Nelson Labs
A Sotera Health company

TABLE OF CONTENTS – Bozeman Customer Transfer Packet

BOZEMAN CUSTOMER SUPPORT HOTLINE

DEDICATED CENTRAL POINT OF CONTACT – BOZEMAN TRANSITION PROGRAM

Bozeman Support Hotline

TransferSupport@nelsonlabs.com
1 (801) 290-7502 | Chat with a Service Center Representative at www.nelsonlabs.com

The above e-mail group will serve as a central point of contact for any/all questions that may arise regarding your transition plan from Nelson Labs Bozeman to Nelson Labs Salt Lake City, UT.

ADDITIONAL SUPPORT

Nelson Service Center
1 (801) 290-7500 | ServiceCenter@nelsonlabs.com | Chat www.nelsonlabs.com

Sales – Account Management
1 (801) 290-7500 | Sales@nelsonlabs.com | Request a Quote Request a Quote from Nelson Labs Tests
See page 6 for additional quoting and account management support

Invoicing & Billing Questions
See page 4 for additional Invoicing and Accounting support

Quality
See page 5 for additional Quality and qualification support

CRITICIAL DATES/TIMELINE

MICROBIOLOGY

17 Sep: Microbiology testing will be sustained in Salt Lake City, UT and discontinued in Bozeman, MT effective immediately.

30 Sep: Last date that Bozeman *will accept MICROBIOLOGY samples for Subcontracting* to Salt Lake City from Bozeman.

VIROLOGY

17 Sep: Last start date: Virology studies put onto test at Bozeman. Virology testing will be discontinued permanently, no resumption in other NL sites.

CLINICAL

Discontinued immediately and permanently, no resumption in other NL sites.

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ACCOUNTING & BILLING INFORMATION

SALT LAKE CITY, UT

Remit To Address | Bank Information
29471 Network Place
Chicago, IL 60673-1294 USA
WIRE: Routing Number: 021000021 | SWIFT: CHASUS33 | Account Number: 641403803
ACH: Routing Number: 124001545 | Account Number: 641403803
Telephone: 801-290-7505 | E-mail: Accounting@nelsonlabs.com
Credit Card Payment: Pay Your Bill for Nelson Labs
Tax ID #: 47-4076134 | See page 12 for a copy of W9

Purchase Orders
Send Purchase Orders to our PO Management team at: POManagement@nelsonlabs.com, or to your Account Manager or provide a copy in the box with your samples

SUBCONTRACTING FROM BOZEMAN *(interim solution while qualifying Salt Lake City)*

For subcontracting, all quotes, submissions, reports, and invoices will continue to flow through Bozeman, MT as they have been previously. This will terminate on 31 Oct 2024.

For subcontracted studies, Nelson Labs will incur any shipping costs associated with transfer & coordination of sample testing to the applicable Nelson facility for performance of requested services.

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QUALITY

REGULATORY CERTIFICATIONS PACKETS

Regulatory Certifications Packet – Salt Lake City, UT, See pages 13-36

SUPPLIER QUESTIONAIRE

Supplier Questionnaire/Audit Packet – Salt Lake City, UT, See pages 37-41

QUALITY AUDIT OPTIONS

Supplier Questionnaire

If compliant with your company's quality management system, accepting the Nelson "Supplier Questionnaire" referenced above may be all that is required to qualify one of our additional sites.

Paper Audit – Salt Lake City, UT, See pages 37-41

If compliant with your company's quality management system, Nelson does offer a paper audit option. This option would cover both the Salt Lake City, UT and Itasca, IL facilities.

3rd Party Audit Option

The Cannon Quality Group, a third-party auditing company, audits Nelson Labs each year. Their most current audit report is available for purchase at https://www.cannonqualitygroup.com/. Additionally, if you are interested in participating in a third party shared audit, more information can be found at https://www.cannonqualitygroup.com/news/supplier-friendly-shared-audits-creating-win-win-medical-device-industry/.

If a copy of the NL audit report is purchased through The Cannon Quality Group, you may be eligible for a credit towards your first transfer test. (Available between now – 31 Oct 2024). For further details please contact: TransferSupport@nelsonlabs.com.

Onsite Audit

If you would like to arrange an onsite audit, please utilize the below contacts for scheduling an onsite audit.

Salt Lake City, UT: Quality Audits: TransferSupport@nelsonlabs.com

We do expect significant on-site audit requests from transferring customers. We encourage you to take advantage of the previously mentioned options if available or schedule your on-site audit as soon as possible. To learn more about our on-site audit options, please visit: Quality Assurance at Nelson Labs.

As an alternative option to this (if your quality management system does require an onsite audit), we are able to subcontract testing through the Bozeman facility until an onsite audit is able to be scheduled. Subcontracting through Bozeman (Available until: 31 Oct 2024, see page 3).

Documentation showing the Salt Lake City, UT facility is on the Bozeman Approved Supplier List, see page 42.

QUALITY AGREEMENTS

For support with Quality Agreements please contact, QualityAudits@nelsonlabs.com.

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LOGISTICS

REQUESTING A QUOTE

Existing Quote:

Any existing Bozeman Microbiology price quotes will be honored at the Nelson Facility that samples are submitted to up until 31 Dec 2024 or the Expiry Date reflected on the quote *(whichever occurs first)*.

New Quote Requests:

For new quote requests contact your Nelson Account Manager, Sales@Nelsonlabs.com, TransferSupport@nelsonlabs.com.
Quote requests can also be submitted through the Nelson website at:
Request a Quote from Nelson Labs Tests

CUSTOMER PORTAL (Salt Lake City, UT)

The Nelson Labs Customer portal can be used to Submit a Sample, Complete an Electronic Sample Submission Form, View Study Tracking, and Access Final Reports. Access the Nelson Labs Customer Portal at: Nelson Labs Secure Portal | Home.

Shared Orders Functionality

The Salt Lake City, UT and Itasca, IL Customer Portal allows the user to share access of orders within your organization, access shared final reports, and remit payment for testing services.

Portal Access

For customers new to the Nelson Labs Customer Portal, you will receive a system-generated e-mail to Activate your account and set a password. The link to re-set a password is valid for 24 hours, if a password Needs to be re-set please contact our Service Center (ServiceCenter@nelsonlabs.com) and they will provide an additional link.

SUBMITTING A SAMPLE DIRECT (Salt Lake City, UT)

The Nelson Labs Electronic Sample Submission Form is located within the customer portal Nelson Labs Secure Portal | Home. After logging into your portal account, select "Submit Samples (Request a Test)".

For support in completing and populating the eSSF (Electronic Sample Submission Form), below are the resource materials available:

- An "Entry Guide", providing a definition and brief description of each field within the form (pages 86-87)
- A "Video Tutorial", providing a walk-through for completing the Submission Form | https://secure.nelsonlabs.com/how-to-videos
- Additional support: For any questions, please reach out to TransferSupport@nelsonlabs.com, our Service Center (ServiceCenter@nelsonlabs.com), or your Account Manager to help guide you through completing the Sample Submission Form and submitting your samples for testing.
- Controlled Substances: Due to the nature of samples, Schedule I and II samples will need a copy of the 222 Form included with the shipment and should be shipped directly to the testing location.

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Addresses for Sample Submission:

- Salt Lake City, UT: Nelson Labs | 6280 S. Redwood Rd. | Salt Lake City, UT 84123 | 801-290-7500

CAPABILITIES BY NELSON LABS FACILITY (US)

See capabilities chart by location, pages 48

NELSON BOZEMAN SUBCONTRACTING APPROVAL FORM

To subcontract testing through Nelson Labs, Bozeman to one of our other qualified facilities, please complete the “Nelson Bozeman Subcontracting Approval Form” (page 43) and e-mail a copy back to TransferSupport@nelsonlabs.com.

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LEGAL & PRICING

MUTUAL NDA

Mutual Non-Disclosure Agreement –Salt Lake City, UT, Itasca, IL, and Bozeman, MT
If you do not have a current mutual non-disclosure agreement that covers Bozeman, SLC, and Itasca, click the below link to initiate an NDA. Or refer to pages 44-47.

For any questions, redlines or additional support, please contact your Account Manager or TransferSupport@nelsonlabs.com.

PRICING

Pricing is harmonized between Bozeman, MT and Salt Lake City, UT for 2024.

Valid price quotes issued from Bozeman will be honored at: Salt Lake City, UT up until the quoted expiry date.

TECHNICAL/SCIENTIFIC SUPPORT:

Method Transfer/CCSs /Method Validation Options

Method Validation and Method Transfer Chart

See page 48. The information in the chart is considered general information based on testing type, for specifics related to your product and exact quantities needed please contact: TransferSupport@nelsonlabs.com.

Justifications

Our team of Senior Scientists can help with justifications and evaluate impact to testing plans.

Expert Advisory Support

Our Expert Advisory Services Board offers a wide breadth of MedTech and pharmaceutical experience to help our clients deliver safe and effective products to market. It encompasses product development, facility and process validation, and product performance testing, as well as regulatory support. If you are looking to take advantage of the time needed to re-validate and wish to assess whether now is a good time to update product family groups, product adoptions, etc. – we can support.

Regulatory Audit Support, Sample & Study Archives

All remaining sponsor samples in Bozeman will be transferred to SLC or returned to the client by 31 Oct 2024. No sample receiving will occur at Bozeman after 31 Oct. Nelson Labs will retain paper and/or electronic archives as per retention policies which will be available through our SLC Quality group to support any client regulatory audit or inquiry.

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FAQs from transfer packet

Q: What will happen to Microbiology samples that are already in-house at Bozeman? **A:** Samples that are already in-process will be tested and completed at Bozeman. Anything received after that date will be transferred or subcontracted to another Nelson site.
Q: Will I need a new quote? **A:** No, our Salt Lake City facility will honor current quotes that are still within the expiry date. Please be sure to reference your quote number on the Sample Submission Form.
Q: Will I need a new PO? **A:** Nelson Labs does not require a Purchase Order to perform testing. Purchase Orders requirements will come directly from your company's accounting group. However, if you are setup to be PO required – we would need an updated Purchase Order with the applicable updated Remit To information, see Transfer Packet for those details.
Q: Where can I go to schedule an audit (either paper or onsite)? **A:** Nelson Labs does offer several different options for testing services between our different facilities. Please refer to Transfer Packet for audit and qualification details.
Q: Will I use my current Sample Submission Form? **A**: If you will be subcontracting testing through the Bozeman facility, you may continue to use your current Sample Submission Form and process. If you are qualifying one of our other facilities and will be shipping direct, they will have a different Sample Submission Form and portal. Please see the Transfer Packet in our Logistics section for details on these processes and the applicable reference materials.
Q: How will I access my final reports if I move testing to another facility? **A:** If you will be subcontracting testing through the Bozeman facility, you will be able to continue to access your final reports as you do today. If you are qualifying one of our other facilities and will be shipping direct, there is a customer portal to access your final reports. Please see the Transfer Packet in our Logistics section for details on these processes and the applicable reference materials.
Q: Who can I contact for existing billing/invoicing questions? **A:** For existing billing or invoicing questions, you can continue to contact our Accounts Receivable team as you do today. For billing/invoicing questions on studies tested directly at one of our other sites, please see the Transfer Packet for additional details.
Q: When I transfer testing to another Nelson facility, will the Tax ID and Bill To information be the same as it is now? **A:** The tax ID number will remain the same as all of our facilities are under the Sotera Parent account, however there are different Remit To and bank information details, see page the page 12.
Q: Who can I go to with questions? **A:** We have a designated Bozeman Support Hotline (TransferSupport@nelsonlabs.com) for customer support throughout this transition and have a dedicated Project Manager to ensure an easy transition with the consolidation to our Centers of Excellence.
Q: Who can I contact for existing Quality Event status updates? **A:** For in-process Quality Event status, you can continue to communicate with your Bozeman Study Director and technical expert.
Q: I am used to talking with my technical expert(s), how will I know who to contact going forward? **A:** At Nelson we value science to aid in our mission of Safeguarding Global Health. The Bozeman Support Hotline will serve as your point of contact initially. From there, your Account Manager will connect you with the applicable technical experts to address any questions you may have regarding testing. Upon sample receipt, you will also receive a system-generated e-mail which will include your study number as well as the applicable Study Director over your test.
Q: Can I get documentation or a letter showing that the Salt Lake City location is on the Nelson Bozeman approved supplier list? **A:** Yes, that documentation is included on page 42.

APPENDIX

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

▶ **Go to *www.irs.gov/FormW9* for instructions and the latest information.**

Give Form to the requester. Do not send to the IRS.

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

Sotera Health Holdings LLC

2 Business name/disregarded entity name, if different from above

Nelson Laboratories LLC

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☐ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☒ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ C

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is **not** disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) 5

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.

9100 South Hills Blvd, Suite 300

Requester's name and address (optional)

6 City, state, and ZIP code

Broadview Heights, OH 44147

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN,* later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

4	7	–	4	0	7	6	1	3	4

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** ▶ | **Date** ▶ 01/11/2023

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9.*

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, *later.*

Nelson Labs
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Salt Lake City, Utah Certifications, Registrations, Licenses
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CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Fulfills the requirements of

ISO/IEC 17025:2017

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 Endotoxins	STP0038	Medical Devices, Drugs	Gel Clot Technique
Bacterial Filtration Efficiency (BFE)	STP0004 based on ASTM F2101, EN14683, ASTM F2100	Medical & Surgical Face Masks	Andersen Sampler
Viral Penetration Testing	STP0062, and STP0174 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. 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, AAMI 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, Template 124, 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
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[2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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
Differential Pressure Testing	STP0217	Surgical Face masks and comparable porous materials	Differential Pressure Apparatus, Air Flow Apparatus, Flow Meter
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
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

Mechanical / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
EN 13795: Performance requirements for surgical gowns and drapes • Microbial penetration resistance (wet and dry) • Microbial evaluation (bioburden) • Particle evaluation • Liquid penetration resistance • Burst strength • Tensile Strength	STP0191 and STP0188 based on EN ISO22610:2006 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

RE: Statement of Compliance to GDUFA Self-Identification Requirement

13 June 2024

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

DocuSigned by:
Darcy Bulkley
Signer Name: Darcy Bulkley
Signing Reason: I approve this document
Signing Time: Jun 13, 2024 | 10:48 AM MDT
09F63F59C1B247F3A330A836785B5050

Darcy Bulkley
Regulatory Affairs Manager
Nelson Laboratories, LLC
dbulkley@nelsonlabs.com
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

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						

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

13 June 2024

Dear Sponsor,

Nelson Laboratories, LLC (NL), 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 1 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 20000341, and DK V 1000342. 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 systems, etc. [See section 2.2 in the inspection report]), and all GMP-relevant topics (e.g., Quality Management System, Personnel, Premises, and Eqipment, 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.

DocuSigned by:
Darcy Bulkley
Signer Name: Darcy Bulkley
Signing Reason: I approve this document
Signing Time: Jun 13, 2024 | 11:09 AM MDT
09F63F59C1B247F3A330A836785B5050

Darcy 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:

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

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

Form #1

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

Jamie Brooks — City Recorder

CITY OF TAYLORSVILLE INCORPORATED SEAL JULY 1, STATE OF UTAH

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

Nelson Labs
A Sotera Health company

Frequently Requested Information / Survey
Salt Lake City

Toll-free: (800) 826-2088 ServiceCenter@nelsonlabs.com
Local: (801) 290-7500 Accounting@nelsonlabs.com
Fax: (801) 290-7998 Sales@nelsonlabs.com

Company Information	
Company Name	Nelson Laboratories, LLC a Sotera Health company
Parent Company	Sotera Health
Established	1985
Company Address	6280 South Redwood Road Salt Lake City, UT 84123-6600
Website	www.nelsonlabs.com
Telephone	(801) 290-7500
Company Description	Nelson Laboratories, LLC (NL) a Sotera Health company, is an industry-leading provider of laboratory testing and consulting services. We perform over 900 rigorous microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. We know that every test matters and requires solutions to complex problems to improve patient outcomes and minimize client risk. A full description of services offered can be found on our website at www.nelsonlabs.com.

Facilities		
Total Square Footage	~ 140,000 ft²	
Laboratory Space	~ 90,500 ft²	
Operating Hours	Primarily one shift, 9am-5pm, 5 days a week. Weekends and swing shifts as required.	
Number of employees	~ 629 in Salt Lake City	Please contact QualityAudits@nelsonlabs.com for the most up-to-date organizational chart.
Quality Staff	~ 52 in Salt Lake City	
Equal Opportunity	NL is an equal opportunity employer	

Contacts			
Critical Contacts	Joseph Shrawder	President of Nelson Labs	Please contact our client services group at (801) 290-7500 to arrange to speak with any of these individuals.
	Robert Katzenbach	VP of North America Operations	
	Krista Bollnow	VP of Sales & Marketing	
	Matthew Cushing	VP of Quality & Science	
	Robert Thoreson	Director of Quality Assurance	
Additional Contacts	Sales	Sales@nelsonlabs.com	
	Accounting	Accounting@nelsonlabs.com	
	Quality Requests & Audit Scheduling	QualityAudits@nelsonlabs.com	
	Quality Agreements	QualityAgreements@nelsonlabs.com	

Business / Payment Information	
Ownership	A Sotera Health company
Federal Tax ID	47-4076134
Business Classification	NL does not meet the criteria for small business classification in 13 CFR Part 121. Sector 54 Professional, Scientific & Technical Services/NAICS 541380: Testing Laboratories.
Dun & Bradstreet Number	15-166-3234
US SAM Entity/ DUNS/ CAGE Code	NELSON LABORATORIES, LLC / 151663234 / 5ESY1

Please note: This document is for informational purposes only and may change at any time.

Nelson Labs
A Sotera Health company

Wire Transfers	Bank Routing and Transit Number: 021000021 SWIFT Code: CHASUS33 Account Number: 641403803							
ACH Transactions	Bank Routing and Transit Number: 124001545 Account Number: 641403803							
Payment Options	**Cash**	U.S. Funds	**Check**	Drawn on U.S. bank in U.S. dollars	**Credit**	Visa, MasterCard, American Express	**Net Terms**	30 Days
Shipping Address	Attn: Login or Receiving 6280 South Redwood Road Salt Lake City, UT 84123-6600 USA							
Billing / Payment Address (Check Remittance)	Nelson Laboratories, LLC 29471 Network Place Chicago, IL 60673-1294							

Proprietary Information	
References	NL policies and procedures ensure the protection of our clients' names, confidential, and proprietary information, thus no references are able to be provided.
Sales/Financial Information	NL sales and financial information is proprietary; thus, no sales or financial information is able to be provided.
Manufacturer Statement	Nelson Labs is not a manufacturer, it is a contract testing laboratory; therefore, information regarding manufacturing processes is not applicable.

Accreditation/Certifications/Registrations		
ISO Accreditation	ISO 17025:2017	For up-to-date certifications and registration please visit our audit website, www.nelsonlabs.com/regulatory-resources.
ISO Registrar	ANAB	
ISO Certificate Number	AT-1382	
FDA CDRH Registration	1721109	
FDA FEI Identifier	# 3000233845	
Date of Last FDA Audit	30 May – 02 Jun 2023	
FDA Audit Information	We are frequently audited by the FDA to GMP, GLP, and GTP guidelines.	
EU GMP Certification	Certificate No: DK H 10000339 (DMA); DK V 10000341 (DMA); DK V 10000342 (DMA)	
Other Certifications	NL also holds certifications from the U.S. EPA, U.S. DEA, and U.S. OSHA	

Nelson Labs
A Sotera Health company

NL has procedures/processes including (but not limited to) the following	
Calibration and Maintenance	SOP0067 – *General Calibration and Maintenance*. The calibration and maintenance of equipment is primarily performed by NL's Metrology Department. Using documented procedures, they work to prevent inaccuracy and deficiencies in data through the use of NIST traceable reference standards, laboratory working standards, and tests for use in calibration.
Change Control and Change Notification	SOP0039 – *Change Management*. Since most of our testing services are based on standard testing procedures (STP), we provide the ability to have an additional "Customer Specification Sheet (CSS) or testing instruction" which provides customer specific instructions for testing (if necessary). The Customer Specification Sheet or testing instructions are reviewed and approved by the NL Study Director and if requested by your company prior to implementation. Additionally, all changes made through our change control process are assessed for the potential impact to you as a customer. We make every effort to contact our customers where appropriate. You may refer to our secure client website at www.nelsonlabs.com for a posting of our most recent customer-applicable changes, as well as a list of all procedural updates.
Complaints	WI0378 – *QE: Complaints*. NL has a formalized complaint resolution process and seeks customer feedback on a regular basis.
Corrective Action / Preventative Action (CAPA)	SOP0136 – *Corrective & Preventive Action (CAPA) System*. WI0377 – *QE: Escalated Events (EE)*. These procedures are in place to address potentially recurring or high-risk quality concerns. These procedures include root cause analysis, verifying and validating corrective and preventive action, implementing and recording changes in applicable procedures, ensuring that the appropriate people are aware and involved in the preventive actions, and effectiveness verification. All EE action plans are reviewed and approved by management.
Customer Feedback	SOP0093 – *Customer Feedback Handling*. Details the procedures for management of the customer feedback system at NL.
Data Integrity	SOP0171 – *Data Integrity*. Describes NL's data integrity system and establishes the company policy for managing the integrity of data, specifically in relation to company and employee independence, integrity and impartiality.
Deviations	SOP0136 – *Corrective & Preventive Action (CAPA) System*. WI0376 – *QE: Deviation, OOS, Complaint, UE, UV, etc. & Action Assignment (AA)*. These procedures detail how to address a deviation or Quality Event (QE), a specific change to a procedure that does not impact safety or efficacy, and complies with the provisions of ISO 17025, EPA and FDA regulations. The procedures require that all deviations be documented, assessed for impact, where appropriate investigated, and properly reviewed and authorized before the release of data. If a deviation impacts a sponsor's test or data, the sponsor is contacted within one business day. Approved deviations are documented in the final report. QEs are routinely tracked and trended.
Disaster Recovery	SOP0131 – *Back-up/Restore Procedures*. Establishes the back-up/restore procedures at NL. NL's disaster recovery plan is a combination of data replication and data backup best practices.
Document Control	SOP0001 – *Management of Controlled Documents*. NL establishes and maintains procedures to control all documents required by regulations, standards, normative documents, test, and calibration methods. Documents are controlled by revision number electronically through MasterControl, our document control software. Documents are reviewed, updated, and approved as necessary.
Equipment	SOP0069 – *Equipment Receiving.* MAN0007 – *Validation Master Plan*. Each piece of equipment is uniquely identified. Before being put into use, a new piece of equipment undergoes IQ, OQ, and PQ.

Health and Safety Program	MAN0004 – *Chemical Hygiene Plan and Safety Manual*. Discusses general safety, office safety, chemical safety, and laboratory safety. Compliance with it provides a safe, healthy, and comfortable working environment for employees and visitors. MAN0005 – *Biosafety Manual*. Discusses safe practices when working with infectious or unknown organisms. It prescribes proper use of facilities, PPE, and proper disposal of infectious waste
Internal Audits	SOP0103 – *Internal Audits*. NL has a formal, documented internal audit program. Each applicable ISO 17025, GMP, GLP, and GTP clauses as well as each NL laboratory section is audited at least once on an annual schedule. Actions to correct deficiencies and prevent recurrence are documented, reviewed, and approved before audit closure.
Management Responsibilities	SOP0089 – *Management Responsibilities*. SOP0099 – *Quality Committee and Management Review Procedures.* NL Management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the NL Quality System on quarterly, semi-annual, and annual bases according to ISO/IEC 17025:2017 and various FDA CFR, EU GMP, and TGA GMP requirements.
Out of Specification (OOS) Results	SOP0136 – *Corrective & Preventive Action (CAPA) System*. WI0376 – *QE: Deviation, OOS, Complaint, UE, UV, etc. & Action Assignment (AA)*. An OOS is a result that falls outside the specification established by a compendial method, SOP, STP, Protocol, or as required by the sponsor. As dictated by procedures an OOS must be documented, root cause identified through a failure investigation, its impact to data assessed and the validity of any results substantiated. If an OOS impacts a sponsor's test or data, the sponsor is contacted within a target of one business day.
Purchasing Controls	SOP0077 – *Incoming Receiving and Inspection.* SOP0167 – *Quality Assessment of Incoming Supplies.* Supplies are received at the warehouse receiving station and initially inspected. Receiving staff verify the purchase order against the packing slip and other receiving documents. Also verified are quantity, product identification and container integrity. Any discrepant items are quarantined until disposition. Items with further inspection and/or testing requirements are transferred to a designated Quality Control (QC) quarantine processing area until required acceptance testing is completed. As with receiving, any discrepant items are quarantined until disposition. Disposition is documented.
Statistical Techniques	MAN0003 – *Statistical Control Manual*. Statistical controls are applied as required by test methods. Any statistical techniques applied to analyze data are described in the final test report. We utilize validated spreadsheets to perform calculation and have uncertainty data calculated for test methods where applicable.
Study Documentation	SOP0082 - *Quality Records and Archives*. Datapacks, which contain study information including raw data, are scanned and maintained. NL's Quality Document retention period is a minimum of 10 years.
Supplier Management	SOP0106 – *Supplier Management*. All suppliers are qualified through our supplier management process. The quality capabilities of vendors/subcontractors are reviewed prior to placing any orders. Supplier performance is assessed on an ongoing basis through product quality tracking systems.
Test Data Review	SOP0090 – *Study Director Responsibilities.* SOP0092 – *GLP Study Procedures*. All raw test data undergoes, at a minimum, a full review by a Study Director. Many studies receive an additional review by a Technical Reviewer or a member of Quality Assurance. For GLP studies, this review is performed by trained Quality Assurance inspectors.
Training	SOP0098 – *Training System*. NL includes an onsite professional development department and an extensive, documented training program for all employees. All employees receive annual GMP, GLP, and GTP training. Additionally, annual proficiency and competency analyses are performed (where applicable).

Traceability	SOP0081 – *Data Recording and Correction*. Process controls are in place to ensure traceability and to prevent contamination. Samples are coded with a bar code sticker. Associated items used in testing are traceable to the batch record, lot number, or part number.
Quality Manual/Policy	MAN0001 – *Nelson Laboratories Quality Manual*. The NL Quality Manual provides the employees, auditors, and customers of Nelson Labs with a description of the Quality Management System and Quality Policy. It is organized according to the format of ISO 17025 to facilitate audits of NL systems to the requirements of these standards.
Validation	SOP0115 – *Test Method Validation.* MAN0007 – *Validation Master Plan*. Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity, (where applicable).

Nelson Labs
A Sotera Health company

16 Sep 2024

To Whom It May Concern:

Nelson Labs Bozeman (NLB), located at 1765 S. 19th Ave. in Bozeman, MT 59718, has approved the below Nelson Labs site as an intracompany subcontractor. NLB must obtain written approval from the client prior to submitting any of their work to another site via the subcontracting process.

Nelson Labs Salt Lake City
6280 S. Redwood Rd.
Salt Lake City, UT 84123

Respectfully submitted,

Signed by:
Robert Thoreson
Signer Name: Robert Thoreson
Signing Reason: I approve this document
Signing Time: Sep 16, 2024 | 1:02 PM MDT
6D561BC75E97432B9FF4CF3EF4893377

Rob Thoreson
Director of Quality Assurance
Nelson Laboratories, LLC
6280 S. Redwood Road
Salt Lake City, UT 84123
rthoreson@nelsonlabs.com
O: 801-290-7618
C: 801-604-0616

SUBCONTRACTOR APPROVAL FORM

CONTACT	
COMPANY	
ADDRESS	
E-MAIL ADDRESS	

SUBCONTRACTOR	Nelson Laboratories: Salt Lake City, UT / Itasca, IL /Bozeman, MT

THIS SUBCONTRACTOR IS QUALIFIED TO PERFORM MICROBIOLOGY TESTING SERVICES.

I AUTHORIZE NELSON LABORATORIES, LLC TO FORWARD SAMPLES SUBMITTED TO THE SUBCONTRACTOR LISTED ABOVE.

SPONSOR APPROVAL: _____ DATE: _____

PLEASE SIGN AND DATE THIS FORM AND RETURN IT TO NELSON LABORATORIES.

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CONFIDENTIALITY AND NONDISCLOSURE AGREEMENT

This Confidentiality and Nondisclosure Agreement ("**Agreement**") is entered into as of _____ ("Effective Date") between **Nelson Laboratories, LLC**, a Delaware limited liability company, having a place of business at 6280 South Redwood Road, Salt Lake City, Utah 84123, for itself and its Affiliates, and _____ for itself and its Affiliates, having a place of business at _____ ("**Company**"). Nelson and Company may be referred to individually as a "**Party**", a "**Discloser**" or a "**Recipient**" or collectively as the "**Parties**" throughout this Agreement.

For their mutual benefit, the Parties intend to engage in, or continue to engage in, discussions to establish or maintain a working relationship in which Nelson may provide general expertise in the field of microbiological and analytical testing services ("**Purpose**"). During such discussions, each Party or its Affiliate(s) may find it necessary or desirable to disclose, or may have already disclosed, certain Confidential Information ("**Discloser**") to the other Party or its Affiliate(s) ("**Recipient**"). For the avoidance of doubt, each Party acknowledges and agrees that it may disclose Confidential Information belonging to its Affiliates (and those Affiliates may also disclose such information themselves directly) to the Recipient (or its Affiliates) and the terms of this Agreement will apply to such disclosures. The Parties acknowledge and agree that Confidential Information regarding the Purpose disclosed prior to, on, or after the Effective Date shall be governed by the terms and conditions of this Agreement.

For purposes of this Agreement, an entity shall be deemed to be an "**Affiliate**" of a Party if it is a company, whether a corporation or other business entity, that is controlling, controlled by or under common control with such Party. "Control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the equity interest in such corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity.

Therefore, in consideration of the covenants and obligations set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are acknowledged by the Parties, it is therefore agreed as follows:

1. ***Confidential Information***. "**Confidential Information**" means and includes proprietary, tangible information as to techniques, formulas, processing, costs, designs, business and product plans and strategies, prices, customer information, concepts, processes, drawings, market information, specifications, know-how, financial and marketing data, technical data, procedures, trade secrets, models, prototypes, samples, and all derivative and related information pertaining thereto, including oral information and information available through visits to a Party's facilities. Confidential Information may be disclosed orally, visually, and in written form (including but not limited to electronic or other media), whether or not marked or designated as "confidential".

2. ***Non-Disclosure of Confidential Information***. The Recipient will exercise the same degree of care and protection with respect to Discloser's Confidential Information which Recipient exercises with respect to its own Confidential Information, which in no event shall be less than a reasonable standard of care. Accordingly, Recipient shall hold Discloser's Confidential Information in strict confidence and: (a) shall not use, copy, disclose, divulge or otherwise make Discloser's Confidential Information available to any other person or entity, except its Representatives (defined below), without the prior written consent of Discloser, which consent shall be in the sole discretion of Discloser; and (b) shall not deface, alter, remove or permit to be defaced, altered or removed any notice indicating the confidential nature of, or the proprietary right of Discloser in and to, Discloser's Confidential Information. Neither party shall reverse engineer, disassemble, or de-compile any tangible information that embodies the Discloser's Confidential Information.

3. Authorized Disclosure of Confidential Information. Each Party shall: (a) use the other Party's Confidential Information only for the Purpose; (b) restrict disclosure of the Confidential Information to Recipient's and its Affiliates' respective officers, directors, employees, consultants, attorneys, advisors and accountants for a party who have a need to know Discloser's Confidential Information in order to perform his, her or its job responsibilities in connection with this Agreement ("**Representatives**"); (c) advise Recipient's Representatives of their respective obligations under this Agreement, provided, Recipient will be responsible for any breach of this Agreement caused by its Representatives; and (d) account for the return or destruction of Discloser's Confidential Information and all copies of all or any part of Discloser's Confidential Information in any form or medium, including all notes, analyses, memoranda or other documents, including electronically stored versions of the same ("**Reproductions**"), except as otherwise provided herein.

4. Required Disclosure. If Recipient or any of its Representatives is required by applicable law, regulation or a valid legal order to disclose any Confidential Information, Recipient shall promptly notify the Discloser, if legally permissible, of such requirements so that the Discloser may contest or seek a protective order or other remedy, at Discloser's sole expense, and Recipient shall reasonably assist Discloser therewith. If Recipient remains legally compelled to make such disclosure, it shall: (a) only disclose that portion of the Confidential Information that it is required to disclose; and (b) ensure that such Confidential Information is afforded confidential treatment.

5. Exceptions to Confidential Information. The obligations of confidentiality set forth in this Agreement shall not apply to any Confidential Information which: (a) is or becomes available to the public through no act or omission by Recipient or its Representatives; (b) was already known by Recipient or its Representatives at the time of the disclosure by Discloser, as evidenced by Recipient's written records existing prior to the date of disclosure by Discloser; (c) is lawfully obtained from a person or entity not a party to this Agreement and without any obligation of confidentiality relative to the information; or (d) is developed independently by Recipient or its Representatives without use or reference to Discloser's Confidential Information.

6. Ownership of Confidential Information and Intellectual Property Rights. All Confidential Information, including Reproductions, shall be deemed to be and remain the property of Discloser. Further, no rights of any kind in and to Discloser's Confidential Information or its inventions, works of authorship, patents, trademarks, copyrights, designs or trade secrets are or shall be deemed licensed, transferred or assigned to Recipient under this Agreement.

7. Return of Confidential Information. On Discloser's written request, Recipient shall promptly return to Discloser, or, at the option of Discloser, destroy all of Discloser's Confidential Information and all Reproductions in its possession, and certify in writing to Recipient the return or destruction of such Confidential Information; provided, however, that Recipient may retain copies of Confidential Information that are stored on Recipient's IT backup and disaster recovery systems until the ordinary course of deletion thereof. In addition, Recipient may retain a single copy set of such materials solely for archival purposes to meet its own recordkeeping and legal obligations. Recipient shall continue to be bound by the terms and conditions of this Agreement with respect to such retained Confidential Information.

8. Termination. Either Party may terminate this Agreement at any time by providing written notice to the other Party. Notwithstanding anything to the contrary herein, each Party's rights and obligations under this Agreement shall survive any such termination until such time as the Confidential Information disclosed hereunder becomes publicly known and made generally available other than due to an act or omission of Recipient or its Representatives.

9. Warranties. Each Party warrants it has the authority to enter into this Agreement. NO WARRANTIES OF ANY KIND ARE GIVEN WITH RESPECT EITHER TO THE CONFIDENTIAL INFORMATION DISCLOSED UNDER THIS AGREEMENT OR TO THE USE THEREOF.

10. ***Remedies***. Each Party acknowledges and agrees that money damages might not be a sufficient remedy for any breach or threatened breach of this Agreement by such Party or its Representatives. Therefore, in addition to all other remedies available at law (which neither Party waives by the exercise of any rights hereunder), the non-breaching Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any such breach or threatened breach, and the Parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such claim. All rights and remedies available to either Party shall be cumulative, and no right or remedy of either Party shall be deemed the exclusive right or remedy of a Party.

11. ***Assignment***. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided, however, assignment by operation of law by a Party pursuant to a sale of equity or merger or similar transaction shall not require the consent of the other Party. No permitted assignment shall relieve the assigning Party of its obligations under this Agreement with respect to Confidential Information disclosed to it prior to the assignment. Any attempted assignment without the prior written consent of the non-assigning Party shall be void. This Agreement shall be binding upon the Parties' respective permitted successors and assigns.

12. ***Severability***. The provisions of this Agreement are severable. If any provision of this Agreement is held invalid or unenforceable, such provision shall be deemed deleted from this Agreement and such invalidity or unenforceability shall not affect any other provision of this Agreement, the balance of which will remain in and have its intended full force and effect; provided, however, that if such invalid or unenforceable provision may be modified so as to be valid and enforceable as a matter of law, such provision shall be deemed to have been modified so as to be valid and enforceable to the maximum extent permitted by law.

13. ***Waiver***. No delay or omission by either Party to exercise any right occurring upon any noncompliance or breach by the other Party with respect to any of the terms of this Agreement shall impair any such right or power or be construed to be a waiver thereof. A waiver by either of the Parties of any of the covenants, conditions or agreements to be performed by the other Party shall be effective only if in writing and signed by an authorized representative of each Party and shall not be construed to be a waiver of any succeeding breach thereof or of any covenant, condition or agreement contained in this Agreement.

14. ***No Obligation to Purchase or Sell.*** Nothing in this Agreement shall obligate either Party to purchase any products or services from the other Party, nor shall it obligate either Party to sell, license, or transfer any products or services to the other Party.

15. ***Relationship of the Parties.*** Nothing in this Agreement creates any license, franchise or agency relationship, partnership, or joint venture between the Parties.

16. ***Governing Law; Jurisdiction.*** The validity, construction, interpretation and enforcement of this Agreement, or any breach thereof, shall be governed solely by the laws of the State of Delaware, without reference to its principles on conflicts of laws, and this Agreement may be enforced in any court of competent jurisdiction.

17. ***Entire Agreement; Modification***. This Agreement represents the entire understanding between the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous communications, agreements and understandings relating thereto, whether written or oral. The provisions of this Agreement may not be modified, amended or waived, except by a written instrument duly executed by authorized representatives of both Parties.

[Signatures on following page]

IN WITNESS WHEREOF, through the signatures of the authorized representatives below, the Parties enter into this Agreement as of the Effective Date.

NELSON LABORATORIES, LLC	**COMPANY**
By: _____	By: _____ (Signature)
Name: _____	Name: _____ (*Name of Signator*)
Title: _____	Title: _____

Nelson Labs
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Testing by Location

Subcontracted--if a test is not offered at a certain location, it can be offered at another location or subcontracted.

		North America			RCA
		Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
Biocompatibility & Toxicology					
Cytotoxicity			x		
Genotoxicity	Ames Mutagenicity Test		x		
	Chromosomal Aberration		x		
	Mouse Lymphoma Testing		x		
	Mouse Micronucleus		x		
Hemocompatibility	Complement Activation		x		
	Hemolysis Test		x		
	In Vivo Thrombogenicity Test		x		
	PTT Test		x		
Implantation with Histopathology Tests			x		
Irritation	In Vitro		x		
	In Vivo		x		
ISO 18562: Biocompatibility Evaluation of Breathing Gas Pathway Devices			x		
Physicochemical USP Plastics Tests	Buffering Capacity		x		
	Heavy Metals		x		
	Nonolatile Residue (NVR)		x		
	Residue on Ignition (ROI)		x		
Risk Assessments	Biological Evaluation Plan (BEP)		x		
	Biological Evaluation Report (BER)		x		
	Biological Risk Assessment		x		
	Gap Analysis		x		
	Opinion Memo		x		
	Toxicological Risk Assessment		x		
Sensitization			x		
Subacute & Subchronic Toxicity			x		
Systemic Toxicity Test			x		
Chemistry Testing - Pharmaceutical					
Analytical Capabilities	Gas Chromatography (GC)		x		
	High Performance Liquid Chromatography (HPLC)				
	Fourier Transform Infrared Spectroscopy (FTIR)		x		
	Ultraviolet-Visible Spectroscopy		x		
	ICP-MS		x		
	Atomic Adsorption (AA)				
	Elemental Analysis (C, N, H)				
Analytical Method Development and Validation					
Antibiotic Potency Test (Analytical Analysis)					
Compendial Testing (USP/EP/JP)			x		
Dissolution Testing					
Drug Assay (Active Ingredient and Dosage Forms)	As is Basis				
	Dried Basis				
	Anydrous Basis				
Excipient Testing					
In-Use Stability Testing for Drug-Device Combinations			x		
Organic impurities Identification					
Water System Testing	TOC		x		
	Conductivity		x		

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Water System Testing	pH		x		
	Particulates		x		
Wet Chemistry Capabilities	Polarimeter and Titrations				
	Colorimetry				
	Gravimetry				
	Thin-Layer Chromatography (TLC)				
	Qualitative Limit Tests (Iron, Lead, Arsenic, chloride, sulfate)				
	Moisture Determinations				

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		North America			RCA
		Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
Reusable Medical Device Processing					
Cleaning Validation - Reuse Device		x	x		
Disinfection Validation - Reuse Device		x	x		
Endoscope and Scope Validations - Reuse Device			x		
Flexible Endoscope Sampling Kit			x		
Functionality & Repeated Use Studies		x	x		
Sterilization Validation - Reuse Device		x	x		
Extractables & Leachables					
Extractables & Leachables - Medical Device (Chemical Characterization)			x		
Extractables & Leachables - Pharmaceutical			x		
Material Characterization Screens of Raw Materials	Differential Scanning Calorimetry (DSC)		x		
	Fourier Transform Infrared Spectroscopy (FTIR)		x		
Physicochemical USP Plastics Tests			x		
Stability Studies - Pharmaceutical			x		
Facility & Process Validation					
Disinfection Efficacy Studies (Coupon Test)			x		
Environmental Monitoring Tests - Air & Water		x	x		
Environmental Monitoring Supplies - Air & Water		x	x		
Filter Sterilization Validations			x		
Material Characterization Screens of Raw Materials	Differential Scanning Calorimetry (DSC)		x		
	Fourier Transform Infrared Spectroscopy (FTIR)		x		
Residual Manufacturing Materials			x		
Water System Validations & Monitoring		x	x		
Method Development			X		
Packaging Solutions					
Accelerated & Real Time Aging			x		
Container Closure Integrity	Dye Immersion		x		
	Bubble Emmision		x		
	Mass Extraction		x		
	Microbial Immersion		x		
Integrity & Strength Tests	Bubble Emission		x		
	Burst Test		x		
	Dye Migration		x		
	Seal Peel Test		x		
Packaging Shelf Life Studies			x		
Transportation and Distribution Performance			x		
Whole Package Integrity Tests			x		
Protective Barriers & Material Performance					
Antimicrobial Efficacy Studies			x		
Bacterial & Viral Filtration Efficiency (BFE/VFE)			x		
Flammability Test			x		
Glove Tests	Glove Heat Aging Degradation Test		x		
	Leakage Evaluation		x		
	Physical Dimentions		x		
	Puncture Resistance		x		
	Residual Powder		x		

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		North America			RCA
		Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
	Tensile Test		x		
	Whole Glove Viral Barrier		x		
Hydrostatic Pressure Test			x		
Microbial Cleanliness for Face Masks			x		
Particle Filtration Efficiency (PFE)			x		
Respirator Pre-Certification Tests - NIOSH	Dioctyl Phthalate (DOP) Challenge		x		
	Sodium Chloride Aerosol Challenge		x		
Spray Impact			x		
Surgical Face Masks and General Use Masks			x		
Surgical Gowns and Drapes			x		
Synthetic Blood Penetration for Liquid Barriers			x		
Tensile and Tear Resistance Tests for Fabrics			x		
Viral Penetration Test			x		

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		North America			RCA
		Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
Sterility Assurance					
Antibiotic Potency Test (Micro)	PBET		x		
Antimicrobial Preservative Effectiveness (Micro)	PBET		x		
Bacterial Endotoxin Test	PBET	x	x		
Biological Indicator - Population Verification	EOC	x	x		
Biological Indicator - Sterility Test	EOC	x	x		
EO Sterilant Residual Tests	Extraction by Fluid Path EOC	x	x		
	Extraction by Submersion EOC	x	x		
Forced Degradation Testing - Pharmaceutical	PBET				
Hold Time/Admixture Testing	PBET				
Impurities Identification	EOC		x		
Microbial Identifications	Genetic Identification BIOB	x	x		
	Gram Stain BIOB	x	x		
Microbial Examination of Nonsterile Products	BIOB		x		
Mycoplasma Testing - PCR & Traditional	PCR BIOB				
	Traditional BIOB				
Particulate Matter (USP/EP)	PBET	x	x		
Product Bioburden - Medical Device + Tissue	BIOB	x	x		
Product Sterility - Cleanroom	PS	x	x		
Product Sterility - Isolator	PS		x		
Radiation Quarterly Dose Audits (QDAs)	BIOB	x	x		
Standard Plate Counts	BIOB	x	x		
Time Kill Studies	PBET		x		
Tissue Testing Services	BIOB		x		
Virus & Virucidial Testing	PBET				
Zone of Inhibition Testing	PBET		x		
Sterilization Validations					
Clinical Batch Release		x	x		
D-Value Determination Studies		x	x		
Filter Sterilization Validations			x		
Product Inoculations		x	x		
Sterilization Bioburden Resistance		x	x		
Sterilization Exposure Cycles		Steam	x		
Sterilization Supplies (BIs & PCDs)		x	x		
Sterilization Validations	EO		x		
	Radiation	x	x		
	Reuse Device	steam	x		