Nelson Labs
A Sotera Health company

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FAIRFIELD CUSTOMER SUPPORT HOTLINE

DEDICATED CENTRAL POINT OF CONTACT – FAIRFIELD TRANSITION PROGRAM

Fairfield 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 Fairfield to any of our qualified Nelson Labs (US) facilities: Itasca, IL; Salt Lake City, UT; and/or Bozeman, MT.

ADDITIONAL SUPPORT

Nelson Service Center
1 (801) 290-7500 | nl-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

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CRITICIAL DATES/TIMELINE

MICROBIOLOGY

No longer starting new Product Sterility or BI Sterility studies at Fairfield
15 Feb 2023: Last start date: Mycoplasma studies put onto test at Fairfield
28 Feb 2023: Last start date: AET Sterility studies put onto test at Fairfield
17 Mar 2023: Last start date: BET studies will be put onto test at Fairfield
31 Mar 2023: Last start date: Bioburden, Microbiology USP <61/62>, Water, IDs, etc. studies put onto test at Fairfield
01 Jun 2023: Last date that Fairfield *will accept MICROBIOLOGY samples for Subcontracting* to Itasca, Salt Lake City, or Bozeman from Fairfield (samples will need to be sent direct to one of those locations)
02 Jun 2023: Last day for on-site Environmental Monitoring services at client sites

CHEMISTRY / STABILITY

31 Jan 2023: Last start date: Stability studies will be put onto test at Fairfield, (no studies longer than 90 days)
01 April 2023: Nelson Labs Pharmaceutical Center of Excellence (Itasca, IL) – Chemistry Expansion LIVE for new Method Transfer and Monograph studies with full capabilities by 01 June 2023
15 May 2023: Last start date: Method Transfer Chemistry studies will be put onto test at Fairfield
31 May 2023: Last start date: Particulates studies will be put onto test at Fairfield
01 Jun 2023: Last date that Fairfield *will accept CHEMISTRY/STABILITY studies for Subcontracting* to Itasca, Salt Lake City, or Bozeman from Fairfield (samples will need to be sent direct to one of those locations)

ANTIMICROBIALS / DISINFECTION / APA

28 Feb 2023: Last start date: Any new studies will be put onto test at Fairfield
01 Jun 2023: Last date that Fairfield *will accept ANTIMICROBIALS / DISINFECTION / APA samples for Subcontracting* to Itasca, Salt Lake City, or Bozeman from Fairfield (samples will need to be sent direct to one of those locations)

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ACCOUNTING & BILLING INFORMATION

ITASCA, IL & 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: nl-ar@nelsonlabs.com
Credit Card Payment: Pay Your Bill for Nelson Labs
Tax ID #: 47-4076134 | See page 13 for a copy of W9

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

BOZEMAN, MT

Remit To Address | Bank Information
Nelson Laboratories Bozeman, LLC
PO Box 772678
Belleville, MI 48277-2678 USA
WIRE: Routing Number: 021000021 | SWIFT Code: CHASUS33 | Account Number: 717021676
General Bank Reference Address: JPMorgan Chase New York, NY 10017
ACH: Routing Number: 071000013 | Account Number: 071000013
Telephone: 406-587-5735 ext. 103 | E-mail: tanderson1@nelsonlabs.com
Tax ID#: 47-4076134 | See page 14 for a copy of W9

Purchase Orders
Send Purchase Orders to your Account Manager or to the Director of Business Development for Nelson Labs, Bozeman: John Dyba JDyba@nelsonlabs.com

SUBCONTRACTING FROM FAIRFIELD *(interim solution while qualifying Itasca, Salt Lake City, and/or Bozeman)*

For subcontracting, all quotes, submissions, reports, and invoices will continue to flow through Fairfield as they have been previously. This will terminate on 01 June 2023.

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 – Itasca, IL, See pages 15-23
Regulatory Certifications Packet – Salt Lake City, UT, See pages 24-67
Regulatory Certifications Packet – Bozeman, MT, See pages 68-75

SUPPLIER QUESTIONAIRE

Supplier Questionnaire/Audit Packet – Itasca, IL, See pages 76-78
Supplier Questionnaire/Audit Packet – Salt Lake City, UT, See pages 79-81
Supplier Questionnaire/Audit Packet– Bozeman, MT, See pages 82-84

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 – Itasca, IL & Salt Lake City, UT, See pages 79-84

If compliant with your company's quality management system, Nelson does offer a paper audit option. This option would cover both the Itasca, IL and Salt Lake City, UT 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 - 30 Jun 2023). 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.

Itasca, IL: TransferSupport@nelsonlabs.com
Salt Lake City, UT: Quality Audits: QualityAudits@nelsonlabs.com
Bozeman, MT: experts@biosciencelabs.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 Fairfield facility until an onsite audit is able to be scheduled. Subcontracting through Fairfield (Available until: 01 Jun, see page 3).

Documentation showing Itasca, Salt Lake City, and Bozeman facilities are all on the Fairfield Approved Supplier List, see page 85.

QUALITY AGREEMENTS

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

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LOGISTICS

REQUESTING A QUOTE

Existing Quote:

Any existing Fairfield price quote will be honored at the Nelson Facility that samples are submitted to up until the Expiry Date reflected on the quote.

New Quote Requests:

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

CUSTOMER PORTAL (Itasca, IL and 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 Itasca and Salt Lake City 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 (nl-servicecenter@nelsonlabs.com) and they will provide an additional link.

SUBMITTING A SAMPLE DIRECT (Itasca, IL and 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 (nl-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:

- Itasca, IL: Nelson Labs | 1500 W. Thorndale Ave. | Itasca, IL 60143 | 801-290-7500
- Salt Lake City, UT: Nelson Labs | 6280 S. Redwood Rd. | Salt Lake City, UT 84123 | 801-290-7500
- Bozeman, MT: Nelson Labs, Bozeman| 1765 S. 19th Ave. | Bozeman, MT 59718 | 877-858-2754
  Website: Home - Nelson Labs - Bozeman (nelsonlabsbozeman.com)

CAPABILITIES BY NELSON LABS FACILITY (US)

See capabilities chart by location, pages 88-92

NELSON FACILITY TRANSFER APPROVAL FORM (between Salt Lake City, UT & Itasca, IL)

To provide you with the fastest turnaround time available, complete the Nelson Facility Transfer Form. This will allow Nelson to initiate an internal transfer between our Itasca and Salt Lake City facilities based on current capacity to ensure the fastest turnaround time and best service possible.

To initiate this process, please complete the "Nelson Transfer Approval Form" (page 103) and e-mail a copy back to either your Account Manager or TransferSupport@nelsonlabs.com.

NELSON FAIRFIELD SUBCONTRACTING APPROVAL FORM

To subcontract testing through Nelson Labs, Fairfield to one of our other qualified facilities, please complete the "Nelson Fairfield Subcontracting Approval Form" (page 93) and e-mail a copy back to either your Account Manager or TransferSupport@nelsonlabs.com.

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LEGAL & PRICING

MUTUAL NDA

Mutual Non-Disclosure Agreement – Itasca, IL, Salt Lake City, UT, and Fairfield, NJ
If you do not have a current mutual non-disclosure agreement that covers Fairfield, SLC, and Itasca, click the below link to initiate an NDA. Or refer to pages 94-97

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

Mutual Non-Disclosure Agreement – Bozeman, MT
If you do not have a current mutual non-disclosure agreement that covers Bozeman, see Pages 98-101 to initiate an NDA.

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

PRICING

Pricing is harmonized between Fairfield, Salt Lake City, and Itasca for 2023.

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

TECHNICAL/SCIENTIFIC SUPPORT:

Method Transfer/CCSs /Method Validation Options

Method Validation and Method Transfer Chart

See page 102. 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.

Looking Forward

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. – 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. Our Expert Advisory Service encompasses product development, facility and process validation, and product performance testing, as well as regulatory support.

Regulatory Audit Support, Sample & Study Archives

All remaining sponsor samples in Fairfield will be transferred to SLC or returned to the client by 30 June 2023. No sample receiving will occur at Fairfield after 01 June. Online archives to access study data & reports using the prior Gibraltar portal will be available thru 31 Dec 2023. 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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FREQUENTLY ASKED QUESTION (FAQ) SHEET

Q: What will happen to samples that are already in-house at Fairfield?

A: Samples that are already in-house or received by 01 June 2023 will be tested and completed at Fairfield or transferred by the dates noted above for specific services. Anything received after that date will be transferred or subcontracted to another Nelson facility based on the specific service. Unused samples and sample archives in storage at Fairfield will be returned to the study sponsor upon discontinuation of Fairfield laboratory services.

Q: Will I need a new quote?

A: No, our Itasca, Salt Lake City, and Bozeman facilities 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 Order requirements will come directly from your company's accounting group. However, if you are setup to be PO required – we will need an updated Purchase Order with the applicable updated Remit To information, see page 4 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 page 5 above for audit and qualification details. If you are inquiring about a study performed at Fairfield in support of a regulatory inquiry or audit, see page xx above regarding Regulatory Audit Support, Sample & Study Archives.

Q: Will I use my current Sample Submission Form?

A: If you will be subcontracting testing through the Fairfield 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, there will be a different Sample Submission Form and portal. Please see page 6 above 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 Fairfield 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 different customer portal to access your final reports. Please see page 6 above in our Logistics section for details on these processes and the applicable reference materials. If you are inquiring about a study performed at Fairfield in support of a regulatory inquiry or audit, see page xx above regarding Regulatory Audit Support, Sample & Study Archives.

Q: Will I be able to access archived final reports from Nelson Fairfield?

A: Archived reports will be available for a limited time on the Nelson Fairfield portal, after which point archive reports will be available upon request at: TransferSupport@nelsonlabs.com. If you are inquiring about a study performed at Fairfield in support of a regulatory inquiry or audit, see page xx above regarding Regulatory Audit Support, Sample & Study Archives.

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 page 4 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 our facilities are under the Sotera Parent account, however there are different Remit To and bank information details, see page 4.

Q: Who can I go to with questions?

A: We have a designated Fairfield Support Hotline TransferSupport@nelsonlabs.com) for customer support throughout this transition and have a dedicated Project Management resources to ensure an easy transition with the consolidation to our expanding 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 Fairfield Study Director and technical expert. If you are inquiring about a study performed at Fairfield in support of a regulatory inquiry or audit, see page xx above regarding Regulatory Audit Support, Sample & Study Archives.

Q: I am used to taking 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 Fairfield 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 Itasca, Salt Lake City, and Bozeman locations are on the Nelson Fairfield approved supplier list?

A: Yes, that documentation is included within this packet. See page 85.

Q: What turnaround time should I expect for moving to the other sites?

A: Fairfield customers are being prioritized through the testing queues at each of our other testing facilities to help mitigate impact and delays related to switching testing locations. For exact/current turnaround times specific to your testing, contact either our Fairfield Support Hotline: TransferSupport@nelsonlabs.com or your Account Manager.

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.*

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 Bozeman, 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.

1765 South 19th Ave

Requester's name and address (optional)

6 City, state, and ZIP code

Bozeman, MT 59718

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** ▶ 12/1/2022

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
A Sotera Health company

Certifications, Registrations, Licenses: Itasca, Illinois

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CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143

Fulfills the requirements of

ISO/IEC 17025:2017

and

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

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 16 March 2025

Certificate Number: AT-1382.01

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143

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

TESTING

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

Microbiological[1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	STP0046; USP<85>; USP<161>; ANSI/AAMI ST72	Medical Devices, Pharmaceuticals	Microplate Reader
Bioburden	STP0036; ISO 11737-1	Medical Devices, Pharmaceuticals	Biosafety Cabinet, Incubators, Laminar Flow Hood
Biological Indicator Sterility	STP0079; ISO 11138-1 to -4; USP<55>; ISO 11135; AAMI TIR 14	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubators
Product Sterility Bacteriostasis / Fungistasis	STP0077; STP0078; ISO 11737-2; USP<71>	Medical Devices, Pharmaceuticals	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms, USP 61/62)	STP0045; USP<55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators
Organism Identification (Genetic and Gram Stain)	STP0173; STP0105; USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope

Microbiological[1]

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

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Particulates	STP0011 based on USP<788>,<789>, EP 2.9.19, 2.9.31, BP Appendix XIII A, BH EN 45502-1, 45502-2-1 ISO 8536-4	Medical Devices, Injectables and Ophthalmic Solutions, Pharmaceutical Products	Liquid Particle Counting System, Microscope

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	STP0016 based on ANSI/AMMI/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	STP0028 based on USP<643>	Water – USP	TOC Analyzer
Biological Marker Analysis Hemoglobin Protein	STP0087, STP0183 based on ASTM F756-13, AAMI TIR30 and Cleaning, Disinfection, Sterilization references previously listed	Medical Devices	Spectrophotometer

Note:

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

Jason Stine, Vice President

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3007950533

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

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/30/2021
Summary Report Print Date: 12/01/2021

Legal Name and Location:

Nelson Laboratories, LLC
1500 W. Thorndale Ave

Itasca, Illinois 60143
USA

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

Reporting Official:

Robert Thoreson, Director of Quality Assurance
6280 South Redwood Road
Salt Lake City, Utah 84123
USA
Phone: 801-290-7618 Ext.
rthoreson@nelsonlabs.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: Yes

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

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

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

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3007950533

Legal Name: Nelson Laboratories, LLC

Drug Establishments Current Registration Site

Share | Tweet | Linkedin | Email | Print

New Search

Search Results for **Nelson Laboratories, LLC**

CSV | Excel

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)	12/31/2023
Nelson Laboratories, LLC	3000717698	032350261	ANALYSIS;	1500 W Thorndale Ave, Itasca, Illinois (IL) 60143, United States (USA)	12/31/2023

Showing 1 to 2 of 2 entries

Previous 1 Next

Data Current through: Monday, Oct 24, 2022

Return to Drug Firm Annual Registration Status Home Page

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 1, 2022**

Expires: May 01, **2023**

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

Registration Number 0819

State of Illinois
2022
Sperm/Tissue Bank Registration

Nelson Labs

Dear Director:

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

Sincerely,

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

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

Nelson Labs
A Sotera Health company

Certifications, Registrations, Licenses: Salt Lake City, Utah

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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 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, 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 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

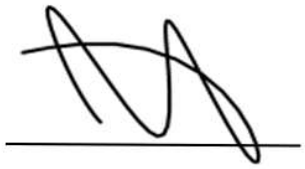
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Barrier Testing: Synthetic Blood and Water Resistance (Hydrostatic Pressure, Impact Penetration)	STP0061, STP0071 and STP0072 based on ASTM F1670, 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: Thursday, January 5, 2023 9:01 PM
To: Matthew D. Cushing <MCushing@nelsonlabs.com>
Subject: [EXTERNAL] Registration Number 1721109: Successful 2023 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 2023:

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, 2023. Registration for 2024 will be conducted between October 1 and December 31, 2023.

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

Nelson Labs
A Sotera Health company

29 Sep 2022

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, UT with Sotera Health located in Broadview Heights, OH.

Under the Generic Drug User Fee Amendments of 2012 (GDUFA), all facilities involved in the manufacture and testing of human generic drugs are now required to electronically self-identify with the FDA.

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 2023 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: 2023
Last Registration Receipt Date: 11/18/2022
Summary Report Print Date: 12/01/2022

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: 07/31/2023

Drug Establishments Current Registration Site

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New Search

Search Results for **Nelson Laboratories, LLC**

CSV | Excel

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)	12/31/2023
Nelson Laboratories, LLC	3000717698	032350261	ANALYSIS;	1500 W Thorndale Ave, Itasca, Illinois (IL) 60143, United States (USA)	12/31/2023

Showing 1 to 2 of 2 entries

Previous 1 Next

Data Current through: Monday, Oct 24, 2022

Return to Drug Firm Annual Registration Status Home Page

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RN0504274	10-31-2023	$296

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	ANALYTICAL LAB	09-20-2022

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.

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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.

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[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.

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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

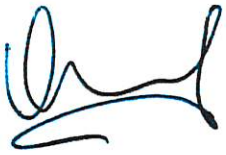
Manufacturer's responses have been received by email on November 19, 2021. All the deficiencies have been adequately addressed and responses are deemed acceptable subject to the corrective and preventive actions being carried out and the deadlines.

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 **09/30/2023**

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: **09/30/2023**

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: May 1, 2023**

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** **DBA: LIC 12-16-22009**	**Business Type(s):**	621512 Diagnostic Imaging Centers
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:	1/31/2022	**Classification:**	Professional Services
Expiration Date:	1/31/2023	**Fees Paid:**	$328.00

Kristi S. Overson — Mayor

CITY OF TAYLORSVILLE INCORPORATED SEAL JULY 1, 1996 STATE OF UTAH

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

Nelson Labs® | Bozeman
A Sotera Health company

Certification and Documentation Packet

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SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017	**Pg. 1 – 3**
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FDA: Drug Establishments Registration	**Pg. 6**
Active IRB Registration	**Pg. 7**

1765 S. 19th Avenue
Bozeman, MT 59718
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SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES BOZEMAN, LLC
1765 South 19th Avenue
Bozeman, MT 59718
Dr. Margret Butler Phone: 406-587-5735 ext. 163
Danielle Goveia Phone: 406-587-5735 ext. 136

BIOLOGICAL

Valid To: May 31, 2024 Certificate Number: 3945.01

In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the laboratory's compliance to *U.S. Food and Drug Administration's GLP (Good Laboratory Practices Act) requirements as specified in the Code of Federal Regulations Title 21 part 58 (21CFR58)*), accreditation is granted to this laboratory to performthe following tests on soaps, hand sanitizers, preoperative skin preparations, hard surface disinfectants, textiles, medical devices,gloves, and condoms:

Test	**Test Method**
Clinical Bactericidal Tests - ***In Vivo***	
Chemical Disinfectants and Antiseptics - Hygienic Hand Rub - Test Method and Requirements (Phase 2/Step 2)	EN1500
Chemical Disinfectants and Antiseptics - Hygienic Handwash - Test Method and Requirements (Phase 2/Step 2)	EN 1499
Standard Test Method for Determining the Bacteria - Eliminating Effectiveness of Hygienic Handwash and Hand Rub Agents Using the Finger Pads of Adults	ASTM E2276
Standard Test Method for Determining the Bacteria - Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults	ASTM E2755
Standard Test Method for Evaluation of Pre-operative, Pre-catheterization, or Pre-injection Skin Preparations	ASTM E1173
Standard Test Method for Evaluation of Surgical Hand Scrub Formulations	ASTM E1115
Standard Test Method for Evaluation of the Effectiveness of Handwash Formulations Using the Paper Towel (Palmar) Method of Hand Contamination	ASTM E2784

Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations	ASTM E1174

Test	**Test Method**
Clinical Bactericidal Tests - *In Vivo* (cont.)	
Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products	ASTM E2752
Clinical Virucidal Tests - *In Vivo*	
Standard Test Method for Determining the Virus - Eliminating Effectiveness of Hygienic Handwash and Hand Rub Gents Using the FingerPads of Adults	ASTM E1838
Clinical Respirator Fit Test - *In Vivo*	
Standard Test Method for Evaluation of Hygienic Handwash and Hand Rub Formulations for Virus - Eliminating Activity Using the Entire Hand	ASTM E2011
Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators	ASTM F3407
***In Vitro* Bactericidal Tests**	
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Basic Bactericidal Activity of Chemical Disinfectants and Antiseptics. Test Method and Requirements (Phase 1)	EN 1040
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Bactericidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic and Institutional Areas. Test Method and Requirements (Phase 2, Step 1)	EN 1276
Chemical Disinfectants and Antiseptics-Quantitative Test Method for the Evaluation of Bactericidal and Yeasticidal Activity on Non-porous Surfaces with Mechanical Action Employing Wipes in the Medical Area (4 - field test) - Test Method and Requirements (Phase 2, Step 2)	EN 16615
Measurement of Antibacterial Activity on Plastics and Other Non-porous Surfaces	ISO 22196
Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time - Kill Procedure	ASTM E2783

Test	**Test Method**
***In Vitro* Virucidal Tests**	
Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Virucidal Activity in the Medical Area - Test Method and Requirements (Phase 2/Step 1) (Includes Amendment :2019)	EN 14476
Measurement of Antiviral Activity on Plastics and Other Non-porous Surfaces	ISO 21702
Standard Practice to Assess the Activity of Microbicides Against Viruses in Suspension	ASTM E1052
Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Non-porous Environmental Surface	ASTM E1053
Textiles - Determination of Antiviral Activity of Textile Products	ISO 18184
Neutralization of Antimicrobial Activity - ***In Vitro***	
Standard Practices for Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054

Accredited Laboratory

A2LA has accredited

NELSON LABORATORIES BOZEMAN, LLC

Bozeman, MT

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the *U.S. Food and Drug Administration's GLP (Good Laboratory Practices Act) requirements as specified in the Code of Federal Regulations Title 21 part 58 (21CFR58). 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*).

Presented this 19th day of July 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3945.01
Valid to May 31, 2024

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.

CDER Direct
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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this GDUFA Self-Identification submission form. required fields.

Header Details

Document Type: * GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION

Set ID: * 112ceaa4-b787-60b3-e054-00144ff8d46c

Version Number: * 11

Root ID: * de0bcd7d-dd9c-22cb-e053-2a95a90a4e98

Effective Date: * 05-02-2022

Registrant Details

Registrant Name: * Nelson Laboratories Bozeman, LLC

Registrant DUNS: * 787813161

Registrant Contact Details

Contact Name: * Amy Juhnke

Contact Email: * ajuhnke@nelsonlabs.com

Contact Phone: * 406-587-5735

Phone Extension: 105

Contact Fax: 406-586-7930

Registrant Contact Address

Country: * United States

Street Address: * 1765 S. 19th Avenue

City: * Bozeman

State: * Montana

Postal Code: * 59718

Facilities

row(s) 1 - 1 of 1

FACILITY DUNS	FACILITY FEI NUMBER	FACILITY NAME
787813161	1000221600	BioScience Laboratories, Inc.

CDER Direct
Electronic Submissions Portal

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Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form required fields.

Header Details

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * 1130a1f8-bcc3-72ec-e054-00144ff8d46c

Root ID: * de0bcd7d-dd9b-22cb-e053-2a95a90a4e98

Version Number: * 11

Effective Date: * 05-02-2022

Registrant Details

Registrant Name: * Nelson Laboratories Bozeman, LLC

Registrant DUNS: * 787813161

Registrant Contact Details

Contact Name: * Amy Juhnke

Contact Email: * ajuhnke@nelsonlabs.com

Contact Phone: * 406-587-5735

Phone Extension: 105

Registrant Contact Address

Country: * United States

Street Address: * 1765 S. 19th Avenue

City: * Bozeman

State: * Montana

Postal Code: * 59718

Establishments

row(s) 1 - 1 of 1

ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
787813161	1000221600	BioScience Laboratories

IRB Organization Information

IORG0004971 - Nelson Laboratories Bozeman, LLC (Active)

Located at: Bozeman, MONTANA
Expires: 05/05/2025

IRBs for this Organization: 1
Agency Only Access

IRB#	IRB Name	City	State/Country	Status	IRB Type
IRB00005939	Gallatin IRB #1	Bozeman	MONTANA	Active	OHRP/FDA

Nelson Labs™
A Sotera Health company

Quality Information – Itasca

Company Information	
Company Name	Nelson Laboratories, LLC, a Sotera Health Company Private corporation. Established in 1985.
Parent Company	Sotera Health
Company Address	1500 West Thorndale Ave. Itasca, IL 60143
Website	nelsonlabs.com
Telephone	630-285-9121
Business Information	
Business Classification	Sector 54 Professional, Scientific & Technical Services/NAICS 541380: Testing Laboratories.
Federal Tax ID	87-0425936
Dun & Bradstreet Number	15-166-3234
US SAM Entity/ DUNS/ CAGE Code	NELSON LABORATORIES, LLC / 151663234 / 5ESY1
Facilities	
Total Square Footage	30,000 ft^2
Lab Space	18,500 ft^2
Operating Hours	Primarily one shift, 8am-4:30pm, 5 days a week. Small crew for receiving and BI testing on Saturdays.
Number of employees	~ 60
Quality Staff	5
Equal Opportunity	NL is an equal opportunity employer
Critical Contacts	
Management	Joseph Spyridakis (Site Leader – Itasca/Ontario/Mexico)
Operations (Microbiology)	Amy Moens & Kelly Foley (Lab Operations Manager)
Operations (Chemistry)	Anthony Nudo (Senior Lab Operations Manager)
Quality/Regulatory	Shana Sanders (Senior Quality Assurance Manager)
Additional Contacts	
Service Center	servicecenter@nelsonlabs.com
Audit Scheduling	Mike Hammond (MHammond@NelsonLabs.com)
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	NL 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
ISO Registrar / Certificate Number	ANAB / AT-2490
FDA FEI Identifier	3000717698
Last FDA Audit	08 Nov 2018
Please note: Up to date certifications are available on the website.	

Payment Information	
Check Remittance / Billing Address	Nelson Laboratories, LLC 29471 Network Place Chicago, IL 60673-1294
Overnight Address	JPMorgan Chase Attn: Nelson Laboratories, LLC - Lockbox 29471 131 S Dearborn, 6th Floor Chicago, IL 60603
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
NL has procedures/processes including (but not limited to) the following:	
Quality Manual/Policy	*MAN0001 - 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.
Change Control and Change Notification	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 (*SOP0039 - Change Management*) are assessed for the potential impact to you as a customer. Every effort is made 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.
Document Control	*SOP0001 - Management of Controlled Procedures and Forms*. 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.
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.
Complaints	*SOP0145 - Complaint Handling*. Describes the practices for customer complaint resolutions.
Customer Feedback	*SOP0093 - Customer Feedback Handling*. Details the customer feedback process.
Control of Non-conforming Product	*SOP0164 - Nonconforming Supplies and Services*. Items which do not conform to established specifications are quarantined.
Corrective Action / Preventative Action	*SOP0096 - Corrective and Preventive Action*. A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring quality problems. The procedure includes 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 CAPA action plans are reviewed and approved by management.
Deviations	*SOP0136 - Quality Events, Investigations, Retests, and Study Discontinuations*. This procedure details how to address a deviation, 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. This procedure requires 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.

Out of Specification (OOS) Results	*SOP0136 - Quality Events, Investigations, Retests, and Study Discontinuations*. An OOS is a result that falls outside the specification established by a compendial method, SOP, STP, Protocol, or as required by the sponsor. According to the Quality Events and Investigations procedure, 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 one business day.
Training	*SOP0098 - Training System*. NL includes 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.
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.
Internal Audits	*SOP0103 - Internal Audits*. Describes the documented internal audit program. Actions to correct deficiencies and prevent recurrence are documented, reviewed, and approved before audit closure.
Management Responsibilities	*SOP0089 - Management Responsibilities*. NL Management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the NL Quality System on a bi-annual basis according to ISO/IEC 17025:2005 and 21 CFR part 820.40.
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 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.
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).
Equipment	*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 where applicable.

Frequently Requested Information – Salt Lake

Toll-free: 800.826.2088 NL-ServiceCenter@NelsonLabs.com
Local: 801-290-7500 NL-Accounting@NelsonLabs.com
Fax: 801-290-7998 NL-Sales@NelsonLabs.com

Last Updated: 05 Apr 2022

Company Information	Nelson Laboratories, LLC (NL) a Sotera Health company, is an industry-leading provider of laboratory testing and consulting services. We perform over 400 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.		
	Established	1985	
Facilities	NL is located in Salt Lake City, Utah. There are five buildings (totaling 128,400 ft²) that comprise the NL campus: Redwood 1 and 2, Redwood 3, Redwood 4, and Redwood 5. The total combined laboratory space of the five buildings is 85,245 ft².		
	The state-of-the-art facilities are clean, organized, and secured with keycard and PIN access. Some key features include a multi-media auditorium, several large conference rooms, a metrology lab, a training lab, a media prep lab, five ISO Class 5 clean rooms, a cafeteria where lunch is catered daily, a children's playroom, and a registered art gallery.		
Audit Availability	An on-site audit may be arranged by contacting NL-QualityAudits@nelsonlabs.com		
References	NL policies and procedures ensure the protection of our clients' names, confidential, and proprietary information, thus no references are able to be provided.		
Critical Contacts	Joe Shrawder	President	Please contact our client services group at 801-290-7500 to arrange to speak with any of these individuals.
	John Bolinder	VP of Operations, North America	
	Krista Bollnow	VP of Sales & Marketing	
	Rob Thoreson	Director of Quality Assurance	

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							
Shifts	Primarily one shift, 9am-5pm, 5 days a week. Weekends and swing shifts as required.							
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: Log In 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		

ISO Accreditation	ISO Standard: ISO 17025 ISO Registrar: ANAB	Certificate Number: AT-1382 Please see up-to-date certificates on our website.	
FDA CDRH Registration	#1721109	**FDA FEI Identifier**	# 3000233845
FDA Audit Information	We are frequently audited by the FDA to GMP, GLP, and GTP guidelines. Please see up-to-date EIRs and responses on our website.		
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		
US SAM Entity/DUNS/CAGE Code	NELSON LABS, LLC / 151663234 / 5ESY1		

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

Change Control and Change Notification	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.
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.
Complaints	NL has a formalized complaint resolution process and seeks customer feedback on a regular basis.
Control of Non-conforming Product	Items which do not conform to purchase order specifications are quarantined.
Corrective Action / Preventative Action	A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring quality problems. The procedure includes 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 CAPA action plans are reviewed and approved by management.
Design Control	Design review is required for most new Standard Test Protocols. Test methods adapted from a compendial standard are exempt.
Deviations	Our Quality Events and Investigations procedure details how to address a deviation, 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. This procedure requires 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.
Document Control	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	Each piece of equipment is uniquely identified. Before being put into use, a new piece of equipment undergoes IQ, OQ, and PQ.
Internal Audits	NL has a formal, documented internal audit program. Each applicable ISO 17025, GMP, GLP, and GTP clause 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	NL Management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the NL Quality System on a bi-annual basis according to ISO/IEC 17025:2005 and 21 CFR part 820.40.
Out of Specification (OOS) Results	An OOS is a result that falls outside the specification established by a compendial method, SOP, STP, Protocol, or as required by the sponsor. According to the Quality Events and Investigations procedure, 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 one business day.

Purchasing Controls	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.
Quality Manual/Policy	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.
Statistical Techniques	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	Datapacks, which contain study information including raw data, are scanned and maintained. NL's Quality Document retention period is 10 years.
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	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.
Traceability	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.
Training	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).
Validation	Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity, (where applicable).

Nelson Laboratories Bozeman, LLC
1755 South 19th Avenue
Bozeman, Montana 59718
Phone: (406) 587-5735

Supplier Questionnaire – Bozeman, Montana Site

Company Information	
Company Name	Nelson Laboratories Bozeman, LLC (NLB)
Parent Company	Sotera Health 9100 South Hills Blvd, Suite 300 Broadview Heights, OH 44147 USA (440) 262-1410
Company Address	1755 South 19th Avenue Bozeman, MT 59718
Website	www.nelsonlabsbozeman.com
Telephone	(406) 587-5735
Business Information	
Business Description	Nelson Laboratories Bozeman, LLC is a contract research testing laboratory with biofilm, clinical, disinfectant, in-vitro microbiology, material testing, skin care, and virology testing capabilities.
DUNS Number	787813161
Facilities	
Total Square Footage	~21,000 ft²
Lab Space	~15,000 ft²
Operating Hours	Primarily one shift, 8 am-5 pm, Monday - Friday. Weekends and evening shifts as required.
Number of employees	~64
Quality Staff	5
Critical Contacts	
President	Joseph A. Shrawder – President, Nelson Laboratories, LLC (Global)
Operations	Chelsey Allison – Senior Manager, Laboratory Operations
Quality	Matt Cushing - VP of Quality and Science (Global) Robert Thoreson - Director of Quality Assurance (North America) Danielle Goveia – Quality Assurance Manager
Sales	John Dyba, MCRA – Director of Business Development
Additional Contacts	
Sales Contact	NL-Sales@nelsonlabs.com
Accounting	NL-Accounting@nelsonlabs.com
Audit Scheduling	DGoveia@nelsonlabs.com
Proprietary Information	
References	Nelson Laboratories Bozeman, LLC policies and procedures ensure the protection of clients' names, confidential, and proprietary information, thus no references are able to be provided.
Sales/Financial Information	As a public company, financials are posted online.
Facility Statement	Nelson Laboratories Bozeman, LLC is a contract research (CRO) testing laboratory, providing ISO/GLP/GCP in-vitro and clinical microbial and viral efficacy evaluations, medical material evaluations, clinical product safety, and performance evaluations.

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Bozeman, Montana 59718
Phone: (406) 587-5735

Accreditation/Certifications/Registrations	
ISO Accreditation	ISO 17025:2017
ISO Registrar	A2LA
ISO Certificate Number	3945.01 (See attached)
Date of Last EPA Audit	June 2019
Date of Last FDA Audit	GCP Compliance: November 2015, July 2016 GLP Compliance: January 2006
FDA Drug Establishment	#1000221600
FDA Generic Drug Facility Identification	#1000221600
IRB Organization (IORG)	IRB00004971
Up to date certifications are available on the various regulatory websites.	
NLF has procedures/processes including (but not limited to) the following:	
Quality Manual/Policy	QM-0002 Quality Manual The NLB Quality Manual provides employees, auditors, and customers ofNelson 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 NLB systems for the requirements of these standards.
Change Control and Change Notification	SOP0649 Documentation Practice – General (previously G-0001) SOP0650 Identification Systems (previously G-0002) SOP0001 Management of Control Procedures and Forms Testing is typically executed per individual study protocol based on standardized methods, where document change control and change notifications are accomplished via protocol amendments, which require sponsor signature and approval.
Document Control	SOP0649 Documentation Practice – General (previously G-0001) SOP0650 Identification Systems (previously G-0002) SOP0001 Management of Control Procedures and Forms SOP0134 Structure of Controlled Procedures/Forms SOP0753 Retention of Controlled Documents (previously G-0008) NLB establishes and maintains procedures to control all documents required by regulations, standards, normative documents, test, and calibration methods. Documents are controlled by revision number and are reviewed, updated, and approved as necessary.
Calibration and Maintenance	SOP0820 Equipment Qualification and Maintenance (previously V-0008) The calibration and maintenance of equipment is performed by outside vendors, as well as by both NL Salt Lake City and NLB Maintenance, Metrology and Operations Department (MMO), as appropriate. Using documented procedures, prevention of inaccuracies and deficiencies of measurement data through the use of NIST traceable reference standards, laboratory standards, and tests for use in calibration is performed.
Complaints	SOP0751 Client Feedback Documentation (previously G-0003) Customer complaint and resolutions are reviewed at the quarterly ISO 17025 Management Review Meetings.
Corrective Action / Preventative Action	SOP0757 Corrective and Preventive Action Systems (CAPA) (previously G-0015) NLB CAPA system addresses potentially recurring or high-risk quality concerns. The procedure includes root cause analysis, verification and validation of corrective and preventive action, implementation of

Nelson Laboratories Bozeman, LLC
1755 South 19th Avenue
Bozeman, Montana 59718
Phone: (406) 587-5735

	changes in applicable procedures, ensuring staff notification of preventive actions, and effectiveness verification. All CAPA action plans are reviewed and approved by test facility and quality management.
Deviations	SOP0773 Deviation Tracking and Recording (previously G-0066) This procedure requires that all deviations be documented, assessed for impact, investigated where appropriate, and properly reviewed and authorized before the release of data in compliance with provisions of ISO 17025, EPA, and FDA. Approved deviations are documented in the final report. Deviations are routinely tracked and trended for continuous improvement.
Training	SOP0089 Training System QA-0001 GLP / GCP Training NLB includes an extensive documented training program for all employees. Each employee receives dedicated training courses for their pertinent job tasks and annual GLP, GCP, and ISO training.
Internal Audits	QA-0002 Quality Assurance Internal Audit Each applicable ISO 17025, GLP, and GCP item is audited at least once annually. Actions to correct deficiencies and prevent recurrence are documented, reviewed, and approved before audit closure.
Management Responsibilities	SOP0761 Corporate Management Responsibilities (previously G-0026) SOP0772 Management Review of the Quality System (previously G-0060) NLB Management has established a quality policy and organizational structure. Management reviews the effectiveness of the NLB quality system on a quarterly basis according to ISO/IEC 17025:2017.
Study Documentation	SOP0649 Documentation Practice – General (previously G-0001) SOP0753 Retention of Controlled Documents (previously G-0008) NLB's quality Document retention period is a minimum of 5 years for GLP and GCP studies and 2 years for non-GLP studies. Study information, including raw data, is scanned and maintained on the secure NLB network which is backed up on a scheduled basis. All studies submitted for a registration permit are archived for the life of the registration as stated in the final report.
Supplier Management	SOP0776 Supplier Qualification (previously G-0032) All suppliers are qualified through our supplier management process. NLB does not subcontract testing. Supplier performance is assessed based on industry standard registrations or certifications on an ongoing basis.
Equipment	SOP0820 Equipment Qualification and Maintenance (previously V-0008) Each piece of equipment is uniquely identified by number. Before being put into use, a new piece of equipment undergoes IQ, OQ, and PQ. Further verification of calibration and planned maintenance is accomplished on a defined schedule.

Danielle Goveia
Quality Assurance Manager
Nelson Laboratories Bozeman, LLC
DGoveia@nelsonlabs.com
O:406-587-5735 ext. 136

Nelson Labs
A Sotera Health company

Nelson Laboratories
122 Fairfield Road
Fairfield, New Jersey 07004
Phone: (973) 227-1531

20 January 2023

Re: Nelson Labs Fairfield Intracompany Subcontracting

To Whom it May Concern:

Nelson Labs Fairfield, with locations at 122 Fairfield Rd. and 16 Montesano Rd. in Fairfield, NJ 07004, has approved the below Nelson Labs sites as intracompany subcontractors. Nelson Labs Fairfield must obtain written approval from the client prior to submitting any of their work to another site.

Nelson Labs Salt Lake City	Nelson Labs Itasca	Nelson Labs Bozeman
6280 South Redwood Road Salt Lake City, UT 84123	1500 West Thorndale Avenue Itasca, IL 60143	1765 South 19th Avenue Bozeman, MT 59718

Respectfully submitted,

Daniel Carrino
Senior Quality Manager
Nelson Labs
122 Fairfield Rd.
Fairfield, NJ 07004
DCarrino@nelsonlabs.com
973-582-1523

Quote #	**Provide the number of the quote you have received from your account representative. Contact your sales representative if you require a new quote. All test codes from the quote will auto populate on the form. You can remove any if not sending samples fo**
P.O. #	Provide the number of the purchase order you would like us to bill your test to. It will be listed on your invoice. The amount of the PO should be sufficient to cover the total amount of testing requested. Orders received without a PO or with insufficient funds will be held until a valid PO or funds are received. Please provide a hard copy with your submission form.
FedEx/UPS Acct #	Provide your courier of preference account number so we may return your samples or containers. There is also a handling fee that will be added to your invoice.
Sponsor Information	Your company, name and email will prepopulate on the form for you. This is the point of contact that will be used throughout they study and listed on the report. List the report address. This will also be used for any returns unless otherwise noted.
Billing Information	This will be where the invoice will be sent for payment.
Sample ID/ Lot#	List your sample ID and/or lot number the way you want it listed on your final report. This also must match the ID found on the physical samples. If additional space is needed please type “see attached” and send a separate attachment. This field is paragraph formatted not a column table.
Comments	List any special handling or specific instructions.
Test information	Check the necessary boxes applicable to your samples. There is an extra charge for STAT , GLP and raw data services. Please indicate if the samples are being added to or are replacements for samples previously sent and received. List the applicable lab number.
Safety	Check the appropriate box for any item that is a controlled substance, biohazard, chemical or physical hazard. An SDS (Safety Data Sheet) must be provided for any hazardous substance. Please complete the Hazardous shipping form found in the link at the top of the form and place on the ***outside*** of the box when shipping. Schedule I and II controlled substances cannot be sent without prior notice and consent. Special handling instructions can be added to the comments section.
Shipping Condition	Check the boxes of how you have shipped your samples.
Sample Storage Condition	Check the boxes of how you would like us to store your samples prior to testing. You must get advanced approval before choosing other to ensure the lab can accommodate your request.
Sample Disposition	Check the boxes of how you would like us to handle your sample disposition. If Discard is checked, your samples will be destroyed and disposed of. If Return is checked, your items will be returned to the address listed in the sponsor information section unless an alternate address is provided. Additional charges will apply. Check pickup if you will come to the facility to pick them up.

Sterilization	Check box of which type of sterilization was done and if the product has been degassed and is safe to handle as well as cycle type, if applicable
Miscellaneous	Check the boxes if you want your outer shipping container/cooler, data logger or supplies returned. It will be returned to the address listed in the sponsor information unless an alternate address is provided. Extra charges will apply.
Test Code	Enter the six digit Alphanumeric test code. This can be found on your Sales quote. For further assistance, please contact the service center or sales representative to obtain your test codes. You will need the correct codes to complete the form. When test codes for some specific tests are entered, additional sections to be completed will appear at the bottom of the form. These fields will capture additional information pertaining these specific tests.
Test Description	The test description for the test code entered will auto populate on the form. It is a read only field. If the description doesn't match the test you want, please contact our service center or sales representative for the proper test code.
# of samples sent	How many total samples you have sent for this test including any extras.
# of samples to test	How many samples of what you have sent for this test would you like us to use for testing purposes.
Test individually	This will produce a separate result for each sample. (this may affect cost)
Test Pooled	We will pool your samples together and produce one result for number of samples pooled together.
# In each pooled set-	This is the number you would like us to test in each pool set. For example: you turn in 6 samples and you want them tested in two sets of 3, you list 3 in this box. You will receive 2 results on your report.
CSS#	List the number of your signed CSS (Customer Specification Sheet) or Protocol if applicable. This is not required.
Add Test	You may add a test to the same group of samples by clicking on the +. ***All information on the fields above must apply to all tests added here*** . Complete a separate from for each group of samples by using the copy icon at the top of the form. Information from the current form will transfer to a new form and you can easily adjust any applicable fields.
Supplemental test specific sections	When some specific test codes are entered, additional sections relating to that specific test will appear at the bottom of the form and will need to be completed. These fields will capture additional information pertaining these specific tests.
Terms agreement	Checking the box shows you agree to our terms and authorize charges for testing. For additional information on terms, click on the link or contact your account representative.

Nelson Labs
A Sotera Health company

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
		Fairfield, NJ	Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
Biocompatibility & Toxicology						
Cytotoxicity		x		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		x		
	Heavy Metals	x		x		
	Nonolatile Residue (NVR)	x		x		
	Residue on Ignition (ROI)	x		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		x		
	High Performance Liquid Chromatography (HPLC)	x				
	Fourier Transform Infrared Spectroscopy (FTIR)	x		x		
	Ultraviolet-Visible Spectroscopy	x		x		
	ICP-MS	x		x		
	Atomic Adsorption (AA)	x				
	Elemental Analysis (C, N, H)	x				
Analytical Method Development and Validation		x				
Antibiotic Potency Test (Analytical Analysis)		x				
Compendial Testing (USP/EP/JP)		x		x		
Dissolution Testing		x				
Drug Assay (Active Ingredient and Dosage Forms)	As is Basis	x				
	Dried Basis	x				
	Anydrous Basis	x				
Excipient Testing		x				
In-Use Stability Testing for Drug-Device Combinations		x		x		
Organic impurities Identification		x				
Water System Testing	TOC	x		x		
	Conductivity	x		x		
	pH	x		x		
	Particulates	x		x		
	Polarimeter and Titrations	x				
	Colorimetry	x				
	Gravimetry	x				

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		North America				RCA
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Wet Chemistry Capabilities	Thin-Layer Chromatography (TLC)	x				
	Qualitative Limit Tests (Iron, Lead, Arsenic, chloride, sulfate)	x				
	Moisture Determinations	x				

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		North America				RCA
		Fairfield, NJ	Itasca, IL	Salt Lake City, UT	Bozeman, MT	Regulatory Compliance Associates
Reusable Medical Device Processing						
Cleaning Validation - Reuse Device		x	x	x		
Disinfection Validation - Reuse Device		x	x	x		
Endoscope and Scope Validations - Reuse Device		x		x		
Flexible Endoscope Sampling Kit				x		
Functionality & Repeated Use Studies		x	x	x		
Sterilization Validation - Reuse Device		x	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		x		
Stability Studies - Pharmaceutical		x		x		
Facility & Process Validation						
Disinfection Efficacy Studies (Coupon Test)		x		x		
Environmental Monitoring Tests - Air & Water		x	x	x		
Environmental Monitoring Supplies - Air & Water		x	x	x		
Filter Sterilization Validations				x		
Material Characterization Screens of Raw Materials	Differential Scanning Calorimetry (DSC)			x		
	Fourier Transform Infrared Spectroscopy (FTIR)	x		x		
Residual Manufacturing Materials		x		x		
Water System Validations & Monitoring		x	x	x		
Method Development		**X**		**X**		
Packaging Solutions						
Accelerated & Real Time Aging		x		x		
Container Closure Integrity	Dye Immersion	x		x		
	Bubble Emmision	x		x		
	Mass Extraction			x		
	Microbial Immersion	x		x		
Integrity & Strength Tests	Bubble Emission	x		x		
	Burst Test	x		x		
	Dye Migration	x		x		
	Seal Peel Test			x		
Packaging Shelf Life Studies		x		x		
Transportation and Distribution Performance				x		
Whole Package Integrity Tests				x		
Protective Barriers & Material Performance						
Antimicrobial Efficacy Studies		x		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		
	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		

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

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.

Nelson Labs™
A Sotera Health company

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 (including, but not limited to, **Nelson Laboratories Fairfield, Inc**.), ("**Nelson**"), 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: _____

MUTUAL NON-DISCLOSURE AGREEMENT

This mutual non-disclosure agreement ("**Agreement**") is made and entered into this _____ day of _____, 2021 (the "**Effective Date**") by and between _____, a [corporation, limited liability company etc.] with a principal business address at _____ ("**Sponsor**") and Nelson Laboratories Bozeman, LLC., a Delaware limited liability company with a principal business address at 1765 So. 19th Ave., Bozeman, Montana 59718, ("**NLB**"). Sponsor and NLB may each be referred to herein as a "**Party**" and together the "**Parties**."

WHEREAS, the Parties acknowledge that each may have access to and obtain knowledge of certain proprietary and confidential information of the other Party and/or its affiliates and as a condition of receiving such information the Parties hereby agree, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, as follows:

1. Purpose. The Parties wish to evaluate and engage in discussions concerning a potential business relationship and/or the evaluation of specific technology (the "**Purpose**").

2. Confidential Information

   A. "**Confidential Information**" means any proprietary or non-public technical, scientific, financial and business information disclosed by or on behalf of a Party and/or its affiliates (the "**Disclosing Party**") to the other Party and/or its affiliates (the "**Receiving Party"**) prior to or after the Effective Date which may be disclosed in any medium including in writing or other tangible form, orally or visually and all embodiments, summaries, extracts, portions and copies thereof including, without limitation, designs, technology, formulas, chemical processes, laboratory and testing procedures, protocols, manufacturing processes, techniques and procedures, know-how, intellectual property, samples, current and future products and services, research, financial information, procurement requirements, customer lists, business forecasts, marketing plans and information, relationships with and information related to third parties.

   B. Notwithstanding the foregoing, Confidential Information will not include information that the Receiving Party can establish by written documentation: (a) was publicly known and available in the public domain prior to the time of disclosure by the Disclosing Party to the Receiving Party; (b) becomes publicly known and available in the public domain after disclosure by the Disclosing Party to the Receiving Party through no action or inaction of the Receiving Party; (c) is, at the time of disclosure, in the possession of the Receiving Party, without confidentiality restrictions; (d) was developed by the Receiving Party independent of any Confidential Information, as shown by written records prepared by the Receiving Party contemporaneously with such independent development; or (e) was received by the Receiving Party in good faith from a third party lawfully in possession thereof and having no obligation known by Receiving Party to keep such information confidential.

3. Non-Disclosure Obligations and Use Restrictions

   A. The Receiving Party shall limit the disclosure of the Disclosing Party's Confidential Information to those of its and its Affiliates' employees, contractors, agents, representatives, accountants, attorneys, and other advisors (collectively, "**Representatives**") who have a need to know such information in furtherance of the Purpose, have been made aware of the confidential nature of the Confidential Information so disclosed and are bound by obligations and restrictions consistent with those set forth herein. The Receiving Party shall (i) take all commercially reasonable measures to prevent its Representatives from taking any action that, if taken by the Receiving Party, would constitute a breach of the terms of this Agreement and (ii) shall be responsible hereunder for any act or omission by any of its Representatives as if such act or omission were its own act or omission.

B. The Receiving Party shall use the Disclosing Party's Confidential Information only in connection with the Purpose and for no other purposes. Without the Disclosing Party's prior written consent, the Receiving Party will not: (i) reverse engineer, decompile, disassemble, determine the chemical composition or otherwise perform any analytical experiments on any Confidential Information disclosed in the form of a sample or other physical material; (ii) make any copy or other reproduction of any Confidential Information except as necessary to effectuate the Purpose and all such copies shall retain confidential and proprietary legends thereon; (iii) use any Confidential Information to communicate with any business contacts, suppliers, or vendors of the Disclosing Party; (iv) alter any proprietary notices contained in any Confidential Information; (v) directly or indirectly, sell, convey, license, or otherwise transfer any Confidential Information; or (vi) create or permit to be created any lien, encumbrance, or other security interests against any Confidential Information in the Receiving Party's possession or control.

C. The Receiving Party shall use the same degree of care to protect the Disclosing Party's Confidential Information and prevent the unauthorized use, dissemination and/or publication of the Disclosing Party's Confidential Information as the Receiving Party uses to protect its own confidential information of similar nature and importance, but in no event less than a reasonable degree of care. The Receiving Party shall immediately notify the Disclosing Party in the event of any unauthorized use or unauthorized disclosure of the Confidential Information.

4. Permitted Disclosures. The Receiving Party may disclose Confidential Information to the extent necessary pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Receiving Party may disclose such Confidential Information, provided that, unless prohibited by applicable law, the Receiving Party will (i) provide the Disclosing Party with advance notice thereof as soon as reasonably possible to enable the Disclosing Party the opportunity to seek a protective order to prevent or limit such disclosure, (ii) furnish only such Confidential Information that the Receiving Party is legally required to furnish, and (iii) reasonably cooperate with the Disclosing Party, at the Disclosing Party's expense, to obtain such protective order or other assurance that confidential treatment will be accorded to such Confidential Information.

5. Ownership; No License. As between the Parties, all Confidential Information disclosed by or on behalf of the Disclosing Party and/or its affiliates is and shall remain the sole property of such Disclosing Party and/or its affiliates as applicable. Except for the limited right to use the Disclosing Party's Confidential Information for the Purpose as expressly provided herein, nothing contained in this Agreement shall be construed as granting or conferring any right or license including under any patent, trademark, copyright, or other proprietary or intellectual property rights of the Disclosing Party under or in connection with any Confidential Information or otherwise. For avoidance of doubt, nothing in this Agreement shall create any right or authority of the Receiving Party to use or disclose the Disclosing Party's Confidential Information in connection with any patent, utility model, or design application or filing.

6. Term; Termination.

A. The term of this Agreement shall begin on the Effective Date and remain in effect until terminated in writing by either Party. The non-disclosure provisions of this Agreement shall survive the termination of this Agreement until the Confidential Information meets one of the exclusions set forth in Section 2.

B. Upon termination or expiration of this Agreement, or at any time at the request of the Disclosing Party, the Receiving Party shall immediately cease use of Confidential Information and return or destroy all tangible items embodying Confidential Information of the Disclosing Party including all written materials, photographs, models, compounds, compositions, and the like, together with all summaries, extracts, and copies thereof, provided, however, that Receiving Party may

retain subject to all the terms hereof, one (1) copy of the Confidential Information in its quality assurance or legal department to the extent that such a copy is necessary to comply with legal or regulatory requirements, provided that it shall not use or disclose such Confidential Information for any purpose except to the extent necessary to comply with such legal or regulatory requirements subject to ongoing obligations of confidentiality and non-use. The Receiving Party may also retain existing archival copies made and kept in the ordinary course of the Receiving Party's IT backup processes provided that such archival copies shall be destroyed in due course, and Receiving Party's employees shall be precluded from accessing such information in the ordinary course of business prior to destruction, other than to restore data for an inaccessible system. Confidential Information included in such archival copies shall continue to be protected under the terms of this Agreement.

7. Other Agreements. In the event the Parties enter into one or more written proposals, protocols, quotations and/or other agreements for the provision of services by NLB for Sponsor (each an "**Other Agreement**") whether prior to the Effective Date or thereafter, the terms of this Agreement shall apply *mutatis mutandis* to such Other Agreements and accordingly, shall apply to Confidential Information generated and/or exchanged thereunder notwithstanding the expiration or earlier termination of this Agreement. For avoidance of doubt, all testing, research and other protocols and all know-how and other intellectual property included in, embodied by or related thereto, are NLB Confidential Information and are and shall remain the sole and exclusive property of NLB. The results and reports generated by NLB in the course of performing services pursuant to an Other Agreement and directly related to the samples and/or materials provided by Sponsor to NLB are Sponsor Confidential Information and are and shall remain the sole and exclusive property of Sponsor; provided however that Sponsor acknowledges and agrees that the results and reports are intended solely for use by Sponsor and not by any third party. Any reproductions or publications of the results and/or reports shall be made in their entirety and not in partial, abbreviated or excerpt form unless to the extent required in connection with Sponsor's regulatory filings and submissions. Sponsor hereby grants to NLB a non-exclusive, worldwide, perpetual right to use the results for NLB's internal purposes. Except as set forth herein no rights in or to a Party's or its affiliate's intellectual property are granted to the other Party. In the event that any provision of any Other Agreement between the Parties is in conflict herewith, the provisions of this Agreement will control.

8. Miscellaneous

A. Neither Party shall, without the prior written consent of the other Party, disclose to any third party that the Parties have entered into this Agreement (or Other Agreement), or the existence or content of any meeting, discussion, or communication between the Parties related thereto, or use the name of the other Party either expressly or by implication, in any disclosure, news, publicity release or in any other communication.

B. This Agreement does not and will not create any obligation on the Parties to enter into a business relationship with each other or disclose any Confidential Information to each other. Without limiting its obligations under this Agreement, either Party shall at all times be free to engage in research, development and/or supply programs and agreements with third parties relating to or encompassing the subject matter of the stated Purpose.

C. All Confidential Information is provided "as is" and neither Party makes any representations or warranties, express, implied or otherwise, including any and representation or warranty of merchantability, fitness, accuracy, completeness, use, performance or non-infringement. Notwithstanding the foregoing, the Disclosing Party represents it has the right to disclose the Confidential Information it discloses hereunder.

D. The Receiving Party acknowledges and agrees that any violation or threatened violation of this Agreement by the Receiving Party or any Receiving Party Representative may cause the Disclosing Party irreparable injury and the Disclosing Party's remedies at law would be

inadequate. Accordingly, in addition to other remedies available to the Disclosing Party at law and/or in equity, the Disclosing Party will have the right to seek equitable remedies including injunctive relief with respect to such violation or threatened violation without the need to post any bond or other security.

E. This Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that no consent shall be required for any assignment in connection with any merger, acquisition, or sale of all or substantially all of the assets of a Party to a third party that agrees in writing to be bound by the terms and conditions of this Agreement. Any assignment or transfer of this Agreement made in contravention of the terms hereof shall be null and void. Subject to the foregoing, this Agreement shall be binding on and inure to the benefit of the Parties' respective successors and permitted assigns.

F. In the event that any provision of this Agreement is held by a court or other tribunal of competent jurisdiction to be unenforceable, the remaining portions hereof shall remain in full force and effect and be construed to carry out the original intent of the Parties. Any failure to enforce any provision of this Agreement shall not constitute a waiver thereof or of any other provision.

G. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware without regard to conflict of law principles.

H. This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior oral agreements and understandings with respect thereto. This Agreement may not be amended or modified except by a writing signed by both Parties hereto.

I. This Agreement may be executed in counterparts, each of which will be deemed original, and both together shall constitute one and the same instrument. This Agreement may be executed by a Party's signature transmitted by facsimile or electronic .pdf format, and copies of this Agreement so executed and delivered shall have the same force and effect as originals.

IN WITNESS WHEREOF, the Parties have executed this Mutual Non-Disclosure Agreement as of the Effective Date.

<Sponsor>	BioScience Laboratories, LLC
By: _____	By: _____
Name: _____	Name: John W. Dyba
Title: _____	Title: Director of Business Development

Nelson Labs
A Sotera Health company

Re-Validation Recommendations for Transfers

		North America						
		Fairfield, NJ	Itasca, IL	Salt Lake City, UT	Bozeman, MT	Would need re-validation or additional testing to "transfer" to other NL facilities	Additional samples will be needed	Notes
Facility & Process Validation								
Disinfection Efficacy Studies (Coupon Test)		X		X		X	X	Neutralization would need to be repeated.
Protective Barriers & Material Performance								
Antimicrobial Efficacy Studies		X		X		X	X	Neutralization would need to be repeated.
Sterility Assurance								
Antibiotic Potency Test (Micro)	PBET	X		X		X	X	Seed Layer test might be needed if testing a new antibiotic the lab hasn't done previously.
Antimicrobial Preservative Effectiveness (Micro)	PBET	X		X		X	X	Neutralization would need to be repeated.
Microbial Examination of Nonsterile Products	BIOB	X		X		X	X	New Suitability
Product Bioburden - Medical Device + Tissue	BIOB	X	X	X		X	See note	Recovery Efficiency: Exhaustive efficiencies could be performed with existing test samples, if the samples contain bioburden. IRE can be performed if samples are compatible with EO sterilization.
Product Sterility - Cleanroom	PS	X	X	X		X	X	New B/F needed, typically 3-6 samples depending on PS method.
Product Sterility - Isolator	PS	X		X		X	X	New B/F needed, typically 3-6 samples depending on PS method.
Time Kill Studies	PBET	X		X		X	X	Neutralization would need to be repeated.

APPROVAL FORM

Inter-Facility Transfer Approval Form
NORTH AMERICA

PREPARED FOR SPONSOR	LABORATORY / CONTRACTOR

Nelson Laboratories, LLC
website: www.nelsonlabs.com

6280 S. REDWOOD ROAD
SALT LAKE CITY, UT 84123-6600
Tel: 801-290-7500

1500 W. THORNDALE AVE
ITASCA, IL 60143
Tel: 630-285-9121

687 S. WANAMAKER AVE
ONTARIO, CA 91761
Tel: 909-390-2120

Contact:

Company:

Email:

I AUTHORIZE NELSON LABORATORIES TO FORWARD TEST SAMPLES TO AN ALTERNATE QUALIFIED NELSON LABORATORIES' FACILITY FOR THE REQUESTED LAB SERVICE(S) AS LISTED ABOVE.

Note: Additional Nelson Laboratory facilities with the same Quality Management System may also be included in this approval.

**** PLEASE REPLY BY EMAIL INDICATING YOUR APPROVAL OR DECLINE BELOW. ****

☐ **SPONSOR APPROVAL**
☐ **SPONSOR DECLINE**
☐ **see attached email (if no signature)**

Signature _____ **Print Name** _____ **Date** _____

IF NO RESPONSE IS RECEIVED AFTER TWO WRITTEN NOTIFICATIONS. NELSON LABORATORIES IS AUTHORIZED TO FORWARD TEST SAMPLES TO A QUALIFIED NELSON FACILITY FOLLOWING INTERNAL PROCEDURES.

☐ **NELSON INITIAL COMMUNICATION: BY** _____ **DATE** _____ **(attach email)**
☐ **NELSON SECOND COMMUNICATION: BY** _____ **DATE** _____ **(attach email)**

**** INTERNAL USE ONLY – TRANSFER AUTHORIZATION ****

☐ **NELSON LABS REPRESENTATIVE (sign below)**

Signature _____ **Print Name** _____ **Date** _____

☐ Sponsor authorization, non-response authorization or rejection documented for future reference

REVIEWED BY _____ **DATE** _____

Internal Use Only:	Maintain company approval for future submissions

*APPROVING THIS DOCUMENT SIGNIFIES AN ACCEPTANCE OF THE NELSON LABORATORIES TESTING TERMS AND CONDITIONS.
DOCUMENT IS MAINTAINED AS PERPETUAL APPROVAL.
The sponsor is responsible for test/control article characterization. This includes, but is not limited to, identity, strength, purity, and stability.
The test article or sample identification is documented on the Sample Submission Form.