
MTT Quantitative Cytotoxicity Test	STP0207 based on ISO10993-5 and ISO10993-12	Medical Devices	Incubator, Microscope, Spectrophotometer
Complement Activation	STP0092 based on IS0 10993-1,4,12	Medical Devices	Spectrophotometer
Partial Thromboplastin Time Test - PTT	STP0094 based on ISO 10993-4, 12 and ASTM F2382	Medical Devices	Incubator
Microbial Retention (Including Filter Bubble Point/Integrity Test)	STP0103 based on ASTM F838-15	Filters	Flow Meter Pressure Gauge ISO Class 5 Hood Incubators
Microbiological Examination of NonSterile Products (Enumeration and Specified Organisms, USP 61/62)	STP0169 and STP0165 based on USP<61> and USP<62>	Medical Devices, Pharmaceuticals	ISO Class 5 Hoods Incubators
Organism Identification (Genetic and Gram Stain)	STP0105, and STP0173 based on USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencers Thermocyclers Automatic Gram Stainer ISO Class 5 Hoods Incubators Microscopes
Product Sterility (Cleanroom and Isolator), MPN Method Suitability (Bacteriostasis /Fungistasis), and Isolator Package Validation	STP0077, STP0081, STP0082 and STP0078 based on USP<71>, USP<161>, USP<797>, ISO 11737-2, 11137-01 and -02, PIC/S PI 012-3, EP 2.6.1, JP XV 4.06, ISO 17665, AAMI TIR 33	Medical Devices, Pharmaceuticals, Biologics, Tissues	ISO Class 5 Cleanrooms and Hoods Incubators Isolator

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Standard Plate Counts	STP0035 based on USP <71> STP0169 based on USP<61>	Water, Food, Cosmetics, Pharmaceuticals	ISO Class 5 Hoods Incubators

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	STP0016 based on ANSI/AMMI/ISO10993-7, 2008, USP <621>	Medical Devices	GC
FTIR, Material Characterization	STP0021 based on USP<851>and USP<197>	Polymers, Non-volatile Residue, Materials	FTIR, Microscope
Water Purity Analysis • TOC • Conductivity • pH	STP0024 and STP0099 based on USP<1231>, USP<1230> and all USP monograph waters, STP0028 based on USP<643> STP0029 based on USP<791> STP0147 based on USP<645>	Water – USP, Water – EP	TOC Analyzer, Conductivity Meter, pH Meter
Biological Marker Analysis • Hemoglobin • Protein • Carbohydrates	STP0087, STP0088, and STP0183 based on ASTM F756-13, AAMI TIR30, and Cleaning, Disinfection, Sterilization references previously listed.	Medical Devices, Reusable Devices	Spectrophotometer
Metals Analysis via Inductively Coupled Plasma – Mass Spectrometry	STP0190 based on USP<233>, and EPA Method 200.8	Medical Devices	Inductively Coupled Plasma – Mass Spectrometer (ICP-MS)
Particulates Testing and VOC Sampling	STP0104 based on ISO 18562-2 and ISO 18562-3	Breathing systems, intubation tubing, other gas pathway devices	DustTrak, Flow meters

Mechanical / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Barrier Testing: Synthetic Blood and Water Resistance (Hydrostatic Pressure, Impact Penetration)	STP0061, STP0071 and STP0072 based on ASTM F1670, AAMI PB70, ISO 16603, AATCC 42 and 127	Textiles, Gloves	Hydrostatic Head Tester, Incubators
Synthetic Blood Resistance	STP0012 based on ASTM F1862 and ISO 22609	Medical facemasks and surgical respirators	Blood testing apparatus
Flammability	STP0073 based on 16 CFR Part 1610	Face masks, surgical gowns, and surgical drapes	Flammability tester
Container Closure Integrity (Dye Ingress)	STP0149 based on ANSI/AAMI/ISO 11607-1,2, ASTM D4491-07, PDA TR 27and FDA Guidance for Industry: Container and Closure Integrity Testing	Packaging Materials for Medical Device & Pharmaceutical	Vacuum Vessel, Spectrophotometer
Container Closure Integrity (Mass Extraction)	STP0140 based on ASTM F3287-17	Nonporous rigid containers	ME2 Mass Extraction Leak Test Instrument, Calibrated Leak Orifices
Particulates	STP0011 based on USP <788>, <789>, EP 2.9.19, 2.9.31, BP Appendix XIII A, BH EN 45502-1, 45502-2-1 ISO 8536-4	Medical Devices, Injectables and Ophthalmic Solutions, Pharmaceutical Products	Liquid Particle Counting System, Microscope
Particulate Filtration Efficiency (PFE)	STP0005 based on ASTM F2299	Medical & Surgical Face Masks	Particle Counter, Particle Generator
Respirator Certification Testing (NIOSH N95/N99) • Respirator Inhalation/Exhalation • Respirator Valve Leak • Sodium Chloride Aerosol Test	STP0145 based on 42 CFR Part 84 and NIOSH TEB – APR-STP-007, RCT- APR-STP-003 STP0143 based on 42 CFR Part 84 and NIOSH TEB-APR-STP-0004 STP0014 based on 42 CFR Part 84and NIOSH TEB-ARP-STP-0058, TEB-ARP-STP-0059	Respirators	Differential Pressure Apparatus, Air Flow Apparatus, Automated Filter Tester, Sodium Chloride Tester, Valve Leak Tester

Mechanical / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
EN 13795: Performance requirements for surgical gowns and drapes • Microbial penetration resistance (wet and dry) • Microbial evaluation (bioburden) • Particle evaluation • Liquid penetration resistance • Burst strength • Tensile Strength	STP0191 and STP0188 based on EN ISO22610 and EN ISO 22612 STP0036 based on ISO 11737-1 (Bioburden method) STP0144 based on EN ISO 9073-10 STP0071 based on AATCC 127 and EN 20811 STP0192 based on EN ISO 13938-1 STP0066 EN 29073-3	Medical & Surgical Gowns and Drapes	ISO Class 5 Hoods Incubators Gelbo Flex Unit Particle counter Burst tester Instron (Tensile) tester Rulla II testers

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1382.

R. Douglas Leonard Jr., VP, PILR SBU

Dear Aaron DeMent:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2020:

Registration Number: 1721109
Owner Operator Number: 10029425
NELSON LABORATORIES, LLC
6280 S Redwood Rd
Salt Lake City, UT 84123
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2020. Registration for 2021 will be conducted between October 1 and December 31, 2020.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Imports & Registration and Listing Team
Division 2 Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1
Email: reglist@cdrh.fda.gov

Nelson Labs™
A Sotera Health company

28 May 2019

Statement of Compliance to GDUFA Self-Identification Requirement

Nelson Laboratories, LLC (NL), a Sotera Health Company, is a provider of full, life-cycle microbiology testing services for pharmaceutical, medical device, natural products, and processed tissue industries. NL's main facility is in Salt Lake City, UT with Sotera Health located in Broadview Heights, OH.

Under the Generic Drug User Fee Amendments of 2012 (GDUFA), all facilities involved in the manufacture and testing of human generic drugs are now required to electronically self-identify with the FDA.

With this letter, NL confirms that all drug facilities, sites and organizations listed below have been registered as of 10 May 2019 under the new GDUFA requirements.

Address	Business Operations	FEI # & DUNS #	Fiscal Year
Nelson Laboratories, LLC 1500 W Thorndale Ave, Itasca, IL 60123 USA	API / FDF Analytical Testing	FEI #**3000717698** DUNS #**032350261**	**FY2020**
Nelson Laboratories, LLC 6280 South Redwood Road Salt Lake City, UT 84123 USA	API / FDF Analytical Testing	FEI #**3000233845** DUNS #**151663234**	**FY2020**

Sincerely,

Matthew D. Cushing
Senior Director, Quality – North America
Nelson Laboratories, LLC
6280 S. Redwood Road
Salt Lake City, UT 84123
mcushing@nelsonlabs.com
O: 801-290-7692
F: 801-290-7998

Drug Establishments Current Registration Site

New Search

Search Results for **Nelson Laboratories**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Nelson Laboratories, LLC	3000233845	151663234	ANALYSIS;	6280 South Redwood Road, Salt Lake City, Utah (UT) 84123, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous 1 Next

Data Current through: Wednesday, Dec 18, 2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3000233845

Other FDA Registrations:
Blood:
Devices: FEI: 0001721109
Drugs: FEI: 0151663234

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2020
Last Registration Receipt Date: 12/09/2019
Summary Report Print Date: 12/10/2019

Legal Name and Location:

Nelson Laboratories, LLC
6280 South Redwood Road

Salt Lake City, Utah 84123
USA

Phone: 801-290-7500 **Ext.:**

Reporting Official:

Matthew D Cushing, Senior Director, Global Quality
6280 South Redwood Road
Salt Lake City, Utah 84123
USA
Phone: 801-290-7692 Ext.
mcushing@nelsonlabs.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: Yes

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane						X						
Blood Vessel						X						
Bone						X						
Cardiac Tissue - non-valved												
Cartilage						X						
Cornea						X						
Dura Mater						X						
Embryo												
Fascia						X						
Heart Valve						X						
HPC Apheresis	Autologous, Family Related					X						
HPC Cord Blood												
Ligament						X						
Nerve Tissue												
Oocyte												
Ovarian Tissue						X						
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium						X						
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera						X						
Semen												
Skin						X						
Tendon						X						
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue						X						

FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020

Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00083416***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Denmark confirms the following:
The manufacturer: ***Nelson Laboratories, Inc.***
Site address: ***6280 South Redwood Road, Salt Lake City, UT, 84123, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-09-29*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

2016-12-22

Name and signature of the authorised person of the Competent Authority of Denmark

Anette Bjerregaard
Danish Medicines Agency
Tel: ***+45 2093 4901***
Fax:

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-05218-1

Issued to:

Nelson Laboratories LLC

Manufacturing Site Address:

6280 South Redwood Road
Salt Lake City UT
United States Of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 17 to 18 December-2018, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products (2013).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 18 December 2020

ISSUE DATE: 18 October 2019

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-05218-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Manufacturing Step
Human Tissue	Sterile & Non Sterile	Testing microbial

The following limitations are applicable to these manufacturing operations:

The certificate is restricted to sterility testing, including bacteriostasis and fungistasis testing.

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0504274	10-31-2020	$244

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	ANALYTICAL LAB	09-25-2019

NELSON LABORATORIES, LLC
6280 S REDWOOD RD
SALT LAKE CITY, UT 84123-6600

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0504274	10-31-2020	$244

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	ANALYTICAL LAB	09-25-2019

NELSON LABORATORIES, LLC
6280 S REDWOOD RD
SALT LAKE CITY, UT 84123-6600

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

LIMITED ACTIVE LICENSE

EFFECTIVE DATE: 05/10/2016

EXPIRATION DATE: 09/30/2021

ISSUED TO: Nelson Laboratories LLC.
6280 South Redwood Rd
Salt Lake City UT 84123

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

9738664-1714 Pharmacy - Class E Business
9738664-8915 Limited Controlled Substance-Business

Limited to Third Party Logistics Provider

SIGNATURE OF HOLDER

ista®

CERTIFIED TESTING LABORATORY

This recognizes that the company listed below is a **Certified Testing Laboratory** member of the International Safe Transit Association (ISTA).

Member ID: 9760 **Valid through: May 1, 2021**

Location: Taylorsville, Utah

Nelson Laboratories, Inc.

A.J. Gruber
ISTA President

Eric Hiser
ISTA Vice President - Technical

OMB Control No. 1018-0092 Expires: 12/31/2018

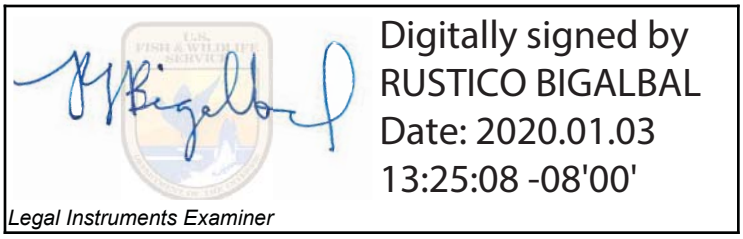
Import/Export License

Permit Number: A16819

Date Effective: 01/03/2020 Date Expires: 12/31/2020

Issuing Office:

Department of the Interior
U.S. FISH AND WILDLIFE SERVICE
Office of Law Enforcement
2800 Cottage Way, RM W2928
Sacramento, CA 95825
Tel: 916-414-6660
Email: permitsWestLE@fws.gov



Legal Instruments Examiner

Permittee:

NELSON LABORATORIES, LLC
6280 S REDWOOD ROAD
SALT LAKE CITY, UT 84123 US

Principal Officer: JEFFERY REES NELSON , PRESIDENT

Authority - Statutes and Regulations: 16 USC 1538(d); 50 CFR 13; 50 CFR 14

Location where authorized activity may be conducted: Any Designated Port per 50 CFR 14 (unless further restricted below).

Reporting Requirements: Licensee is required to maintain records per 50 CFR 13 and 14. Acceptance of this license authorizes inspection of records per 50 CFR 13.

Conditions and Authorizations:

A. General conditions set out in Subpart D of 50 CFR 13, and specific conditions contained in federal regulations cited above, are hereby made a part of this permit. All activities authorized herein must be carried out in accord with and for the purposes described in the application submitted. Continued validity, or renewal, of this permit is subject to complete and timely compliance with all applicable conditions, including the filing of all required information and reports.
B. The validity of this permit is also conditioned upon strict observance of all applicable foreign, state, local, tribal, or other federal law.
C. Valid for use by **permittee** named above.
D. Licensee is responsible for requesting renewal of license at least 30 days prior to the expiration date as outlined in 50 CFR 13. Service Law Enforcement Officers will not clear shipments presented for import or export under expired licenses.
E. Licensee is authorized to import/export wildlife and/or wildlife products at the port(s) specified above.
F. Licensee must comply with all import/export procedures as outlined in 50 CFR 14.