Nelson Labs
A Sotera Health company

Certifications, Registrations, Licenses: Itasca, Illinois

Table of Contents

1500 W. Thorndale Ave.

Itasca, IL 60143

+1 (630) 285-9121 | nelsonlabs.com

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143

Fulfills the requirements of

ISO/IEC 17025:2017

and

Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21 CFR Part 58 Accreditation Program

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.

Jason Stine, Vice President

Expiry Date: 16 March 2025

Certificate Number: AT-1382.01

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

GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM [1]

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143

Shana Sanders 630-285-9121
SSanders@nelsonlabs.com

TESTING

Valid to: **March 16, 2025** Certificate Number: **AT-1382.01**

Microbiological[1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	STP0046; USP<85>; USP<161>; ANSI/AAMI ST72	Medical Devices, Pharmaceuticals, Tissues	Microplate Reader
Bioburden	STP0036; ISO 11737-1	Medical Devices, Pharmaceuticals, Tissues	Biosafety Cabinet, Incubators, Laminar Flow Hood
Biological Indicator Sterility	STP0079; ISO 11138-1 to -4; USP<55>; ISO 11135; AAMI TIR 14	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubators
Product Sterility Bacteriostasis / Fungistasis	STP0077; STP0078; ISO 11737-2; USP<71>	Medical Devices, Pharmaceuticals, Tissues	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms)	STP0045; USP<55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators
Organism Identification (Genetic and Gram Stain)	STP0173; STP0105; USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope

Microbiological[1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
TOC	STP0028 based on USP<643>	Medical Devices, Pharmaceuticals	Washer/Disinfectors Sterilizers (Steam) UV/VIS Spectrophotometer
Radiation Dose Unit	STP0044	Medical Devices	Biosafety Cabinet, Laminar Flow Hood Product Sterility Suite ISO Class 5 Hoods Incubators

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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

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/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	STP0028 based on USP<643>	Water – USP	TOC Analyzer
Water Conductivity	STP0147 USP <645>	Water – USP	Conductivity Meter
pH	STP0029 USP <791>	Water – USP	pH Meter

Note:

1. Microbiological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1382.01.

Jason Stine, Vice President

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **nelson laboratories**

CSVExcel
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)	12/31/2024
Nelson Laboratories, LLC	3000717698	032350261	ANALYSIS;	1500 W Thorndale Ave, Itasca, Illinois (IL) 60143, United States (USA)	12/31/2024

Showing 1 to 2 of 2 entries
Previous1Next
Data Current through: Wednesday, Nov 29, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

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: 3007950533

Other FDA Registrations:
Blood:
Devices:
Drugs: FEI: 3000717698

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/16/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

Nelson Laboratories, LLC
1500 W. Thorndale Ave

Itasca, Illinois 60143
USA

Phone: 630-285-9121 **Ext.:**

Reporting Official:

Robert Thoreson, Director of Quality Assurance
6280 South Redwood Road
Salt Lake City, Utah 84123
USA
Phone: 801-290-7618 Ext.
rthoreson@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		X						
Cardiac Tissue - non-valved				X		X						
Cartilage						X						
Cornea				X		X						
Dura Mater						X						
Embryo												
Fascia						X						
Heart Valve				X		X						
HPC Apheresis	Autologous, Family Related					X						
HPC Cord Blood												
Ligament				X		X						
Nerve Tissue						X						
Oocyte												
Ovarian Tissue						X						
Pancreatic Islet Cells - autologous						X						
Parathyroid						X						
Pericardium						X						
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane						X						
Sclera						X						
Semen												
Skin				X		X						
Tendon				X		X						
Testicular Tissue						X						
Tooth Pulp						X						
Umbilical Cord Tissue						X						

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3007950533

Legal Name: Nelson Laboratories, LLC

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2024**

Expires: May 01, **2025**

Joseph Spyridakis, Facility Director
Nelson Labs
1500 W Thorndale Ave
Itasca, IL 60143

Registration Number 0819

State of Illinois
2024
Sperm/Tissue Bank Registration

Nelson Labs

Dear Director:

We are in receipt of your **Registration** with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter I: Department of Public Health Subchapter D:* ***Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.***

Sincerely,

Brandon Rakowski
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.

Nelson Labs
A Sotera Health company

31 Mar 2023

Regulatory Inspection History, GMP and GLP Compliance, and Debarment Statement

Dear Sponsor,

Nelson Laboratories (NL), LLC located at 1500 W. Thorndale, Itasca, IL 60143, is audited by the U.S. Food and Drug Administration (FDA) according to current good manufacturing practices (GMP), good laboratory practices (GLP), and good tissue practices (GTP), as applicable. We are also currently ISO 17025:2017 accredited by the ANSI- ASQ National Accreditation Board (ANAB) as a testing laboratory.

We certify that the facility, tests, and controls that are used in the analysis of your products are in compliance with the following:

- Current Good Manufacturing Practices, as codified in 21 CFR 210/211 and 820
- Current Good Tissue Practices, as codified in 21 CFR 1270/1271
- Current Good Laboratory Practices, as codified in 21 CFR 58 or 40 CFR 160, when requested
- Current E.U. and TGA Good Manufacturing Practices

10 Year Regulatory Inspection History

FDA:		
2011	07-08 Oct	CDRH, CDER, CBER,
2013	30 May-12 June	CDRH, CDER, CBER, CFSAN
2016	11 Mar	CDRH, CDER, CBER, CVM
2018	06-08 Nov	CDER, CVM
2021	14 Apr	*FDA 4003a Document audit

Pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 D.S.C. 335a (k), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), NL certifies that it did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of the Generic Drug Enforcement Act of 1992. No person employed by NL has currently or in the past five (5) years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. NL has not been debarred by the FDA and is not currently involved in any debarment proceeding with the FDA.

Sincerely,

DocuSigned by:
Robert Thorseon
Signer Name: Robert Thorseon
Signing Reason: I approve this document
Signing Time: Apr 3, 2023 | 4:24 PM MDT
6D561BC75E97432B9FF4CF3EF4893377

Rob Thoreson
Director of Quality Assurance
801-290-7618
RThoreson@nelsonlabs.com

2023-SDSU-00021-A

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

INDUSTRIAL ALCOHOL USER PERMIT

PERMIT NUMBER
SDS-IL-20134

EFFECTIVE DATE
01/25/2023

NELSON LABORATORIES LLC
DBA: NELSON LABORATORIES, LLC
1500 W THORNDALE AVE
ITASCA, IL 60143

MAXIMUM QUANTITY TO BE WITHDRAWN PER CALENDAR YEAR 500

[X] **GALLONS** [ ] **PROOF GALLONS**

You are hereby authorized to:

- [ ] Withdraw and use alcohol free of tax
- [ ] Recover/restore alcohol free of tax
- [X] Withdraw and use specially denatured alcohol/rum
- [ ] Withdraw and deal in specially denatured alcohol/rum
- [ ] Recover/restore and use specially denatured alcohol/rum

Operations must be conducted at the above address, subject to applicable law and regulations, the Federal Water Pollution Control Act, and to the conditions set forth below.

This permit is continuing and will remain in force unless suspended, revoked, voluntarily surrendered or automatically terminated.

This permit is not transferable. In the event of any lease, sale or other transfer of the operations authorized or of any other changes in the proprietorship of such operations, this permit shall automatically terminate unless the successor requalifies by the end of thirty days. If a timely application is filed, the outstanding permit will continue in effect until the application is acted upon by the National Revenue Center or Puerto Rico Operations Office.

Tax free alcohol may not be used for any purpose or in any manner not shown on an approved permit application.

THIS PERMIT IS SUBJECT TO THE FOLLOWING CONDITIONS:

GENERAL CONDITIONS

1. That the permittee complies with the provisions of 26 U.S.C., Chapter 51 and its regulations.
2. That the permittee has made no false statement as to any material fact in the application for this permit.
3. That the permittee furnishes all the material information required by law and regulations.
4. That the permittee and all persons interested in the permitted operations, shall not violate or conspire to violate any law of the United States relating to intoxicating liquor and shall not be convicted of any offense under the United States Code punishable as a felony or of any conspiracy to commit such an offense.
5. That the permittee continues, by reasons of operations, to be warranted to procure, possess and dispose of/use, as the case may be, specially denatured alcohol/rum or alcohol free of tax.
6. That the permittee timely prepares and maintains at the address stated on this permit, adequate and accurate records and reports as required by 26 U.S.C. 5275 and its regulations, and makes timely, true and complete reports of operations as required by law and regulations.
7. That the permittee has not discontinued the operations authorized by this permit for a period exceeding two years.

SPECIFIC TAX FREE CONDITIONS

That the permittee uses alcohol withdrawn free of tax only for the purposes set forth in this permit and within the conditions and limitations specified in 26 U.S.C. 5214 (a)(2) or (3).

SPECIFIC SPECIALLY DENATURED ALCOHOL/RUM CONDITIONS

1. That the permittee shall use specially denatured alcohol/rum in the manufacture of an article in accordance with an approved formula (including any general use formulas). When using specially denatured alcohol, for laboratory or mechanical purposes, not in the development of a product, use in the manner provided by law and regulations.
2. That the permittee manufactures, labels, advertises and sells or uses articles in the manner provided by law and regulations.
3. That the permittee, if authorized by this permit, recovers completely denatured alcohol, specially denatured alcohol/rum, or articles, in accordance with approved statements of process, in the manner provided by law and regulations.
4. That the permittee shall not dispose of specially denatured alcohol/rum to a user without a valid copy of the user's permit.

THIS IS AN [ ] **ORIGINAL PERMIT** [X] **AMENDED PERMIT**

REASON FOR AMENDMENT (If applicable)
See Attachments

DATE OF AMENDMENT
03/22/2023

SIGNATURE AND TITLE OF AUTHORIZED TTB OFFICIAL

Technician

ATTACHMENT TO TTB F 5150.9

NELSON LABORATORIES LLC

Nelson Laboratories, LLC

1500 W THORNDALE AVE
ITASCA, IL 60143

Reason for Amendment :

Change in Withdrawal Amount

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0657695	10-31-2024	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ANALYTICAL LAB	08-08-2023

NELSON LABORATORIES LLC
DBA NELSON LABS
1500 W THORNDALE AVE
ITASCA, IL 601431133

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
RN0657695	10-31-2024	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ANALYTICAL LAB	08-08-2023

NELSON LABORATORIES LLC
DBA NELSON LABS
1500 W THORNDALE AVE
ITASCA, IL 601431133

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)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0657695	10-31-2024	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ANALYTICAL LAB	08-08-2023

NELSON LABORATORIES LLC
DBA NELSON LABS
1500 W THORNDALE AVE
ITASCA, IL 601431133

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
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.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes: