Nelson Labs
A Sotera Health company

Salt Lake City, Utah Certifications, Registrations, Licenses

Table of Contents

Document	Page(s)
EMA Report – Danish Medicines Agency	23-41
Utah State Business License	42
ISTA Testing Laboratory Certification	43
Business License: City of Taylorsville	44

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

and

FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices

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

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

FDA ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT PROGRAM - BIOCOMPATIBILITY TESTING OF MEDICAL DEVICES [1]

GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM [2]

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Loxane Konesavanh lkonesavanh@nelsonlabs.com
Robert Thoreson rthoreson@nelsonlabs.com
www.nelsonlabs.com 801-290-7500

TESTING

Valid to: **March 16, 2025** Certificate Number: **AT-1382**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices [1,2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
MEM Elution Cytotoxicity	ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices – Part 5 (FDA Recognition No.2-245); ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices -part 12 (FDA Recognition No. 2-191)	Medical Devices	ISO Class 5 Hoods, Microscope, Incubators

Microbiological[2]

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

Microbiological[2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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
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, BI Sterility)	STP0045, and STP0079, 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

Microbiological[2]

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 sub-analyses (separately accredited): • Hemoglobin • Protein • Carbohydrates • MEM elution • TOC • Bioburden	Template 122, STP0129, STP0194 and Template 202 based on AAMI TIR 12, ASTM ST98, 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	Medical Devices, Reusable Devices	Washer/Disinfectors Sterilizers (Steam, EO, VHP) UV/VIS Spectrophotometer
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

Microbiological[2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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)	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 6 Cleanrooms and ISO Class 5 Hoods Incubators Isolator
Standard Plate Counts	STP0035 based on USP <71> STP0165 based on USP<61>	Water, Food, Cosmetics, Pharmaceuticals	ISO Class 5 Hoods Incubators
Antimicrobial Potency Assay	STP0085 based on USP <81> and 21 CFR Part 436 Subpart D – Microbiological Assay Methods	Antibiotics	Incubator Calipers Waterbath pH meter

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	GC
FTIR, Material Characterization	STP0021 based on USP<851> and USP<197>	Polymers, Non-volatile Residue, Materials	FTIR, Microscope

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Water Purity Analysis • TOC • Conductivity • pH	STP0024 and STP0099 based on USP<1231>, USP<1230> And All USP monographs 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 ST98, 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, Nitrogen source
Identification of Non-Volatile Organic Compounds	STP0166 (APCI) and STP0215 (ESI) based on ISO-10993-12, 18, USP<621> and EP 2.2.29	Medical devices and general plastics used in packaging final pharmaceutical products	Liquid Chromatography/ Mass Spectrometry (LC/MS)
Identification of Semi-Volatile Organic Compounds	STP0314 based on ISO-10993-12, 18, USP<621> and EP 2.2.28	Medical devices and general plastics used in packaging final pharmaceutical products	Gas Chromatography/ Mass Spectrometry (GC/MS)

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

Mechanical / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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<787>, <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 Pre-Certification Testing (NIOSH N95/N99) and Barrier Face Coverings • Sodium Chloride Aerosol and Air Resistance Test (Respirator and barrier face covering) • Inhalation/Exhalation (Respirator) • Valve Lead (Respirator)	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 84, NIOSH TEB-ARP-STP-0058, and 0059, and ASTM F3502	Respirators and Barrier Face Coverings	Differential Pressure Apparatus, Air Flow Apparatus, Automated Filter Tester, Sodium Chloride Tester, Valve Leak Tester
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 13938-2 STP0066 EN 29073-3	Medical & Surgical Gowns and Drapes	ISO Class 6 Hoods Incubators Gelbo Flex Unit Particle counter Burst tester Instron (Tensile) tester Rulla II testers

Note:

1. Testing is in conformance to the FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices.
2. Biological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.
3. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1382.

Jason Stine, Vice President

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Wednesday, January 10, 2024 7:33 AM
To: Matthew D. Cushing <MCushing@nelsonlabs.com>
Subject: [EXTERNAL] Registration Number 1721109: Successful 2024 Medical Device Establishment Registration

Dear Matthew Cushing:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2024:

Registration Number: 1721109
Owner Operator Number: 10062765
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, 2024. Registration for 2025 will be conducted between October 1 and December 31, 2024.

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

12 Feb 2024

RE: 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, 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: Generic Drug Facilities, Sites and Organization Lists | FDA for the 2024 fiscal year.

6280 S. Redwood Road, Salt Lake City, UT, 84123
+1 (801) 290-7500 | nelsonlabs.com

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: 2024
Last Registration Receipt Date: 11/16/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

Nelson Laboratories, LLC
6280 South Redwood Road

Salt Lake City, Utah 84123
USA

Phone: 801-290-7500 **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

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)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0504274	10-31-2024	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	ANALYTICAL LAB	10-17-2023

NELSON LABORATORIES, LLC
6280 S REDWOOD RD
SALT LAKE CITY, UT 841236600

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	10-31-2024	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	ANALYTICAL LAB	10-17-2023

NELSON LABORATORIES, LLC
6280 S REDWOOD RD
SALT LAKE CITY, UT 841236600

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)

Nelson Labs
A Sotera Health company

RE: EU GMP Compliance Certification

Dear Sponsor,

Nelson Laboratories (NL), LLC, located at 6280 South Redwood Road, Salt Lake City, UT 84123, was audited by the Danish Medicines Agency on behalf of the European Medicines Agency (EMA) on 21-24 Sep 2021, and was found to be in compliance with the requirements of Directive(s) 2003/94/EC and 91/412/EEC of the Good Manufacturing Practice published in "The Rules Governing Medicinal Products in the European Union," Vol. 4, EU GMP part I and related annexes.

The redacted inspection report is included with this memo, as are the three EU GMP certificates issued: DK H 10000339, DK V 10000341, and DK V 10000342. Each certificate represents a product which was within the scope of the inspection; the product is listed on page 2 of the certificate. Due to confidentiality, the product information has been redacted.

The lead auditor was contacted for clarification in regard to the following verbiage: *Any restrictions related to the scope of this certificate.* In response to our request, Ms. Holm explained that all the underlying activities to 1.6.1, 1.6.2, and 1.6.3 of the certificates are covered, such as the inspected areas (e.g., sample receiving area, media preparation, glassware, and water system, etc. [See section 2.2 in the inspection report]), and all GMP-relevant topics (e.g., Quality Management System, Personnel, Premises, and Equipment, etc. [See section 5.3 to section 5.10, inspection report]) are covered by the inspection. Ms. Holm further clarified that EU compliance will also apply to products and requests for sponsors to the extent that the activities are covered by the inspected areas and associated GMP-relevant topics.

D Bulkley

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

Danish Medicines Agency

CERTIFICATE NUMBER : ***DK H 10000339***

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 .

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-09-24*** , 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.

---

[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

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				[redacted]

2021-12-16

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

Ms. Pernille Kaae Holm
Danish Medicines Agency
Tel:***+45 9351 8729***
Fax:

Danish Medicines Agency

CERTIFICATE NUMBER : ***DK V 10000341***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/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. 44(3) of Regulation 726/2004/EC .

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-09-24*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

---

[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

Veterinary 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

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				[redacted]

2021-12-16

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

Ms. Pernille Kaae Holm
Danish Medicines Agency
Tel:***+45 9351 8729***
Fax:

Danish Medicines Agency

CERTIFICATE NUMBER : ***DK V 10000342***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/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. 80(4) of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-09-24*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

---

[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

Veterinary 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

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				[redacted]

2021-12-07

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

Ms. Pernille Kaae Holm
Danish Medicines Agency
Tel:***+45 9351 8729***
Fax:

Report Reference no.	Inspection Reference Numbers: INS/GMP/2019/049 INS/GMP/2021/074
Name of product(s) and pharmaceutical form(s)	[redacted]
Inspected site	Remote inspection of: Nelson Laboratories, Inc. 6280 South Redwood Road Salt Lake City UT 84123-6600 USA EudraGMDP document reference no.: INS/GMP/2019/049 and INS/GMP/2021/074

Activities carried out

	Human	Veterinary	IMP
Manufacture of finished products			
Sterile	☐	☐	☐
Non-sterile	☐	☐	☐
Biologicals	☐	☐	☐
Sterilisation of excipient, active substance or medicinal product	☐	☐	☐
Primary packaging	☐	☐	☐
Secondary packaging	☐	☐	☐
Quality control testing	☒	☒	☐
Importing	☐	☐	☐
Batch certification	☐	☐	☐
Storage and distribution	☐	☐	☐
Manufacture of active substance	☐	☐	☐
Other:	☐	☐	☐

Inspection date(s)	21, 22, 23 and 24 September 2021
Inspector(s) and expert(s)	Pernille Kaae Holm, Medicines Inspector at the Danish Medicines Agency (DMA), Lead authority Vincent Neuviale, Inspector at the French Veterinary Medicines Agency (Anses-ANMV), Supporting Authority
References	Reference number of marketing and/or manufacturing authorisations. [redacted]

1 Introduction

Nelson Labs is provider of microbiological and biopharma testing services across 13 global lab locations. Nelson Labs perform microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. Nelson Labs offers more than 700 various tests across the product lifecycle, from initial product validation to ongoing quality control and extractables and leachables testing and have more than 2500 active customers in more than 50 different countries.

The current EMA inspection concerns only the inspection of Nelson Lab in Salt Lake City (Utah). The inspection was originally scheduled for 2019, but was postponed due to the Covid-19 pandemic. It was decided to carry out the inspection in 2021, but due to the continuing Covid-19 pandemic, the inspection was conducted as a remote inspection. The inspection of the relevant premises was carried out using pre-recorded videos that were uploaded to a SharePoint website, where all documentation prior to and during the inspection was also uploaded. In addition, the inspection was conducted based on live tours with video in the laboratories as well as interviews and review of documentation via Teams.

FDA did not take part in the inspection.

Major changes since last EMA inspection is that Nelson Labs was acquired by Sterigenics International in April 2016. In November 2017, Sterigenics International changed name to Sotera Health. However, Nelson Labs maintained its name and quality management system.

The last EMA inspection of the company was performed the 27, 28 and 29 September 2016 by medicines inspectors Anette Bjerregaard and Henning Willads Petersen from the Danish Medicines Agency (case No. 2016081359).

2 Brief report of the inspection activities

2.1 *Scope of inspection*

This inspection was requested by EMA and was a post-approval re-inspection of Nelson Lab in Salt Lake City (Utah). This facility has more than 700 employees. The products in scope of this inspection are:

- [redacted]
- [redacted]

The marketing authorization holder (MAH) for the covered products [redacted]

2.2 *Inspected areas and main steps/history of the inspection*

All relevant areas were inspected.

The following facilities in scope were inspected on the live tour and/or on the pre-recorded video and the uploaded key procedures:

- Sample receiving area
  - Area: Redwood 1 Second Floor, Rooms B101 and B130
  - Procedure: SOP0079 – Log In
- Media Preparation
  - Area: Redwood 2, Second Floor, Rooms U47 and U48
  - Procedure: SOP0041 – Sterility Media Production
- Glassware and Water System
  - Area: Redwood 3 Second Floor, Room 208

- Procedure: SOP0025 – Glassware Processing, Handling, and Storage and SOP0027 – Water
- Sterility Assurance Lab including Cleanroom suites where "Product Sterility test" is performed
  - Area: Redwood 2 Second Floor, Rooms U38 (Processing room, ISO class 8) and U29 through U33 (Testing suites, ISO class 6 with LAF, ISO class 5), and U23 through U27 (Walk-in incubators for incubation of samples, non-classified)
  - Procedure: STP0077 – Product Sterility
- Packaging Lab where "Mass Extraction Leak Test" ("Container Closure Integrity") is performed
  - Area: Redwood 1 First Floor, Room A127
  - Procedure: STP0140 – Mass Extraction Leak Test
- BET lab where "Bacterial Endotoxin Test" is performed
  - Area: Redwood 3 Second Floor, Rooms 202 and 203
  - Procedure: STP0046 – Bacterial Endotoxins Test
- Microbiology Lab where "Microbial Examination of Non-Sterile Products" is performed
  - Area: Redwood 3 Second Floor, Room 226 and 227 (Preparation, incubation and reads)
  - Procedure: STP0165 – Microbial Examination of Nonsterile Products and STP0034 Environmental Monitoring
- Particulates Lab where" Sizing and Counting Particulate Matter" is performed
  - Area: Redwood 3 Second Floor, Room 221
  - Procedure: STP0011 – Sizing/Counting Particulate Matter
- File cabinets: locked file cabinets for archiving paper documentation. Access restricted.

Inspected documentation included instructions/procedures, validation, qualification and calibration reports, log books, deviations, OOS, change requests, complaints, contracts, self-inspection reports, training records. Further details can be found in attached list/sections below

3 Activities not inspected

All relevant areas (i.e. areas concerned by the quality control of the 3 products in scope) were inspected. Other areas were not inspected.

4 Personnel met during the inspection

See annex 1

5 Inspectors findings and observations relevant to the inspection and deficiencies

5.1 *Overview of inspection findings from last inspection and the corrective action taken*

Follow ups from last inspection was randomly checked. Deficiency number in last EMA inspection report concerning:

1) Definition of roles and responsibilities contracts / quality agreement were weak.
2) Inadequate traceability between test code and Standard Test Procedure (STP)
3) Good Housekeeping practise was weak
4) Documentation of training was weak
5) Inadequate follow-up on finding from pest control

The status of these deficiencies was checked during the inspection and it was confirmed that the findings seemed to have been corrected. CAPA for these findings (CAPA0262: "DMA, EU GMP") was initiated shortly after the last inspection and effectiveness verification for the deficiencies resulted in findings were performed and found to be adequate.

5.2 ***Quality Management***

The company has put in place a quality management system and a quality policy that is described in MAN001 (Nelson Laboratories Quality Manual) with relevant refence to EudraLex. In addition, the procedure SOP0169 (Quality Overview) is designed to give an overview and awareness of quality processes for all employees. The system provides procedures for the activities on which the inspection is based.

Management Review (QMR)

The company carry out QMR semi-annually and annually. The quality committee meets regularly to review the quality management system to ascertain its adequacy and effectiveness and to assess opportunities for improvement as described in SOP 0099 (Quality committee and management review procedures). The summary of the annual management meeting for 2020 and the semi-annual management review Q3-Q4 2020 was presented together with a list of additional actions from the last-mentioned meeting. These actions are controlled in MasterControl.

Quality Risk Management

The company has implemented a risk management system, which was reviewed by random sampling:

- Risk assessment for sterility test (E050-1 _ Risk Analyses for Monitoring of Cleanroom Suite): hazards coming from surfaces, test samples, supplies /media, equipment, air, people, attire have been considered. Nelson considers the Cleanroom hazards identified in the risk analysis under control.
- Electronic Data Integrity Assessment for REES system (FRM1115 – Dec 2019). REES is the electronic system used for the monitoring and recording of environmental conditioning (temperature, pressure).

Product Quality Review (PQR)

N/A

5.3 ***Personnel***

The hierarchical relationship of the company is defined in an organisation chart, which was reviewed. The total headcount of employee at Nelson Labs is 1000+, of which 700+ are employee at Nelson Lab, Utah.

The SOP0098 (Training System) was reviewed. Training is typically recorded in MasterControl and training documents are maintained. Annual reviews of applicable procedural training and a review of the employee's training documentation are performed by the employee and the supervisor. The following are typically reviewed: the training documentation, the job assignments, and the training needs.
Training documents were reviewed randomly, e.g.:

- Study director ([redacted]): training as study director and as reviewer
- Analyst ([redacted]): training in Quantitative USP 61 and USP 62, Plate Reads, training checklist, vision test /colour perception test in conjunction with onboarding (Dec. 2017), re-test every year in Sterility Test
- Analyst ([redacted]): training in STP0077 (sterility), Sterility Suite Gowning Qualification Record, FRM0164 (Feb. 2021) and gowning qualification (12. Mar 2021). Retraining every year

Training was documented and staff appeared qualified and skilled with respect to their tasks and roles

5.4 ***Premises and equipment***

Access control.

Access control to the premises is ensured with keys and cards.

Pest control
The company has taken adequate measures against the intrusion of pests. Pest control procedure SOP SOP0030 was reviewed and the monthly pest control monitoring report (Aug 2021) covering Redwood 1, 2, 3, 4 and 5 was presented.

The premises of the company were inspected.
See section 2.2 above.

Premises classification

The premises of the undertaking are classified as: non-classified, ISO class 8, 7, 6 and 5.
Moreover, see section 2.2 above.

An appropriate environmental monitoring programme for classified premises, including alarm and action limits as well as trend data, has been established.
The following environmental monitoring documentation was reviewed:

- Procedure for Cleanroom Environmental Monitoring for Microorganisms (SOP0121)
- Procedure for Environmental Monitoring: Incubation and Enumeration (STP0034)
- Working Instruction for Product Sterility Test Session Environmental Monitoring (WI0222)
- Cleanroom monthly particle monitoring (August 2021)
- Environmental monitoring performed during the microbiological test of [redacted]

Qualification of premises

The qualification and/or re-qualification of the following premises was reviewed:
[environmental monitoring, loading, ventilation, etc].

- Semi-annual requalification report of cleanroom facilities redwood II, E131-35 (Aug. 2021) including cleanroom suite and the sterility processing room with its soft-wall area and pass-through.

Temperature mapping studies were considered for the controlled chamber E-6295: procedure for controlled chamber verification (SOP0073) and verification report of May 2021):

Hygiene
The company has established programs for personnel hygiene.

There was deviation to premises

Utilities
The company uses the following utilities:

- Purified water

Water quality data are collected and compiled by the QC-department internal purified water systems for Redwood 1, 2, 3 and 5 buildings based on reverse osmosis. Weekly in-house water monitoring collected in a monthly report (Sep 2021) showing that all RO/DI, DI, Milli-Q were tested for the month of august 2021 met the acceptance criteria to be considered purified water.

Qualification, calibration and maintenance of equipment
The company has a plan for qualification, calibration and equipment maintenance. The following equipment were inspected:

- Micropipette (E-4242): Calibrate certificate (Aug. 2021) and logbook with daily check of E-4242
- IR thermometer (E-6663) calibration: Sept 2021

- Temperature probe refrigerator (E-6295) calibration: Jan 2021
- Balance (E-2588) calibration: March 2021
- Laminar air flow hood (3944): HEPA filter certification of the hood in room U29, certification report for laminar flow device (July 2021) by [redacted] review and QA approved (Aug 2021)
- Laminar air flow hood (E-2662) of ISO class 5 at rest: Sept 2021
- Incubator (E-1632) 20-25°C: Annual calibration (Feb. 2021)
- Washing machine (4621) room 208: Qualification, IQ OQ Miele Washer PG8583, protocol (Nov 2017) and report (Feb 2018) and PQ protocol (Dec. 2017) and report (Mar 2018) showing that gentamycin and soap is effectively removed
- Requalification for steam sterilizers Redwood 2 (E-1601-1605): PQ report (May 2017)

There was deviation for qualification, calibration and maintenance.

Computer systems
Inventory of the GMP-critical computer systems used was presented with validation status and functionality. The following systems were inspected with respect to access control, user rights, audit trail, audit trail review, validation as well as backup and restorage of data:

- WinKQCL (software for Bacteria Endotoxin Test)
- Leak RX (software for Mass Extraction Leak)
- Annual requalification report (April 2021) for the REES system

There were deviations to computer systems.

5.5 ***Documentation***
The company's document management system was presented.

Specifications and manufacturing formulas
The company has a system which ensures that control processes are carried out according to defined specifications and formulas. Quality records and archiving procedure was found to be in general compliance.

Deviations
The company has a system to manage with deviations. The list of deviations for the period 1. Sep. 2019 to the inspection date was presented and the following deviations (Quality Events, QE) were examined:

- QE25152: STP0046 (Bacterial Endotoxins Test) "The negative control was not added to the 96 well plate" (Sep 2021)
- QE21575: STP0140 (Mass Extraction Leak Test) " - The syringe method was selected" (Jan 2020)
- QE25099: STP0078 (Sterility and MPN Method suitability) - Incubation time for bioburden was exceeded the 5 days maximum authorized by the procedure (Aug 2021)
- QE20793: STP0165 (Microbiological Examination of Nonsterile Products) – organisms screens were not be filtered prior to being placed in enrichment broth – the testing method was not respected. (Sept 2019)

The SOP0096 (Corrective and Preventive Action) was presented. Moreover, a list of CAPA for the period 1. Sep. 2019 to the current inspection date was presented and the following CAPAs were examined with respect to CAPA investigation and action plan and CAPA scope review:

- CAPA0269: Incorrectly reported product sterility result (Mar 2020)
- CAPA0262: DMA (EU GMP)

Change control
The company has a system to manage change cases. The change management system is described in the SOP0039, which was reviewed. The list of major change controls for the period September 2019 to September 2021 was presented and the following changes were examined:

- CC01554: Update of the Sample Submission Form (SSF) process, to allow for electronic sample submissions (May 2021) – Major Software
- CC01565: Reduction of the time for the particle control count before and after each test article (Jun 2020)

5.6 *Production*

Not applicable to the company

5.7 *Quality control*

The company has a system, which ensures that quality control is carried out according to established procedures and methods of analysis.

The following processes were in scope and inspected:

Sample receiving area
Samples are delivered and received at a locked gate, where access control is controlled by card. The contract giver completes a sample submission form, specifying which tests to be performed on the product and reference to a test code. The Log-in procedure SOP0079 and the inventory checklist (FRM0103) ensures control of transport and storage conditions in connection with sample reception as well as assignment of unique sample number by the CRM system. Samples are analyzed according to the Log-in prioritization list (AUX1191). Testing is done according to a protocol agreed by the customer and each test is assigned a study and lab number.

Media Preparation
Sterility Media Production is described in SOP0041. Washing machines and autoclaves are maintained and calibrated with defined intervals.

The following analyses were in scope and examined. A final analysis report stating the test article, test type, laboratory number and test results is prepared when the study director has reviewed the test results. The traceability between the test code and the standard test procedure (STP) is stated in raw data and is part of the raw data package. Batch documentation was selected from a list of tested samples since last EMA inspection (Sep. 2016). The raw data package presented comprised of sample submission form including sponsor-, sample- and test-information such as test code, test description, information about shipping- and storage-conditions and return of temperature data logger (if relevant).

Product Sterility test
Test product: [redacted]
Procedure: STP0077 – Product Sterility. The sterility test of [redacted] is performed in LAF hood ISO class 5 (i.e. sterility testing in isolator not relevant).
Customer Specification Sheet: [redacted]
Batch documentation: [redacted]

Positive Sterility tests: Trending for positive sterility tests, showed that there have been no positive tests in the period since the last EMA inspection.

Mass Extraction Leak Test (Container Closure Integrity)
Test product: [redacted]
Procedure: STP0140 – Mass Extraction Leak Test
Customer Specification Sheet: [redacted]
Batch documentation: [redacted]

Bacterial Endotoxin Test
Test product: [redacted]
Procedure: STP0046 – Bacterial Endotoxins Test
Customer Specification Sheet: [redacted]
Batch documentation: [redacted]

Microbiological Examination of Non-Sterile Products and Enumeration Tests
Test products: [redacted]
Tests also on environmental samples (swabs of surface contact and viable (air) plates)
Procedure: STP 0165 – Microbiological Examination of Nonsterile Products, STP0169 – Microbiological Examination of Non-Sterile Products: Microbial Enumeration Test and STP0034 – Environmental monitoring: Incubation and Enumeration
Customer Specification Sheets: [redacted]
Batch documentation: [redacted]

Sizing and Counting Particulate Matter
Test product: [redacted]
Procedure: STP0011 - Sizing and Counting Particulate Matter
Customer Specification Sheet: [redacted]
Batch documentation: [redacted]

The following validation and verifications were reviewed:

- Bacterial Endotoxin test (BET) validation report M031-2 (Dec. 2002) and report M031-3 (July 2015)

There were deviations to QC laboratories

OOS
The company has a system for the handling of OOS. The overview of the OOS covering the period from 1. Sep 2019 to the inspection date and the following OOS was reviewed:

- QE24298: STP0011 (sizing/Counting Particulate Matter), OOS + laboratory investigation (July 2021)
- QE21868: STP0077 (Product Sterility) Media/Reagents - Oxidation Level. OOS + laboratory investigation (Mar 2020)

- QE24996: STP0165 (Microbiological Examination of Nonsterile Products) – 1 CFU was recovered on the negative diluent control for total aerobic microbial count (TAMAC) – Control OOS (Aug 2021)
- QE22468: STP 0175 (Growth Promotion) – The average titer for Pseudomonas aeruginosa was 119 CFU (specification: < 100 CFU) – Titer OOS (Jun 2020)
- QE22136: STP0165 (Microbiological Examination of Nonsterile products) – Growth was recovered on the Clostridia screen negative control – Control OOS (April 2020)
- QE22619: STP0169 (Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests: Growth was recovered on the Total Aerobic Microbial Count (TAMC) negative control – Control OOS. (Jun 2020)

Reference and retention samples
N/A.

Stability
N/A

5.8 ***Contract manufacture and analysis***
The following activities have been contracted out by the company: there is no sub-contracting activities

For the 3 products in scope, the company performs contract work for the following companies and the following tests:
[redacted]

The following contracts were examined.:
[redacted]

Supplier management

The procedures for selection, risk assessment, qualification, accreditation and maintenance are in place for GMP-critical suppliers. SOP 0106 (Supplier Management) and a list of GMP-critical suppliers were presented. There are no suppliers in category 1 and 2 of relevance for this inspection.

Remote archiving is handled by [redacted] which is categorized as a group 3 supplier. The customer agreement with [redacted] was presented.

5.9 ***Complaints and product recall***
The company has a system for the handling of complaints and recalls, including a procedure for mock recall. SOP 0145 (Complaint Handling) and the lists of complaints since the last inspection were reviewed and the following were examined:

- COM2020022: USP <61> suitability test – the percentage of recovery for A.brasiliensis was not met (July 2020)

- COM2019035: Environmental moni
  34.5-35.5°C instead of 20-25°C.
- COM2019041: Approved protocol / CSS not followed (Nov 2019)

5.10 ***Self-inspection***
The company has a self-inspection plan which was presented. The overview of self-inspections carried out was examined on a random basis. Internal audit procedure (SOP0103) was presented together with Internal audit opening meeting agenda which specify the audit team and their audit assignments (June 2021).

Moreover, Good Housekeeping audit Schedule (Q1, Q2, Q3 2021), Good Housekeeping form (FRM1844) and observation response were presented.

6 Distribution and shipment
N/A

7 Questions raised relating to the assessment of a marketing application
N/A

8 Other specific issues identified
None

9 Site Master File
N/A

10 Miscellaneous
No samples were taken.

11 Annexes attached
Annex 1: Personnel met during the inspection

12 List of deficiencies classified into critical, major and others

Critical or major deficiencies
None

Other deficiencies
1. The microbiological environmental monitoring in operation for laminar air flow hood where aseptic conditions are required (for sterility test for example) is not adapted because action level is defined in SOP0121 (Cleanroom Environmental Monitoring for Microorganisms) as >2 cfu/plate (for gloves, cart surface, hood surface, floor surface, active air) and not as <1 cfu/plate. In this context, aseptic conditions are not guaranteed.
   EU GMP, Vol. IV, Annex 1, items 19 and 20

Deficiency #1 **Company Response**	
Details:	The cleanroom microbial monitoring action levels had been established based on historical data and review of regulations and guidance. Nelson had not claimed Annex 1 Grade A compliance. Additional factors include: 1) The Annex 1 limits are identified as "recommended," 2) Nelson is a testing laboratory and not an aseptic manufacturer, and therefore, contamination risks do not directly impact consumers (i.e., risk of false sterility positive result), and 3) Nelson's EM program had been established based on risk and historical data – this program had been regularly reviewed and accepted by customers and regulators in the past, including multiple EMA inspections.
Action:	Establish action levels of ≥1 (i.e., any growth = action) to align with Annex 1 recommendations for limits during operations. Establish the process for responding to Grade A action level excursions. *Note: These levels will apply to test session monitors (Active Air, Passive Air, Hood Surface, Glove) representing the Grade A environment for sterility testing requested to comply with European regulations. Other test session monitors (Cart, Floor, Gown, Sleeves) are currently aligned with Grade B levels.* 1. Update SOP0121 (Cleanroom Environmental Monitoring for Microorganisms to establish the action level and response program. Owner: Weston Turner; ESTCD: 31 Jan 2022 2. Establish a documentation form (FRM) which includes the items below. Owner: Joseph Summerhays; ESTCD: 31 Jan 2022 a. Comparison of results to specification b. Action level response 3. Update the sterility Customer Specification sheets (CSS) template (Template 90) to include the items below. Owner: Joseph Summerhays; ESTCD: 31 Jan 2022 a. Identification of a customer request to testing with compliance to EMA Annex 1. b. Instruction to test in a Grade A hood. c. Reference to the Grade A action level documentation form. 4. Perform group training once the process is established to support go-live. Owner: Joseph Summerhays; ESTCD: 28 Feb 2022 5. Establish a test service offering for EMA – Annex 1, Grade A Sterility Testing: Change Control (CC01637) was initated 17 Nov 2021 to manage the new Annex 1 sterility test offering The offering is anticipated to go live shortly after the upcoming cleanroom requalification and shutdown, planned for mid-January 2022. Owner:Eric Monson; ESTCD: 28 Feb 2022
Evidence	*Will be provided following implementation.*

Deficiency #1 **Inspectors' assessment**
The response is acceptable.

2. The qualification the laminar air flow hood (ISO class 5) in the Sterility Area is considered insufficient
   a) It is only done with the 0.5 µm particles as defined in the dedicated SOP (SOP 0062 – Hood and HEPA filter certification) whereas 5 µm particles are not counted.
   EU GMP, Vol. IV, Annex 1, item 4
   b) It is not defined in the dedicated SOP (SOP 0062) that particles counts must be done at rest and in operation. In effect, in the annual qualification report of the ISO class 5 hood (E-3944) performed on 14 July 2021, only one condition was tested (at rest or in operation).
   EU GMP, Vol. IV, Annex 1, item 4

c) Acceptance criteria for Air velocity is defined to 55-80 ft/min. This is lower that what is required in the EU GMP guideline without justification (70-110 ft/min which corresponds to 0.36-0.54 m/s) EU GMP, Volume IV, Annex 1, item 3

Deficiency #2 **Company Response**	
Details:	The sterility test is designed to comply with the USP compendial method, and is expected to be performed with GMP cleanroom behaviors. The hoods are qualified and classified according to the general industry standard (ISO 14644, Class 5) and the qualification/classification program was not designed to specifically align with EMA Annex 1 Grade A. ISO Class 5 classification had been acceptable to customers, regulators, and provided adequate control over the cleanroom. Nelson Labs does not manufacture products and contamination risks present business but not patient risk (false positive) – for this reason, Nelson Labs considered itself to have justification for not applying all specifications for Grade A presented in the Annex 1 guidance documents intended for aseptic manufacturers. Note: The flow rates cited in the finding apply to biosafety cabinets/hoods (BSC 55-80 ft/min), whereas horizonal, laminar flow hood have an established flow rate of 70-115 ft/min. Specific to BSC, the flow rate was established based on equipment manufacturer recommendations (operating manuals) and BSC which meet Grade A flow rate requirements do not appear to currently be commercially available in the US.
Action:	One horizontal, laminar flow hood (planned to be Cleanroom 5, Hood #4708) will be qualified to meet Annex 1 Grade A particulate and air flow requirements. 1. Update SOP0062 and SOP0120 to establish the Grade A Hood qualification process and requirements. Owners: Tim Mikesell [SOP0120] & Rich Lipscomb [SOP0062]; ESTCD: 31 Dec 2021 a. Grade A Particle Limits: i. SOP0062: Add at-rest 5 µm testing and specification to the semi-Annual qualification process (current at-rest 0.5 µm testing/spec. is aligned). ii. SOP0120: Add in-operation testing and specification, for both 0.5 µm and 5 µm particles, to the semi-annual qualification process. b. Grade A air flow velocity rates i. SOP0062: Update specification for Grade A hoods to meet 90 – 110 ft/min. c. Create a calibration procedure/form to document the results in comparison with Grade A specifications. Owners: Rich Lipscomb; ESTCD: 31 Dec 2021 Note: *The hood requalification (SOP0062) and the cleanroom requalification (SOP0120) are separately established but are coordinated and performed together, during the semi-annual cleanroom shutdown.* 2. Qualify the hood to meet Annex 1 Grade A (during the cleanroon shutdown Jan 2022). Owner: Tim Mikesell; ESTCD: 31 Jan 2022 As noted for deficiency #1, Change Control (CC01637) was initated 17 Nov 2021 to accommodate the new Annex 1 offering and will include an assessment of any changes to the equipment (hood).
Evidence:	*Will be provided following implementation.*

Deficiency #2 **Inspectors' assessment**
The response is acceptable.

3. In room U38 in the Sterility Area a cardboard box was observed. This is a deviation from the dedicated SOP (SOP0079 - Biological Indicator (BI) Sterility test) which does not allow cardboard boxes in the Sterility area.
EU GMP, Volume IV, Annex 1, item 75 and Part 1, Chapter 4, item 4.1

Deficiency #3 **Company Response**	
Details:	SOP0079 revision 32 section 15.2 states, "Do not transport cardboard from Log In to the lab area unless required as part of the test system. Painted or sealed cardboard is acceptable to be moved to the lab area. If removing an item from the cardboard compromises the item, the box can be stored in an outer packaging, such as a plastic bag." Although this procedure identifies a cardboard policy, the procedure is specific to receipt, processing, and distribution of samples and does not address handling of supplies. It also does not address corrugated cardboard, which could cause microbial contamination. The observed cardboard box in room U38 contained sterile syringe test supplies; however, the procedure that governs transport of supplies (SOP0077) from the warehouse does not address cardboard management. In addition, cardboard management is not addressed in an overarching laboratory procedure, such as the biosafety and contamination manual, to ensure appropriate handling of samples and supplies stored in cardboard once delivered to the lab. Training is established but does not provide sufficient detail. As a result, the policy regarding acceptable types of exposed cardboard, specific locations, and management of cardboard in events that exposure could potentially impact testing has not been clearly detailed. There is insufficient proceduralization and training of cardboard management in the lab to ensure that it is consistently and appropriately handled to mitigate the risk of contamination of testing or samples.
Action:	1. Immediately correct and address the observation: a. The cardboard box (noted in the finding) was removed from room U38. Completed 21 Sep 2021 b. The Sterility Assurance (SA) department was notified by SA management that exposed cardboard is unacceptable in room U38. Completed 22-24 Sep 2021. c. Note: This event is considered a deviation and is handled as such as part of QE25395 which includes impact assessment (determined to have negligible impact to testing). 2. A visual assessment for exposed cardboard in laboratory spaces was performed (23 Sep 2021). Exposed cardboard, associated with both samples and supplies, was observed and removed from additional locations. Due to identification of other instances of exposed cardboard during the visual assessment of the laboratory, the scope of the investigation extended to assess general company practices. a. It was identified that a more detailed policy regarding exposed cardboard which differentiated acceptable locations was required based on risk of contamination of the test system or sample. b. Note: Due to the nature of some testing (e.g., specific packaging or ethylene oxide sterilization test), exposed cardboard is either part of the test system or is the test sample. In other instances, storage of the test sample to prevent damage requires sample specific packaging which includes exposed cardboard. 3. An SA department norming agreement, which identified that exposed cardboard is not allowed in room U38 due to potential contamination of test articles, was completed with SA personnel (05 Nov 2021). The agreement addressed individual responsibility to ensure exposed cardboard does not enter the room and that disciplinary action could be taken with violation of the agreement. 4. An additional assessment of practices was conducted (02 Nov 2021) to ensure full containment of exposed cardboard in laboratory spaces at the SLC facility. Cardboard was either removed from the lab or bagged to prevent shedding of particulates/fibers or microbial contamination.

	Update Policy: 5. Update MAN0005 – Biosafety Manual to establish the policy regarding cardboard management, control, and storage. Include the items below. Owner: Rebecca Anderson; ESTCD: 15 Jan 2022 a. Based on a location's risk of test contamination, certain types of cardboard may be acceptable or unacceptable. b. Include details on types of cardboard and risk mitigation practices (e.g., use of outer packaging). 6. Update SOP0079 – Log In: Add further details of cardboard that is acceptable in laboratory spaces. For example, certain types of cardboard such as coated, non-shedding, non-corrugated (1-ply) cardboard, are acceptable in lab areas without additional mitigation. Owner: Connie Hansen; ESTCD: 15 Jan 2022 7. Update SOP0077 – Incoming Receiving and Inspection of Supplies: Include details for appropriate handling of supplies stored in cardboard when delivered or picked up from the warehouse. Owner: Connie Hansen; ESTCD: 15 Jan 2022 8. To support the policy changes, update WI0364 – Transporting Supplies/Samples to Separate Buildings: Include details for appropriate handling of samples stored in cardboard. Owner: Connie Hansen; ESTCD: 15 Jan 2022 Update Training: 9. Establish training on cardboard policies/practices: Create new training for all lab staff, Login and Warehouse personnel, and QA to identify the policy around cardboard handling in the laboratories and ancillary spaces which aligns with updates to MAN0005 and provides sufficient examples to ensure better adherence to the policy. Owner: Rebecca Anderson; ESTCD: 15 Jan 2022 10. Update general aseptic practice training: Course-0318 (NEO Aseptic Technique Training) and Course-0836 (Annual Aseptic Technique Retraining) to add detail to align with the cardboard policy listed in MAN0005. Owner: Tim Owen; ESTCD: 15 Jan 2022 11. To support the updates to the policy and SOP0079, update Course-1160 – LOG – Study Director Training to include information regarding the cardboard policy and test samples received from Login. Owner: Connie Hansen; ESTCD: 15 Jan 2022 Facility Management Updates: 12. Add cardboard requirements to room signs on laboratory floors to identify acceptable types of cardboard for a specific location. Owner: Nina Moreno; ESTCD: 15 Jan 2022
Evidence	Deficiency 3 Action 1, 2, 4: Cardboard in Room U38 - Actions Memo Deficiency 3 Action 3: Department Norming Agreement *Additional evidence will be provided following implementation.*

Deficiency #3 **Inspectors' assessment**
The response is acceptable.

4. It was observed that an employee repeatedly moves hands back and forth between the laminar air flow hood (ISO class 5) and the surroundings (ISO class 6) without disinfecting the gloves. This behavior is not SOP-described, and no rationale or risk assessment have been prepared for this. EU GMP, Volume IV, Annex 1, item 3 and 64

Deficiency #4 **Company Response**	
Details:	Glove sanitization practices had been established and included in training, but formal documentation of these practices was lacking in training and procedure. Note: Specific to the finding, testing analysts must routinely move hands in and out of the hood during testing but are trained and expected to sanitize gloves regularly and to sanitize or change gloves after encountering specific scenarios/risks (see glove risk assessment and rationale for more

	information).
Action:	1. Complete a risk assessment and rationale of current practices. Completed 19 Nov 2021. This provided a basis for the actions below. 2. Update training Course-1297 (Cleanroom) to include details on glove sanitization and changes. Completed 23 Sep 2021 during the EMA inspection. The Test Session Sanitization TBS (training breakdown sheet) document was added to the course. 3. Perform a group training to review/discuss the new content (Course-1297) with testing analysts. Owner: Joseph Summerhays; ESTCD: 31 Dec 2021 4. Update WI0224 (test session sanitization) to include procedural instruction/expectation for glove sanitization during testing. Owner: Weston Turner; ESTCD: 31 Dec 2021
Evidence:	Deficiency 4 Action 1: Glove Risk Assessment and Rationale Deficiency 4 Action 2: Course-1297, Test Session Sanitization TBS Content Additional evidence will be provided following implementation.

Deficiency #4 **Inspectors' assessment**
The response is acceptable.

5. There is regular backup of all electronic data, but the ability to restore the data from software from analysis equipment such as software WinKQCL and software Leak RX has not been checked. Moreover, it is also not defined when periodic checks of these data should be performed.
EU GMP, Volume IV, Annex 11, item 7.1 and 7.2

Deficiency #5 **Company Response**	
Details:	A back-up process is established for each system, according to procedure, but there is no requirement to verify the restore process for each computerized quality system during system onboarding. Verification of the backup/restore process had been conducted on a limited scope as part of the annual back-up/restore and IT audit program. There is no procedural requirement to periodically check the restore process for each computerized quality system.
Action:	1. Each computerized quality system (four in total) within the scope of the EMA inspection was reviewed to assess the backup and restore process. All systems were backed up, but none had a documented verification of the restore process. A restore from the backup for each system was performed and verified. Completed 19 Nov 2021. 2. Update SOP0130 (Computer Systems: Validation and Change Control) to require a documented verification of the back-up and restore process for each computerized quality system during onboarding. Owner: Karl Perkes, Tod Hadley; ESTCD: 31 Mar 2022 3. Update SOP0131 (revision 12) - Back-up/Restore Procedures to align with updates to SOP0130. Owner: Karl Perkes, Tod Hadley; ESTCD: 31 Mar 2022 4. Establish a documented periodic verification for each computerized quality system according to an established frequency. Owner: Karl Perkes, Tod Hadley; ESTCD: 31 Mar 2022 Note: *Restoration for additional, existing systems currently in place will be assessed through the periodic verification process established above.*
Evidence:	Deficiency 5 Action 1: Verification Memo

Deficiency #5 **Inspectors' assessment**
The response is acceptable.

6. The frequency, based on a risk assessment, for audit trail review is not defined for all software, for example, the frequency of audit trail review for Leak RX software is not defined.
EU GMP, Volume IV, Annex 11, item 9

Deficiency #6 **Company Response**	
Details:	Nelson uses a variety of computer systems and each is assessed based on risk to determine audit trail practices, including review practices. Procedures, guidance, and tools were established to accommodate a risk-based approach, but there was no standard process for assessing the risk and establishing a review frequency.
Action:	1. Assess all applicable software within the scope of the EMA inspection to determine whether audit trail review frequency is established. Completed 25 Oct 2021. The results are discussed below: a. Uniflow (SOP0147) & WinKQCL (CQL0027) systems: Audit trails exist and are visible and reviewed with each study. No action needed. b. LeakRx (WI0339) & PharmSpec (CQS0001): Audit trails exist. Both systems prevent operators from modifying data; therefore, there is minimal risk related to audit trail review with these systems; therefore, no established review frequency is required. PharmSpec procedures do not establish any review frequency – no action needed. LeakRx procedure (WI0339) does state "typically weekly" as a frequency – this has been updated (see below). 2. Update WI0339 - CQS: ATC Mass Extractor ME2, LeakRx (revision 1) to remove the requirement for a periodic audit trial review. Completed 12 Nov 2021. Establish and implement a formal risk assessment of the audit trail to determine the minimum review frequency for each system: 3. Update SOP0130 (Computer Systems: Validation and Change Control) to require assignment of a system risk categorization (according to GAMP 5). Owner: K. Perkes; ESTCD: 31 Mar 2022 4. Update SOP0046 (IT Compliance Policies and Procedures) and FRM1115 (Electronic Data Integrity Assessment) to establish the risk assessment process (i.e., failure mode assessment) specific to audit trails and to define expected or required frequency of review based on this assessment. Owner: K. Perkes; ESTCD: 31 Mar 2022 5. Once established, the audit trail assessment will be performed on all existing systems. As needed, update system-specific instructions to establish audit trial review frequencies for each system in alignment with the actions above. Owner: Rob Thoreson; ESTCD: 30 Sep 2022
Evidence	Deficiency 6 Action 1: Leak Rx Audit Trail Assessment Deficiency 6 Action 2: WI0339 Rev. 02 Update *Additional evidence will be provided following implementation.*

Deficiency #6 **Inspectors' assessment**
The response is acceptable.

13 Summary and conclusion

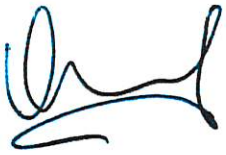
Manufacturer's responses have been received by email on November 19, 2021. All the deficiencies have been adequately addressed and responses are deemed acceptable subject to the corrective and preventive actions being carried out and the deadlines.

Within the scope of the inspection, taking in account the noted deficiencies and the proposed corrective actions it is the opinion of the inspection team that Nelson Lab in Salt Lake City (Utah), operates in good compliance with the requirements of Directive(s) 2003/94/EC and 91/412/EEC the Good Manufacturing

Practice published in "The Rules Governing Medicinal products in the European Union", Vol. 4, EU GMP part I and related annexes.

The EU GMP certificates will be issued.

14 Signatures

Name(s)	Pernille Kaae Holm Vincent Neuviale	
Organisation(s)	Medicines Inspector at the Danish Medicines Agency (DMA), Lead authority Inspector at the French Veterinary Medicines Agency (Anses-ANMV), Supporting Authority	
Date	December 7, 2021	December 7, 2021
Signature(s)		
Distribution of report	DMA, Anses-ANMV	

Definition of Significant Deficiencies

Critical Deficiency:

A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.

Major Deficiency:

A non-critical deficiency:

which has produced or may produce a product, which does not comply with its marketing authorisation;
or
which indicates a major deviation from EU Good Manufacturing Practice;
or
(within EU) which indicates a major deviation from the terms of the manufacturing authorisation;
or
which indicates a failure to carry out satisfactory procedures for release of batches or (within EU) a failure of the Qualified Person to fulfil his legal duties;
or
a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such;

Other Deficiency:

A deficiency, which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice.
(A deficiency may be "other" either because it is judged as minor or because there is insufficient information to classify it as a major or critical).

Annex 1 Personnel met during the inspection

Opening Meeting Attendance (21 Sep 2021):

- Matthew Cushing – Vice President of North American Quality and Science
- Robert Thoreson – Director of Quality Assurance
- D Bulkely – Regulatory Affairs Manager
- Garrett Lynch – Regulatory Specialist
- Robert Katzenbach – Vice President of North American Operations
- Nina Moreno – Director of Laboratory Operations
- Tiffany Anderson – Senior Manager, Global Quality Compliance
- Dania Cortes – Director of Laboratory Operations
- Kate Rice – Senior Regulatory Specialist
- Johanny Gonzalez – Regulatory Specialist

Employees observed during the audit:

- Bill Manuha – Supervisor of Order Processing (Login Process)
- Phil Tuckett – Department Scientist (USP 61 & 62)
- Emily Spackman – Consulting Study Director (BET)
- Quinton Inglet – Senior Lab Operations Manager (BET)
- Joseph Summerhayes – Department Scientist (Sterility Assurance)
- Rebecca Evans – Laboratory Analyst (Sterility Assurance)
- Preston Zook – Regional Account Manager (Particulates)
- Camrann Pacheco – Lab Operations Manager (Particulates)
- Jennifer Mussatt – Study Director (Mass Extraction)
- Jen Gygi – Expert Technical Consultant (Mass Extraction)
- James McCulloch – Senior Lab Operations Manager (Media)
- Chelsea Van Der Spek - Department Training Specialist (Media)

Closing Meeting Attendance (24 Sep 2021):

- Matthew Cushing – Vice President of North American Quality and Science
- Robert Thoreson – Director of Quality Assurance
- D Bulkely – Regulatory Affairs Manager
- Garrett Lynch – Regulatory Specialist
- Joe Shrawder - President
- Tiffany Anderson – Senior Manager, Global Quality Compliance
- Kate Rice – Senior Regulatory Specialist
- Johanny Gonzalez – Regulatory Specialist
- Rebecca Anderson – Regulatory Specialist
- Loxane Konesavanh – Regulatory Specialist
- Kevin Buckingham – Global Quality Compliance Officer
- Katie Kelson – Global Quality Compliance Officer
- Jessica Olson – Director of Operational Excellence
- Eric Monson – Senior Lab Operations Manager
- Dania Cortes – Director of Laboratory Operations

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Nelson Laboratories LLC.

EFFECTIVE **05/10/2016**

EXPIRATION **09/30/2025**

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

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

Third Party Logistics Provider

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

NELSON LABORATORIES LLC.
6280 S REDWOOD RD
SALT LAKE CITY UT 84123

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LIMITED LICENSE

EFFECTIVE DATE: **05/10/2016**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **Nelson Laboratories LLC.**
6280 S 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

Third Party Logistics Provider

DBA: None Associated

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: June 1, 2025**

Location: Taylorsville, UT, United States

Nelson Laboratories, Inc.

A.J. Gruber
ISTA President

Eric Hiser
ISTA Vice President - Technical

City of Taylorsville

BUSINESS LICENSE

The license is granted to the named company to do business in the City of Taylorsville at the named address.

Business Name:	**NELSON LABORATORIES, LLC**	**Business Type(s):**	541380 Testing Laboratories
Business Location:	6280 S REDWOOD RD TAYLORSVILLE, UT 84123-6600	**Mailing Address:**	6280 S REDWOOD RD TAYLORSVILLE, UT 84123-6600
Owner:			
License Number:	GEN-31112-2021	**License Type:**	General
Issued Date:	1/30/2024	**Classification:**	Professional Services
Expiration Date:	1/31/2025	**Fees Paid:**	$128.00

Kristi S. Overson
Mayor

SEAL

Jamie Brooks
City Recorder

This license is non transferable between owners and/or locations. This license is valid only for the type of business stated.
2600 W. Taylorsville Blvd. Taylorsville, UT 84129 (801) 963-5400

TO BE POSTED IN A CONSPICUOUS PLACE