Frequently Requested Information / Quality Survey
Nelson Labs – Ontario

ServiceCenter@nelsonlabs.com
Toll-free: (800) 826-2088
Local: (909) 390-2120
Fax: (801) 290-7998

Company Information	
Company Name	Nelson Laboratories, LLC a Sotera Health company
Parent Company	Sotera Health
Established	1985 Facility previously part of SteriPro Labs, became part of Nelson Laboratories in 2017
Company Address	687 South Wanamaker Avenue Ontario, CA 91761
Website	www.nelsonlabs.com
Telephone	(909) 390-2120
Company Description	Nelson Laboratories, LLC (Nelson Labs) a Sotera Health company, is an industry-leading provider of laboratory testing and consulting services. We perform over 900 rigorous microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. We know that every test matters and requires solutions to complex problems to improve patient outcomes and minimize client risk. A full description of services offered can be found on our website at www.nelsonlabs.com.

Facilities		
Total Square Footage	~ 1,500 ft²	
Laboratory Space	~ 1,500 ft²	
Operating Hours	Primarily one shift, 9am-5pm, 5 days a week. Weekends and swing shifts as required.	
Number of employees	~ 10 in Ontario ~ 900 globally	Please contact QualityAudits@nelsonlabs.com for the most up-to-date information
Quality Staff	~ 2 in Ontario ~ 80 globally	
Equal Opportunity	Nelson Labs is an equal opportunity employer	

Contacts			
Critical Contacts	Joseph Shrawder	President of Nelson Labs	Please contact our client services group at (801) 290-7500 to arrange to speak with any of these individuals.
	David Bryant	Senior VP of North America Operations	
	Caitlin Corr	Senior Marketing Manager	
	Matthew Cushing	VP of Quality & Science	
	Kevyn House	Senior Quality Assurance Manager	
	John Gutierrez	Senior Laboratory Operations Manager	
Additional Contacts	Sales	Sales@nelsonlabs.com	
	Accounting	Accounting@nelsonlabs.com	
	Quality Requests & Audit Scheduling	QualityAudits@nelsonlabs.com	
	Quality Agreements	QualityAgreements@nelsonlabs.com	

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

Wire Transfers	Bank Routing and Transit Number: 021000021 SWIFT Code: CHASUS33 Account Number: 641403803							
ACH Transactions	Bank Routing and Transit Number: 124001545 Account Number: 641403803							
Payment Options	**Cash**	U.S. Funds	**Check**	Drawn on U.S. bank in U.S. dollars	**Credit**	Visa, MasterCard, American Express	**Net Terms**	30 Days
Shipping Address	Attn: Log-In or Receiving 687 South Wanamaker Avenue Ontario, CA 91761 USA							
Billing / Payment Address (Check Remittance)	Nelson Laboratories, LLC 29471 Network Place Chicago, IL 60673-1294							

Proprietary Information	
References	Nelson Labs policies and procedures ensure the protection of our clients' names, confidentiality, and proprietary information; therefore, we cannot provide any references.
Sales/Financial Information	Sotera Health (parent company to Nelson Labs) is a publicly traded company, stock ticker SHC. Sales and financial information can be found at Investor Relations | Sotera Health.
Manufacturer Statement	Nelson Labs is not a manufacturer, it is a contract testing laboratory; therefore, information regarding manufacturing processes is not applicable.

Accreditation/Certifications/Registrations		
ISO Accreditation	ISO 17025:2017	For up-to-date certifications and registrations please visit our audit website, https://www.nelsonlabs.com/quality/
ISO Registrar	ANAB	
ISO Certificate Number	AT-1382.02	

Nelson Labs has procedures/processes including (but not limited to) the following	
Calibration and Maintenance	NEL-SOP-0067 – *General Calibration and Maintenance*. The calibration and maintenance of equipment is primarily performed by Nelson Labs' Metrology Department. Using documented procedures, they work to prevent inaccuracy and deficiencies in data through the use of NIST traceable reference standards, laboratory working standards, and tests for use in calibration.
Change Control and Change Notification	NEL-SOP-0039 – *Change Management*. Since most of our testing services are based on standard testing procedures (STP), we provide the ability to have an additional "Customer Specification Sheet (CSS) or testing instruction" which provides customer specific instructions for testing (if necessary). The Customer Specification Sheet or testing instructions are reviewed and approved by the Nelson Labs Study Director and if requested by your company prior to implementation. Additionally, all changes made through our change control process are assessed for the potential impact to you as a customer. We make every effort to contact our customers where appropriate. You may refer to our secure client website at www.nelsonlabs.com for a posting of our most recent customer-applicable changes, as well as a list of all procedural updates.
Complaints	NEL-WI-0378 – *QE: Complaints*. Nelson Labs has a formalized complaint resolution process and seeks customer feedback on a regular basis.
Corrective Action / Preventative Action (CAPA)	NEL-SOP-0136 – *Corrective & Preventive Action (CAPA) System*. NEL-WI-0377 – *QE: Escalated Events (EE)*. These procedures are in place to address potentially recurring or high-risk quality concerns. These procedures include root cause analysis, verifying and validating corrective and preventive action, implementing and recording changes in applicable procedures, ensuring that the appropriate people are aware and involved in the preventive actions, and effectiveness verification. All EE action plans are reviewed and approved by management.
Customer Feedback	NEL-SOP-0093 – *Customer Feedback Handling*. Details the procedures for management of the customer feedback system at Nelson Labs.
Deviations	NEL-SOP-0136 – *Corrective & Preventive Action (CAPA) System*. NEL-WI-0376 – *QE: Deviation, OOS, Complaint, UE, UV, etc. & Action Assignment (AA)*. These procedures detail how to address a deviation or Quality Event (QE), a specific change to a procedure that does not impact safety or efficacy, and complies with the provisions of ISO 17025, EPA, and FDA regulations. The procedures require that all deviations be documented, assessed for impact, where appropriate investigated, and properly reviewed and authorized before the release of data. If a deviation impacts a sponsor's test or data, the sponsor is contacted within one business day. Approved deviations are documented in the final report. QEs are routinely tracked and trended.
Disaster Recovery	NEL-SOP-0131 – *Back-up/Restore Procedures*. Establishes the back-up/restore procedures at Nelson Labs. Nelson Labs' disaster recovery plan is a combination of data replication and data backup best practices.
Document Control	NEL-SOP-0001 – *Management of Controlled Documents*. Nelson Labs 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 Master Control, our document control software. Documents are reviewed, updated, and approved, as necessary.
Equipment	NEL-SOP-0069 – *Equipment Receiving*. NEL-MAN-0007 – *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.
Internal Audits	NEL-SOP-0103 – *Internal Audits*. Nelson Labs has a formal, documented internal audit program. Each applicable ISO 17025, GMP, GLP, and GTP clauses as well as each Nelson Labs 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	NEL-SOP-0089 – *Management Responsibilities*. NEL-SOP-0099 – *Quality Committee and Management Review Procedures.* Nelson Labs management has established a Quality Policy and organizational structure. Management reviews the effectiveness of the Nelson Labs Quality System on quarterly, semi-annual, and annual bases according to ISO/IEC 17025:2017 and various FDA CFR, EU GMP, and TGA GMP requirements.
Non-Conforming Product	NEL-SOP-0106 – *Supplier Management*. Items which do not conform to purchase order specifications are quarantined until resolution can be obtained.
Out of Specification (OOS) Results	NEL-SOP-0136 – *Corrective & Preventive Action (CAPA) System*. NEL-WI-0502 – *Sample OOS and UV*. An OOS is a result that falls outside the specification established by a compendial method, SOP, STP, Protocol, or as required by the sponsor. As dictated by procedures an OOS must be documented, root cause identified through a failure investigation, its impact to data assessed and the validity of any results substantiated. If an OOS impacts a sponsor's test or data, the sponsor is contacted within a target of one business day.
Purchasing Controls	NEL-SOP-0077 – *Incoming Receiving and Inspection.* NEL-SOP-0167 – *Quality Assessment of Incoming Supplies.* Supplies are received at the warehouse receiving station and initially inspected. Receiving staff verify the purchase order against the packing slip and other receiving documents. Also verified are quantity, product identification and container integrity. Any discrepant items are quarantined until disposition. Items with further inspection and/or testing requirements are transferred to a designated Quality Control (QC) quarantine processing area until required acceptance testing is completed. As with receiving, any discrepant items are quarantined until disposition. Disposition is documented.
Study Documentation	NEL-SOP-0081 – *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. NEL-SOP-0082 - *Quality Records and Archives*. Datapacks, which contain study information including raw data, are scanned, and maintained. Nelson Labs' Quality Document retention period is a minimum of 10 years.
Supplier Management	NEL-SOP-0106 – *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.
Training	NEL-SOP-0098 – *Training System*. Nelson Labs includes an onsite professional development department and an extensive, documented training program for all employees. All employees receive annual GMP, GLP, and GTP training. Additionally, annual proficiency and competency analyses are performed (where applicable).
Traceability	NEL-SOP-0080 – *Identification, Handling and Disposition of Test Samples.* A unique, non-duplicatable lab number is assigned to each study received at Nelson Labs. This lab number provides traceability to all samples and data throughout the test life cycle. If individual test samples within a study have unique identifiers, those unique identifiers are maintained throughout the life cycle of the test. Test samples are dispositioned at the end of testing per the customer instructions provided on the Sample Submission Form (e.g., disposed, returned to customer, consumed during testing, etc.).
Quality Manual/Policy	NEL-MAN-0001 – *Nelson Laboratories Quality Manual*. The Nelson Labs 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 Nelson Labs systems to the requirements of these standards.

Validation	NEL-SOP-0115 – *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).