Certifications: Itasca

Table of Contents

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

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 2023
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

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143

Julie Arinaga 630-285-9121
JArinaga@nelsonlabs.com

TESTING

Valid to: **March 16, 2023** Certificate Number: **AT-1382.01**

Microbiological

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	Microplate Reader
Bioburden	STP0036; ISO 11737-1	Medical Devices, Pharmaceuticals	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 Incubator
Product Sterility Bacteriostasis / Fungistasis	STP0077; STP0078; ISO 11737-2; USP <71>	Medical Devices, Pharmaceuticals	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms, USP 61/62)	STP0045; USP <55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators
Organism Identification (Genetic and Gram Stain)	STP0173; STP0105; USP <1113>	Medical Devices and Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cleaning, Disinfection, Sterilization Including the following subanalyses (separately accredited): Hemoglobin Protein TOC	Template 122 and Template 202 based on AAMI TIR 12,30, ASTM E1837, ISO 17664 STP0086 based on ANSI/AAMI ST79, AAMITIR12, AAMI/ISO 17665, USP <1211> Template 98 and Template 124 based on ISO 17664, ANSI/AAMI ST79, ANSI/AAMI ST77, ANSI/AAMI/ISO 11135, AAMI TIR30	Medical Devices, Reusable Devices	Washer/Disinfectors Sterilizers (Steam) UV/VIS Spectrophotometer

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

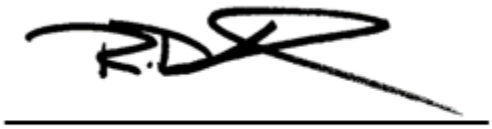
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	STP0016 based on ANSI/AMMI/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	STP0028 based on USP <643>	Water – USP	TOC Analyzer

Chemical

Biological Marker Analysis Hemoglobin Protein	STP0087, STP0183 based on ASTM F756-13, AAMI TIR30 and Cleaning, Disinfection, Sterilization references previously listed	Medical Devices, Reusable Devices	Spectrophotometer

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1382.01.



R. Douglas Leonard Jr., VP, PILR SBU

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: 2021
Last Registration Receipt Date: 11/23/2020
Summary Report Print Date: 11/30/2020

Legal Name and Location:

Nelson Laboratories, LLC
1500 W. Thorndale Ave

Itasca, Illinois 60143
USA

Phone: 630-285-9121 **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		X						
Bone				X		X						
Cardiac Tissue - non-valved												
Cartilage				X		X						
Cornea				X		X						
Dura Mater												
Embryo												
Fascia				X		X						
Heart Valve				X		X						
HPC Apheresis												
HPC Cord Blood												
Ligament				X		X						
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera				X		X						
Semen												
Skin				X		X						
Tendon				X		X						
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue				X		X						

FDA information collection OMB Control number: 0910-0543, expiration date: 07/31/2023

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3007950533

Legal Name: Nelson Laboratories, LLC

Nelson Labs™
A Sotera Health company

22 Jun 2020

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 14 May 2020 under the 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**	**FY2021**
Nelson Laboratories, LLC 6280 South Redwood Road Salt Lake City, UT 84123 USA	API / FDF Analytical Testing	FEI #**3000233845** DUNS #**151663234**	**FY2021**

Sincerely,

Matthew D. Cushing
Senior Director, Global Quality
Nelson Laboratories, LLC
6280 S. Redwood Road
Salt Lake City, UT 84123
mcushing@nelsonlabs.com

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 01, 2020** Expires: **May 01, 2021**

Michael J Rahn, Facility Director
Nelson Labs
1500 W Thorndale Ave
Itasca, IL 60143

Registration Number 0819

State of Illinois
2020
Sperm And Tissue
Establishment 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,

Juan Garcia
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.