# Nelson Labs Itasca

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| **Company Information** | Nelson Labs Itasca provides *in vitro* microbiology, chemistry, biocompatibility, and physical laboratory testing. A full description of services offered can be found on nelsonlabs.com | | | |
| | **Established** | 1978 | **Number of Employees** | Overall total: 38<br>Total Lab Staff: 25<br>Total Support Staff: 9<br>Total Quality Staff: 4 |
| **Facilities** | Nelson Labs has 4 North American facilities: Itasca, IL; Ontario, CA; Mexico City, MX (SteriPro Labs); Salt Lake City, UT. The Itasca facility is a standalone single story building that is approximately 25,000 ft². The facility contains around 15,000 ft² of laboratory space. | | | |
| | The facilities are clean, organized, and secured with key access and video monitoring. Some key features of the facility include segregated laboratories for different testing, a media production laboratory with two steam sterilizers, and three ISO class VII sterility testing rooms. | | | |
| **Audit Availability** | An onsite audit may be arranged through our Quality Department. Please contact Shane Rakow. | | | srakow@nelsonlabs.com |
| **References** | Nelson Labs policies and procedures ensure the protection of our clients' names, confidential, and proprietary information, thus no references are able to be provided. | | | |
| **Critical Contacts** | Mike Rahn | | Sr. Director, Lab Operations | mrahn@nelsonlabs.com |
| | Julie Arinaga | | Quality Assurance Manager | jarinaga@nelsonlabs.com |
| | Anthony Nudo | | Senior Lab Operations Manager ( Chemistry) | anudo@nelsonlabs.com |
| | Joseph Spyridakis | | Senior Lab Operations Manager ( Microbiology) | jspyridakis@nelsonlabs.com |
| | Keishana Crenshaw | | Service Center Manager | kcrenshaw@nelsonlabs.com |

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| **Ownership** | A Sotera Health Company |
| **Shifts** | Primarily one shift 8:00 AM- 4:30 PM, 6 days a week. |
| **Company Address** | Nelson Laboratories, LLC.<br>1500 W. Thorndale Ave.<br>Itasca, IL 60143 |

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| **ISO Accreditation** | ISO Standard: ISO 17025<br>ISO Registrar: ANAB | Certificate Numbers: AT-2490 |
| **FDA Facility Identifier** | 3007950533 | |
| **FDA Audit Information** | Nelson Labs Itasca is routinely audited by the FDA to GMP guidelines. The facility is in good standing with the FDA and the most recent audit was performed March 2016. | |

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| **Change Control and Change Notification** | Since our testing services are based on Standards Operating Procedures and Work Instructions, we provide the ability to have an additional "Customer Specification Sheet (CSS)" which provides customer specific instructions for testing. The CSS or testing instructions are reviewed and approved by Quality Assurance 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. |
| **Calibration and Maintenance** | The calibration and maintenance of equipment is performed by Nelson Labs personnel and outside vendors. 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. Outside vendors are qualified and reviewed on a routine basis to ensure the highest standards are met. |
| **Complaints** | Nelson Labs has a formalized complaint resolution process and seeks customer feedback on a regular basis. |
| **Control of Non-Conforming Product** | Nelson Labs has a documented procedure for controling Non-Conforming Product and Materials. Items which do not conform to purchase order specifications, are put in quarantine. |
| **Corrective Action / 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** | Our deficiency handling procedure details how to address deviations and non-conformances from procedures and testing. The procedure complies with the provisions of ISO 17025 and FDA regulations. This procedure requires that all deficiencies be documented, assessed for impact, 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 2 business days of identification. Approved deficiencies are documented in the final report. |
| **Document Control** | 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 MasterControl and Merlin, our document control software systems. 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, PQ as required. |
| **Internal Audits** | Nelson Labs has a formal, documented internal audit program. Each facility is audited at least once on an annual basis to ensure the laboratory is meeting the applicable clauses in ISO and FDA regulations as well as internal procedures. |
| **Management Responsibilities** | Nelson Labs Management has an established a Quality Policy and organizational structure Management reviews the effectiveness of the Quality system on a Bi-annual basis to ensure complicance to FDA and ISO regulations. |
| **Out of Specification Results** | An OOS is a result that falls outside the specificaiton established by a method, SOP, Protocol, or as required by the sponsor. According to documented procedures OOS results are documented and investigated through a failure investigation and its impact to data assessed and the validity of any results substantiated. Sponsor's are contacted as soon as possible of an OOS result. |

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| **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 ocntainer integrity. Any discrepant items are quarantined until disposition. Disposition is documented. |
| **Quality Manual/ Policy** | The 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 accoriding to the format of ISO regualtions in order to facilitate audits of the QMS to 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 where applicable. |
| **Record Management and Retention** | There is a formal documented procedure for the handling, storage, and archiving of Quality Records. Record retention periods vary based on the type of document. Notification to customers is given prior to document destruction and return of documentation to customers can be arranged at customers expense. |
| **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 a review by a technical reviewer. Many studies receive an additional review by Management as well as Quality Assurance. |
| **Traceability** | Process controls are in place to ensure traceability and prevent contamination. All samples are assigned a work order number and associated items used in testing are traceable to the batch record, lot number, or part number. |
| **Training** | Nelson Labs has a formal documented training program. All training performed is documented and retained in individual training files for each employee. Employees are only assigned and can only perform tasks for which they are trained an qualified. Some testing activities requires intitial qualification and periodic requalification. |
| **Validation** | Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity, (where applicable). The validation process is documented in a Standard Operating Procedure and a Validation Master Plan is in place. |