# Itasca, Illinois Certifications, Registrations, Licenses Table of Contents

Document	Page(s)
Table of Contents	1
ISO 17025 - Certificate of Accreditation	2
ISO 17025 – Scope of Accreditation	3-5
FDA: Generic Drug Statement of Compliance (GDUFA)	6
Memo	
FDA: Establishment Registration and Listing for Human Cells,	7-8
Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	
FDA: Drug Establishment Registration	9
Regulatory Inspection History, GMP and GLP compliance,	10
and Debarment Statement	
DEA: Controlled Substance Registration Certificate	11-12
Controlled Substance Registration – State of Illinois	13
Sperm/Tissue Bank Registration – State of Illinois	14
Industrial Alcohol User (SDA) Permit	15-16
Business License – State of Illinois	17-18
Business License – Village of Itasca	19



# **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 <a href="https://www.anab.org">www.anab.org</a>.

Jason Stine, Vice President Expiry Date: 16 March 2027

Certificate Number: AT-1382.01









# SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

## GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM <sup>1</sup>

# Nelson Laboratories, LLC

1500 West Thorndale Avenue Itasca, IL 60143

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

## **TESTING**

Valid to: March 16, 2027 Certificate Number: AT-1382.01

## Microbiological<sup>1</sup>

Version 019 Issued: February 25, 2025

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	NEL-STP-0046; USP<85>; USP<161>; EP 2.6.14 JP 4.01 ANSI/AAMI ST72	Medical Devices, Pharmaceuticals, Tissues	Microplate Reader
Bioburden	NEL-STP-0036; ISO 11737-1	Medical Devices, Pharmaceuticals, Tissues	Biosafety Cabinet, Incubators, Laminar Flow Hood
Biological Indicator Sterility	NEL-STP-0079; 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	NEL-STP-0077; NEL-STP-0078; ISO 11737-2; USP<71> EP 2.6.1 JP 4.06	Medical Devices, Pharmaceuticals, Tissues	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms)	NEL-STP-0045; USP<55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators





# $Microbiological^1\\$

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Organism Identification (Genetic and Gram Stain)	NEL-STP-0173; NEL-STP-0105; USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope
TOC	NEL-STP-0028 based on USP<643>	Medical Devices, Pharmaceuticals	Washer/Disinfectors Sterilizers (Steam) UV/VIS Spectrophotometer
Radiation Dose Unit	NEL-STP-0044 ISO 11737-1 ISO 11737-2	Medical Devices	Biosafety Cabinet, Laminar Flow Hood Product Sterility Suite ISO Class 5 Hoods Incubators

## Mechanical

Specific Tests and/or Properties Measured	Specificat <mark>ion, Standard,</mark> Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Particulates	NEL-STP-0011 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	NEL-STP-0016 based on ANSI/AMMI/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	NEL-STP-0028 based on USP<643>	Water – USP	TOC Analyzer
Water Conductivity	NEL-STP-0147 USP <645>	Water – USP	Conductivity Meter
рН	NEL-STP-0029 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







### **RE: Statement of Compliance to GDUFA Self-Identification Requirement**

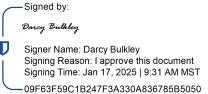
17 Jan 2025

Dear Sponsor,

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, Utah, with Sotera Health located in Broadview Heights, Ohio.

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.

GDUFA has a list for the facilities that renew their registration. Our registration can be found on the FDA's website: <u>Generic Drug Facilities</u>, <u>Sites and Organization Lists | FDA</u> for the current fiscal year.



### Darcy Bulkley

Regulatory Affairs Manager Nelson Laboratories, LLC <u>dbulkley@nelsonlabs.com</u> O: 801-290-9009

# 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

Ext.:

FEI: 3007950533

Other FDA Registrations:

Blood: Devices:

Drugs: FEI: 3000717698

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/12/2024 Summary Report Print Date: 12/20/2024

Legal Name and Location:

Nelson Laboratories, LLC 1500 W. Thorndale Ave

Itasca, Illinois 60143

Phone: 630-285-9121

USA

Reporting Official:
Shana Sanders, Sr. Manager Quality Assurance

1500 W. Thorndale Ave Itasca, Illinois 60143

USA

Phone: 630-285-9121 Ext. 6901 ssanders@nelsonlabs.com

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

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)).

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

Additional Information: No addi

No additional information provided.

Proprietary Name(s):

FEI: 3007950533

Legal Name:

Nelson Laboratories, LLC



Search FDA.gov





# Drug Establishments Current Registration Site

**New Search** 

**Search Results for Nelson Lab** 

Showing 1 to 2 of 2 Show entries (filtered from 4 total entries) Show entries

Firm Name	FDA Establishment   Identifier	DUNS \$	Business Operations	Address	Registration Expiration Date
Nelson Laboratories, LLC	3000233845	151663234	ANALYSIS	6280 South Redwood Road, Salt Lake City, Utah (UT) 84123, United States (USA)	12/31/2025
Nelson Laboratories, LLC	3000717698	032350261	ANALYSIS	1500 W Thorndale Ave, Itasca, Illinois (IL) 60143, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Dec 20, 2024

**New Search** 



04 Sep 2024

### 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

Date		Inspection Scope
2016	11 Mar	CDRH, CDER, CBER, CVM
2018	06-08 Nov	CDER, CVM
2021	14 Apr	*FDA 4003a Document audit
2024	22-25 July	Pharma GMP

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,



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

> 1500 W Thorndale Itasca, IL 60143 630-285-9121 nelsonlabs.com

DEA REGISTRAT	ION THIS REGISTRATION	FEE	
NUMBER	EXPIRES	PAID	
RN0657695	10-31-2025	\$296	
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE	
2,2N,3, 3N,4,5	ANALYTICAL LAB	09-19-2024	
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 REGISTRA NUMBER	THIS RECISTRATION EXPIRES	PAID
RN0657695	5 10-31-2025	\$296
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ANALYTICAL LAB	09-19-2024

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

Form DEA-223 (9/2016)

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.

DEA REGISTRA NUMBER	TION THIS REGISTRATION EXPIRES	FEE PAID
RN0657695	10-31-2025	\$296
	100	
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ANALYTICAL LAB	09-19-2024
DBA NELSO	PRNDALE AVE	

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

 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:



Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4642238





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 <u>2024</u> 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.

2020 0000 00021 77			
DEPARTMENT OF THE TREASURY	PERMIT NUMBER		
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU	SDS-IL-20134		
INDUSTRIAL ALCOHOL USER PERMIT	EFFECTIVE DATE		
	01/25/2023		
NELSON LABORATORIES LLC	MAXIMUM QUANTITY TO BE WITHDRAWN PER CALENDAR YEAR		
DBA: NELSON LABORATORIES, LLC	500		
1500 W THORNDALE AVE	✓ GALLONS PROOF GALLONS		
ITASCA, IL 60143	X GALLONS PROOF GALLONS		
You are hereby authorized to:  X  Withdraw and use specially	y denatured alcohol/rum		
Withdraw and use alcohol free of tax  Withdraw and deal in spec	ially denatured alcohol/rum		
Recover/restore alcohol free of tax  Recover/restore and use s	pecially denatured alcohol/rum		
Operations must be conducted at the above address, subject to applicable law and regreater, and to the conditions set forth below.	ulations, the Federal Water Pollution Control		
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 in the proprietorship of such operations, this permit shall automatically terminate unless days. If a timely application is filed, the outstanding permit will continue in effect until the Revenue Center or Puerto Rico Operations Office.	the successor requalifies by the end of thirty		
Tax free alcohol may not be used for any purpose or in any manner not shown on an ap	proved permit application.		
THIS PERMIT IS SUBJECT TO THE FOLLOWING CONDITIONS:	¥		
GENERAL CONDITIONS			
<ol> <li>That the permittee complies with the provisions of 26 U.S.C., Chapter 51 and its regulations.</li> <li>That the permittee has made no false statement as to any material fact in the application for this permit.</li> <li>That the permittee furnishes all the material information required by law and regulations.</li> <li>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.</li> <li>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.</li> </ol>			
6. That the permittee timely prepares and maintains at the address stated on this permitand some required by 26 LLS C. 5275 and its regulations, and makes timely true			
and reports as required by 26 U.S.C. 5275 and its regulations, and makes timely, true as required by law and regulations.	e and complete reports of operations		
7. That the permittee has not discontinued the operations authorized by this permit for a SPECIFIC TAX FREE CONDITIONS	period exceeding two years.		
That the permittee uses alcohol withdrawn free of tax only for the purposes set forth in t limitations specified in 26 U.S.C. 5214 (a)(2) or (3).	his permit and within the conditions and		
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 AMENDED PERMIT			
REASON FOR AMENDMENT (If applicable)	DATE OF AMENDMENT		
See Attachments 03/22/2023			
SIGNATURE AND TITLE OF AUTHORIZED TTB OFFICIAL			
Technician			

TTB F 5150.9 (01/2005)

## **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



# Taxpayer Notification **Business Authorization**



#BWNKMGV #CNXX X112 3492 52X1# NELSON LABORATORIES LLC 6280 S REDWOOD RD SALT LAKE CITY UT 84123-6600 December 31, 2024

Letter ID: CNXXX112349252X1

**Account ID:** 4282-0340

# We have issued your Certificate of Registration.

We have issued your Illinois Business Authorization.

Please verify that all of the information on the Business Authorization is correct. If all of the information is correct, you may print a paper copy from a MyTax Illinois account to visibly display at the business address listed.

Your Illinois Business Authorization is an important tax document that indicates that you are registered or licensed with the Illinois Department of Revenue to legally do business in Illinois.

If you wish to be registered for any other taxes or fees, you must complete a new application. For questions, visit our website at **tax.illinois.gov** or call us weekdays between 8:00 a.m. and 4:30 p.m. at the telephone number below.

CENTRAL REGISTRATION DIVISION ILLINOIS DEPARTMENT OF REVENUE PO BOX 19030 SPRINGFIELD IL 62794-9030 Rev.CRD@illinois.gov

217 785-3707

### Verify that all of your Illinois Business Authorization information is correct.

If not, contact us immediately.

If all of the information is correct, you may print and visibly display at the business listed. Your Illinois Business Authorization is an important tax document that indicates that you are registered or licensed with the Illinois Department of Revenue to legally do business in Illinois.





# **VILLAGE OF ITASCA**

**LICENSING YEAR: 2025** 

**BUSINESS LICENSE** 

550 W. IRVING PARK RD.

ITASCA · ILLINOIS · 60143

**DATE ISSUED: 1/01/2025** 

**LICENSE #: 0694** 

**DATE EXPIRES:** 12/31/2025

**BUSINESS NAME: NELSON LABS, LLC** 

**CATEGORY:** Laboratory / Testing Facility

**BUSINESS ADDRESS:** 

MAIL TO:

1500 W. THORNDALE AVE.

NELSON LABS, LLC

1500 W. THORNDALE AVE.

ITASCA IL 60143

MUST DISPLAY THIS CERTIFICATE FOR PUBLIC VIEW

