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	~ 45
Quality Staff	5
Equal Opportunity	NL is an equal opportunity employer
Critical Contacts	
Management	Mike Rahn (Senior Director, Lab Operations – North America)
Operations (Microbiology)	Joseph Spyridakis (Senior Lab Operations Manager)
Operations (Chemistry)	Anthony Nudo (Senior Lab Operations Manager)
Quality	Julie Arinaga (Senior Quality Assurance Manager)
Service Center	Keishana Crenshaw (Service Center Manager)
Additional Contacts	
Service Center	servicecenter@nelsonlabs.com
Audit Scheduling	Laura Chess (LChess@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

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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.