Nelson Labs
A Sotera Health company

Frequently Requested Information / Quality Survey
Nelson Labs – Leuven

LeuvenCustomerService@nelsonlabs.com
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Company Information	
Company Name	Nelson Labs NV a Sotera Health company
Parent Company	Sotera Health
Established	1985 Facility previously Toxicon Europe NV, established in 1991. Became part of Nelson Labs in 2017.
Company Address	Romeinsestraat 12 3001 Leuven Belgium
Website	www.nelsonlabs.com
Telephone	+32 (16) 40 04 84
Company Description	Nelson Labs NV (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	~ 4700 m²	
Laboratory Space	~ 2100 m²	
Operating Hours	Primarily one shift, 9am-5pm, 5 days a week.	
Number of employees	~ 200 in Leuven ~ 900 globally	Please contact QAInbox_Europe@nelsonlabs.com for the most up-to-date information
Quality Staff	~ 14 in Leuven ~ 80 globally	
Equal Opportunity	Nelson Labs is an equal opportunity employer	

Contacts			
Critical Contacts	Riaz Bandali	President of Nelson Labs	Please contact our client services group at +32 (16) 40 04 84 to arrange to speak with any of these individuals.
	Kurt Peeters	General Manager	
	Lise Vanderkelen	Director Lab Operations	
	Rudi Segers	Senior Manager Quality Assurance	
	Isabelle Liesenborghs	Sr. Manager Sales & Marketing EMEAA	
Additional Contacts	Sales	InfoEurope@nelsonlabs.com	
	Accounting	Accounting_EU@nelsonlabs.com	
	Quality Requests & Audit Scheduling	QAInbox_Europe@nelsonlabs.com	
	Quality Agreements	QAInbox_Europe@nelsonlabs.com	

Business / Payment Information	
Ownership	A Sotera Health company
Federal Tax ID	BTW BE 0442.395.719
Legal Form	Public limited company
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	76-695-1479

Wire Transfers	EUR Account: IBAN BE13 5490 0105 9839 SWIFT Code: CHASBEBX USD Account: BE88 5490 0106 0041 SWIFT Code: CHASBEBX							
Payment Options	**Cash**	N/A	**Check**	N/A	**Credit**	N/A	**Net Terms**	30 Days
Shipping Address	Attn: Log-In or Receiving Romeinsestraat 12 3001 Leuven Belgium							
Billing / Payment Address (Check Remittance)	Attn: Accounts Receivable Romeinsestraat 12 3001 Leuven Belgium							

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. For Nelson Labs NV specific information, see https://consult.cbso.nbb.be/ (use enterprise number 0442395719).
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	BELAC	
ISO Certificate Number	363-TEST	
FDA FEI Identifier	3005742674	
Regulatory Body Audit Information	We are frequently audited to ISO 17025, GMP, and GLP, guidelines. See website for additional details.	
EU GMP Certification	GMDP 1844 Human and Veterinary medicinal products (FAHMP) Human Medicinal Products Certificate: BE/GMP/2024/057 Veterinary Medicinal Products Certificate: BE/GMP/2024/058	
GLP Compliance	OECD Directive 2004/9/EC. Certificate: T02 (Sciensano)	

Nelson Labs has procedures/processes including (but not limited to) the following	
Calibration and Maintenance	NEL-SOP-0383 – *General Procedures Including Use and Maintenance for Laboratory Systems*, NEL-SOP-0386 – *System validation*, and NEL-MAN-0012 – *Validation Policy*. The calibration and maintenance of equipment is primarily performed by experienced system owners or qualified suppliers of maintenance and/or calibration activities. Using documented procedures and Nelson Labs NV approved protocols, they work to prevent inaccuracy and deficiencies in data through the use of NIST traceable reference standards, laboratory working standards and standards for calibration activities.
Change Control and Change Notification	NEL-SOP-0387 – *Operational Change Control* and NEL-SOP-0413 – *Development, Change Control, Periodic Review and Archiving of a Standard Operating Procedure*. Nelson Labs NV allows the Sponsor the choice to initiate a Study with or without a sponsor approved protocol. All changes as per protocol are communicated to the Sponsor. Additionally, all changes made through our change control process (changes of test methods, use and maintenance of GxP critical equipment, business changes) are assessed for the potential impact to you as a customer. The customer is always notified in case potential impact cannot be excluded.
Complaints	NEL-SOP-0428 – *Dealing with Complaints*. Describes the practices for customer complaint resolutions.
Corrective Action / Preventative Action (CAPA)	NEL-SOP-0427 – *Corrective / Preventive Action Procedures*. A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring quality problems. The procedure includes 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 responsible management. All actions are tracked to completion.
Customer Feedback	NEL-SOP-0450 – *Customer Survey*. Details the periodic customer survey process.
Data Integrity	NEL-SOP-0430 – *Good Documentation Practice (GDP) and Signature Policy* and NEL-MAN-0014 – *Data Integrity Policy*. These documents describe Nelson Labs NV's data integrity system and establish the company policy for managing the integrity of data according to the principles of ALCOA++, including e-records and e-signatures and requirements for computerized systems. Driving regulations for the QMS are 21CFR11, EU GMP Annex 11, OECD GLP 17 and principles from GAMP 5.
Deviations	NEL-SOP-0426 – *Quality Events (Including Retest).* This procedure details how to address quality events (e.g. deviations, system criteria fails, atypical or out of trend results). This procedure requires that all quality events are documented, assessed for impact, where appropriate investigated and actions defined and properly reviewed and authorized before the release of data to the Sponsor. If potential impact of a quality event on the test or data cannot be excluded, the Sponsor is to be notified.
Document Control	NEL-SOP-0413 – *Development, Change Control, Periodic Review and Archiving of a Standard Operating Procedure*. Nelson Labs NV 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 management software. Documents are reviewed, updated and approved as necessary.
Equipment	NEL-MAN-0012 – *Validation Policy* and NEL-SOP-0386 – *System Validation*. Each piece of equipment is uniquely identified. Before being put into use, a new piece of equipment undergoes a qualification (IQ, OQ, and PQ) or calibration, where applicable. Qualification, validation and/or calibration efforts are based on the system category as described in NEL-SOP-0386.

Internal Audits	NEL-SOP-0421 – *Internal Audit: Process and Facility Based Inspections*. Describes the documented internal audit program. Actions to correct deficiencies and prevent recurrence are documented, reviewed and approved before audit closure. NEL-SOP-0423 – *Periodic review of (critical GxP) computerized systems* describes the documented periodic review program for GxP critical systems. Actions to correct deficiencies and/or prevent recurrence are documented, reviewed and approved before periodic review report closure.
Management Responsibilities	NEL-SOP-0448 – *Company organization table* and NEL-SOP-0449 – *Management review procedures*. Nelson Labs NV Management has established a Quality Policy and Quality unit which acts independently within the organizational structure. Management reviews the effectiveness of the Nelson Labs NV Quality System on an annual basis according to ISO/IEC 17025:2017.
Non-Conforming Product	NEL-SOP-0200 – *Study Logging Procedures, Sample Receipt, Storage and Contamination Control Practices Using LOMS System* and NEL-SOP-0377 – *Management of Inventories (Chemicals and Consumables) at Nelson Labs*. Samples and lab inventory which do not conform procedural criteria are quarantined.
Out of Specification (OOS) Results	NEL-SOP-0429 – *Out-of-Specification Procedure*. An OOS is a result that falls outside the specification established by a compendial method, or as required by the Sponsor. According to the OOS 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, after internal investigation, no clearly defined error can be identified, the Sponsor is to be notified.
Study Documentation	NEL-SOP-0392 – *Archive procedures*. Data packages, which contain study information including raw data, are maintained. Nelson Labs NV's Quality Document retention period is 10 years for study related data. Data will never be destroyed without prior notification and approval of the Sponsor. Non-study related quality records are maintained until end of business.
Supplier Management	NEL-SOP-0381 – *Vendor and Subcontractor qualification and monitoring procedures*. 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 and evaluated on a yearly supplier evaluation.
Test Data Review	NEL-SOP-0425 – *Quality Assurance and Quality Control*. All raw test data undergoes, at a minimum, a full review by a reviewer (Data Review). Reporting by Study Director, (Associate) Scientific Project Manager or Scientific Expert is also assessed by a second person (Cross Review). Finally, a final project review is performed by a member of the Quality Assurance department.
Training	NEL-SOP-0419 – *Personnel and Training*. Nelson Labs NV includes an extensive, documented training program for all employees based on a plan-do-check-act cycle. The completion of initial training needs is not the end of the training. New or revised procedures, QA audit findings, quality events, strategic corporate initiatives, critical incidents, ongoing needs, sponsor complaints… can induce short-term training needs. Provision of these trainings should be coordinated by Management and QA. Employees receive annual GMP and GLP training, whenever appropriate. Additionally, annual proficiency analyses are performed and a retraining program is implemented.
Traceability	NEL-SOP-0417 – *Development, review, reconciliation and archiving of forms and raw data*. Process controls are in place to ensure traceability and to prevent contamination. Samples are uniquely identifiable. Associated items used in testing are traceable to the batch record, lot number, or part number. Laboratory records are kept in lab and logbooks, Raw Data Sheets (RDS) or Raw Data Packages (RDP).

Quality Manual/Policy and Site Master File	NEL-MAN-0010 – *Quality Manual / Site Master File*. The Nelson Labs NV Quality Manual / Site Master File provides the employees, auditors, and customers of Nelson Labs NV with a description of the Quality Management System and Quality Policy.
Validation	NEL-SOP-0204 – *Method Validation*, NEL-MAN-0012 – *Validation Policy*, and NEL-SOP-0386 – *System Validation*. Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity (where applicable). Computerized systems undergo a lifecycle and are validated based on their system category (based on USP <1058> and GAMP 5) as described in NEL-SOP-0386.