Nelson Laboratories, Inc.

Frequently Requested Information

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Last Updated: 16 April 2013

Company Information	Nelson Laboratories, Inc. (NLI) provides *in vitro* microbiology, chemistry, biocompatibility, and physical laboratory testing. A full description of services offered can be found on our website at www.nelsonlabs.com.			
	Established	1985	**Number of Employees**	500+
Facilities	NLI has one world-wide location in Salt Lake City, Utah. There are three buildings (totaling 122,500 ft²) that comprise the NLI campus: Redwood 1 and 2 , Redwood 3, and Redwood 4. The total combined laboratory space of the three buildings is 90,500 ft². The facility was completed in four phases: Redwood I was completed in 1994, Redwood II was added in 2001, Redwood III was added in 2010, and Redwood IV added in 2012.			
	The state-of-the-art facilities are clean, well organized, and secured with keycard and biometric 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 V 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 through our Regulatory Assistant, Julie Pizza, 801-290-7652 or jpizza@nelsonlabs.com			
References	NLI policies and procedures ensure the protection of our clients' names, confidential, and proprietary information, thus no references are able to be provided.			
Critical Contacts	Jeff Nelson	President and CEO	Please contact our client services group at 801-290-7500 to arrange to speak with any of these individuals.	
	Dr. Jerry Nelson	Chief Science Officer		
	Jeff Hone	VP Quality		
	Jeff Hills	Chief Operating Officer		
	Lane Jensen	VP Sales/Marketing		
	Sherri Robbins	Director, Regulatory Affairs, Management Rep		
	Aaron Woffinden	Director, Quality Assurance		

Ownership	Privately held, Utah S-Corporation				**Federal Tax ID Number**	87-0425936
Business Classification	NLI 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 No.:	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
	Wire	Wire and ACH transfers accepted in U.S. funds only. Contact accounting@nelsonlabs.com for wire details			**Terms**	Net 30 days
Shipping Address	Attn: Log In or Receiving, 6280 South Redwood Road, Salt Lake City, UT 84123-6600 USA		**Billing / Payment Address**	Attn: Accounting, P.O. Box 571830, Salt Lake City, UT 84157 USA		

ISO Accreditation	ISO Standard: ISO 17025 ISO Registrar: ACLASS		Certificate Number: AT-1382 Please see up-to-date certificates on our website
FDA CDER 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.		
Other Standards	NLI also holds certifications from the U.S. EPA, U.S. DEA, and U.S. OSHA		

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

Change Control and Change Notification	With all testing services, we provide the ability to test according to a Protocol Detail Sheet (PDS), which provides customer specific instructions for testing. These Protocol Detail Sheets are reviewed and approved by the NLI Study Director and your company prior to implementation. Any revision to a test method using a PDS will require a review and approval of your company. 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 NLI's Metrology Department. Using documented procedures, they work to prevent inaccuracy and deficiencies in data thru the use of NIST traceable reference standards, laboratory working standards, and tests for use in calibration.
Complaints	NLI 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	NLI 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	NLI has a formal, documented internal audit program. Each applicable ISO 17025, GMP, GLP, and GTP clause as well as each NLI 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	NLI Management has established an NLI Quality Policy and organizational structure. Management reviews the effectiveness of the NLI 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.

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Quality Manual/Policy	The NLI Quality Manual provides the employees, auditors, and customers of Nelson Laboratories, Inc. (NLI) 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 NLI 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. NLI'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	Nelson Laboratories 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).