Nelson Labs™
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Dear Valued Customer,

We recognize that our customers are facing increased competition and ever-growing demands to get their products to market quickly and cost effectively. As part of our goal to meet our customers' needs, we have expanded our laboratory presence globally. Nelson Labs now has a network of 14 lab locations in eight countries that are working together to meet the needs of our customers worldwide.

As service to our customers, we have initiated a program to assess and qualify each of the Nelson Labs facilities. Each location will be assessed to our high quality standards following strict ISO 17025 requirements and applicable GMP regulatory expectations. This assures you that the same strict quality and regulatory standards apply to each of our labs—without the need to audit each location. The advantages of this program are:

- Nelson Labs' entire network maintains the same high standard of quality.
- Access to the same trusted Nelson Labs contacts, experts, and quality oversite regardless of location.
- Multiple Nelson Labs locations provides testing redundancy and improved turnaround times—especially during maintenance shutdowns and increased demands on capacity.
- Using a laboratory with closer proximity may help to reduce costs and turnaround times.

As part of the qualification process, we have compiled a packet of information for your internal qualification process. This qualification packet includes the following:

- **Site Certificate of Qualification**. Certifying that the quality system meets Nelson Labs standards as defined in our Quality Manual—MAN0001 Rev. 16.
- **Scope of Site Qualification.** Documents the requirements met during the evaluation by the Nelson Labs Quality team.
- **Site Qualification Assessment Summary**. Stating when the on-site assessment was conducted, to what standards the assessment was performed, and if the lab meets these standards and quality requirements.
- **Site Quality Information Matrix.** Quality, business, and location-specific information to help answer your questions concerning each location.

We maintain the scientific, quality, and regulatory expertise to support your needs. We welcome the opportunity to speak with you about how our global network of labs will help meet your testing needs. Please contact your sales representative for more information. We appreciate your business and continued partnership to help safeguard global health.

Sincerely,

Matt Cushing

Matthew D. Cushing
Senior Director Global Quality

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

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CERTIFICATE OF QUALIFICATION | Safeguarding Global Health™

CERTIFICATE

OF QUALIFICATION

Nelson Labs Fairfield, Inc.
122 Fairfield Road
Fairfield, NJ 07004

Nelson Labs Fairfield, Inc.
16 Montesano Road
Fairfield, NJ 07004

An evaluation was performed on the above sites according to Nelson Labs procedures for On-site Supplier/Subcontractor Audit Process - SOP0159 Rev 4. Nelson Labs certifies that the quality system meets company standards as defined in the NL Quality Manual – MAN0001 Rev 16.

Please refer to the accompanying Scope of Evaluation for information detailing the evaluation criteria and methods for continuous monitoring of the site to assure continued compliance.

Matt Cushing

Matt Cushing, Senior Director Global Quality

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SCOPE OF SITE QUALIFICATION

Nelson Labs Fairfield
122 Fairfield Rd 16 Montesano Rd
Fairfield, NJ 07004

Has been evaluated by the Nelson Labs quality team and found to meet the requirements of the following:

cGMP - FDA FEI #2219947	• Evaluated to general requirements of CFR 210, 211, 820 and 1271 Subpart D (Drug/Device/Tissue) for a testing laboratory. • The most recent FDA inspection was reviewed – corrections were verified to be complete and satisfactory.
ISO 17025 – A2LA Certificate # 0056.01, 0056.02	• Evaluated through ANSI-ASQ National Accreditation Board. • Evaluated through NL internal audits procedure – SOP0103 which is performed annually to all applicable causes of ISO 17025. • Evaluated during the assessment according to NL SOP0106
NL Quality Manual MAN0001 Rev 16	• Evaluated through assessment performed Oct 2018 • Sites comply with MAN0001 which details the quality policy and quality requirements of NL. Nelson Labs Fairfield complies with and employees are trained to SOP0556 Quality Manual.
Continuous Monitoring Activities	• Monitored through Nelson Labs Fairfield internal audits procedure – SOP0551 which is performed annually to all applicable clauses of ISO 17025.

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Facility – Nelson Labs Fairfield

122 Fairfield Rd. Fairfield, NJ 07004

16 Montesano Rd. Fairfield, NJ 07004

Site Qualification Assessment Summary

Assessment Summary: An on-site assessment was performed on 02-04 Oct 2018 to evaluate compliance with the following:

- CFR 210, 211, 820 and 1271
- ISO 17025:2005
- Nelson Labs (NL) Quality Manual – MAN0001 and quality policy

Purpose: The assessment was performed to determine the qualification status of the site based on the industry regulations and the high quality standards that Nelson Laboratories expects from qualified suppliers, subcontractors and its own testing labs.

This assessment was also performed on your behalf to determine if the site meets the high quality standards and regulatory requirements to perform testing as a qualified supplier for you and to assure you that Nelson Labs quality standards are maintained at this site.

Conclusion: APPROVED

As a result of this assessment the NL facilities located at 122 Fairfield Rd. and 16 Montesano Rd. in Fairfield, NJ are considered **APPROVED** for full use of services. The Fairfield locations meet and/or exceed the requirements of the NL quality manual (MAN0001), the NL supplier management program (SOP0106), as well as the applicable CFRs and ISO standards for a quality management system.

This documented approval is intended to be used as qualification documentation for your files in order for you to fulfill internal requirements for qualification of facility as a laboratory testing provider.

Ongoing Monitoring: In addition to meeting the requirements for qualification the Fairfield locations will be continuously monitored for quality performance through regular reporting/oversight, internal audits and site visits.

Evaluation date: 02-04 Oct 2018
Site evaluation performed by: Matt Cushing, Senior Director Global Quality

Matt Cushing

Matt Cushing, Senior Director Global Quality

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Nelson Labs Fairfield, Inc.
122 Fairfield Road
Fairfield, New Jersey 07004
Phone: (973) 227-6882

Supplier Survey – Fairfield, NJ Site

Company Information	
Company Name	Nelson Labs Fairfield, Inc.
Parent Company	Sotera Health 9100 South Hills Blvd, Suite 300 Broadview Heights, OH 44147 USA (440) 262-1410
Company Address	122 Fairfield Rd Fairfield, NJ 07004
Website	www.nelsonlabs.com/nelson-labs-fairfield/
Telephone	(973) 227-6882
Business Information	
Business Classification	Self-identified per FDUFA requirements as "API/FDF Analytical Testing" and "In Vitro Bioequivalence or Bioanalytical Testing"
DUNS Number	122 Fairfield Rd. (DUNS 062032693) and 16 Montesano Rd. (DUNS 078394591) in Fairfield, NJ 07004
Facilities	
Total Square Footage	~18,000 ft²
Lab Space	~14,000 ft²
Operating Hours	Primarily one shift, 9am-5pm, 5 days a week. Weekends and swing shifts as required.
Number of employees	~80 (Nelson Labs Fairfield Site)
Quality Staff	7 (Nelson Labs Fairfield Site)
Critical Contacts	
President	Joe Shrawder – President, Nelson Labs (Global)
Operations	Zachary Anderson - Director, Laboratory Operations (**Fairfield Site Leader**) zanderson@nelsonlabs.com
Quality	Matt Cushing - VP of Quality and Science (Global) Rob Thoreson - Director of Quality Assurance (North America) Daniel Carrino – Sr. Quality Manager (**Fairfield**, NJ) dcarrino@nelsonlabs.com David Peterson – Quality Assurance Manager (**Fairfield**, NJ) dlpeterson@nelsonlabs.com
Sales	Krista Bollnow (VP of Sales & Marketing) Danina Rinaldi (Manager, Technical Services) drinaldi@nelsonlabs.com
Please contact our client services group at (973) 227-6882 to arrange to speak with any of these individuals.	
Additional Contacts	
Sales Contact	NL-Sales@nelsonlabs.com
Accounting	NL-Accounting@nelsonlabs.com
Audit Scheduling	customeraudits-nj@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 beprovided.
Manufacturer Statement	Nelson Labs Fairfield is not a manufacturer, it is a contract testing laboratory; therefore, information regardingmanufacturing processes is not applicable.
Accreditation/Certifications/Registrations	
ISO Accreditation	ISO 17025:2017

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ISO Registrar	A2LA
ISO Certificate Number	0056.01 & 0056.02
FDA FEI Identifier	# 2219947
Date of Last FDA Audit	Nov 2019
Please note: Up to date certifications are available on the website.	
NLF has procedures/processes including (but not limited to) the following:	
Quality Manual/Policy	SOP0556 -Quality Manual. The NLF 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.
Change Control and Change Notification	Since most of our testing services are based on standard operating procedures (SOP), 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 (SOP0566-Change Control) 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.
Document Control	SOP0001 – Management of Controlled Procedures and Forms SOP0548 – Document Control and Change Control NLF establishes and maintains procedures to control all documents required by regulations, standards, normative documents, test, and calibrationmethods. Documents are controlled by revision number. Documents are reviewed, updated, and approved as necessary.
Calibration and Maintenance	SOP0539 -Calibration, Preventive Maintenance and Certification of General Instruments. The calibration and maintenance of equipment isperformed by a vendor, as well as by NLF's Metrology Department as appropriate. 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	SOP0569- Complaint Handling - describes the practices for customer complaint resolutions.
Corrective Action / Preventative Action	SOP0573 - Corrective and Preventive Actions. A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring or high-risk quality concerns. 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	SOP0580 - Quality Events, Investigations, Retests, and Study Discontinuations. This procedure details how to address a deviation or Quality Event (QE), a specific change to a procedure that does not impact safety or efficacy, and complies with the provisions of ISO 17025, EPA and FDA regulations. 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. QEs are routinely tracked and trended.
Out of Specification (OOS) Results	SOP0580 - 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	SOP098 – Training System SOP0527 - Training and Proficiency Testing of Technicians and New Employees. NLF includes an extensive, documented training program for all employees. All employees receive annual GMP, GLP, andGTP training. Additionally, annual proficiency and competency analyses are performed (where applicable).
Traceability	SOP0542 - Data Recording, Correction, Review and Reporting. 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	SOP0581 - Data Integrity Policy- describes NLF'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	SOP0551 - Quality Auditing Procedure - describes the documented internal audit program. Each applicable ISO 17025,GMP, GLP, and GTP clauses as well as each NLF 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	SOP0532 - Quality System/Management Review. NLF Management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the NL Quality System on a minimum bi-annual (twice a year) basis according to ISO/IEC 17025:2017 and 21 CFR part 820.40.
Study Documentation	SOP0577 – Document Scanning, Archiving, and Use of the Drivve Document Management System. Datapacks, which contain study information including raw data, are scanned and maintained. NLF's Quality Document retention period is a minimum of 10 years.
Supplier Management	SOP0545 – Vendor and Service Provider Qualifications. 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.
Test Data Review	SOP0551 – Quality Auditing Procedure, SOP 33G – Management of GLP Studies. All raw test data undergoes, at a minimum, a full review by a Study Director. Many studies receive an additional review by a TechnicalReviewer or a member of Quality Assurance. For GLP studies, this review is performed by trained Quality Assurance inspectors.
Validation	SOP0531 – Validation of Analytical Methods. Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity,(where applicable).
Equipment	SOP0522 – Validations, Qualifications, and 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.