Nelson Labs™
A Sotera Health company

Dear Valued Customer,

We recognize that our customers are facing increased competition and ever-growing demands to get their products to market quickly and cost effectively. As part of our goal to meet our customers' needs, we have expanded our laboratory presence globally. Nelson Labs now has a network of 13 lab locations in eight countries that are working together to meet the needs of our customers worldwide.

As service to our customers, we have initiated a program to assess and qualify each of the Nelson Labs facilities. Each location will be assessed to our high quality standards following strict ISO 17025 requirements and applicable GMP regulatory expectations. This assures you that the same strict quality and regulatory standards apply to each of our labs—without the need to audit each location. The advantages of this program are:

- Nelson Labs' entire network maintains the same high standard of quality.
- Access to the same trusted Nelson Labs contacts, experts, and quality oversite regardless of location.
- Multiple Nelson Labs locations provides testing redundancy and improved turnaround times—especially during maintenance shutdowns and increased demands on capacity.
- Using a laboratory with closer proximity may help to reduce costs and turnaround times.

As part of the qualification process, we have compiled a packet of information for your internal qualification process. This qualification packet includes the following:

- **Site Certificate of Qualification**. Certifying that the quality system meets Nelson Labs standards as defined in our Quality Manual—MAN0001 Rev. 16.
- **Scope of Site Qualification.** Documents the requirements met during the evaluation by the Nelson Labs Quality team.
- **Site Qualification Assessment Summary**. Stating when the on-site assessment was conducted, to what standards the assessment was performed, and if the lab meets these standards and quality requirements.
- **Site Quality Information Matrix.** Quality, business, and location-specific information to help answer your questions concerning each location.

We maintain the scientific, quality, and regulatory expertise to support your needs. We welcome the opportunity to speak with you about how our global network of labs will help meet your testing needs. Please contact your sales representative for more information. We appreciate your business and continued partnership to help safeguard global health.

Sincerely,

Matt Cushing

Matthew D. Cushing
Senior Director Global Quality

6280 S. Redwood Road
Salt Lake City, UT 84123
801-290-7500 | nelsonlabs.com

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CERTIFICATE OF QUALIFICATION | Safeguarding Global Health™

CERTIFICATE

OF QUALIFICATION

Gibraltar Laboratories
122 Fairfield Road
Fairfield, NJ 07004

Gibraltar Laboratories
16 Montesano Road
Fairfield, NJ 07004

An evaluation was performed on the above sites according to Nelson Labs procedures for On-site Supplier/Subcontractor Audit Process - SOP0159 Rev 4. Nelson Labs certifies that the quality system meets company standards as defined in the NL Quality Manual – MAN0001 Rev 16.

Please refer to the accompanying Scope of Evaluation for information detailing the evaluation criteria and methods for continuous monitoring of the site to assure continued compliance.

Matt Cushing

Matt Cushing, Senior Director Global Quality

QualityAudits@NelsonLabs.com | +1 (801) 290-7500
6280 South Redwood Road | Salt Lake City, UT 84123–6600 U.S.A.

SCOPE OF SITE QUALIFICATION

Gibraltar Laboratories 122 Fairfield Rd Fairfield, NJ 07004	Gibraltar Laboratories 16 Montesano Rd Fairfield, NJ 07004

These sites have been evaluated by the Nelson Labs quality team and found to meet the requirements of the following:

cGMP - FDA FEI #2219947	• Evaluated to general requirements of CFR 210, 211, 820 and 1271 Subpart D (Drug/Device/Tissue) for a testing laboratory. • The most recent FDA inspection was reviewed – corrections were verified to be complete and satisfactory.
ISO 17025 – A2LA Certificate # 0056.01, 0056.02	• Evaluated through ANSI-ASQ National Accreditation Board. • Evaluated through NL internal audits procedure – SOP0103 which is performed annually to all applicable causes of ISO 17025. • Evaluated during the assessment according to NL SOP0106 requirements according to FRM0528.
NL Quality Manual MAN0001 Rev 16	• Evaluated through assessment performed Oct 2018 • Sites comply with MAN0001 which details the quality policy and quality requirements of NL. Gibraltar complies with and employees are trained to SOP40G Quality Manual.
Continuous Monitoring Activities	• Monitored through Gibraltar internal audits procedure – SOP 25G which is performed annually to all applicable clauses of ISO 17025. • Monitored through NL supplier management system – SOP0106 and continually evaluated as an approved supplier on the NL qualified supplier list.

Valid to: 31 Dec 2020

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Site Qualification Assessment Summary

Assessment Summary: An on-site assessment was performed on 02-04 Oct 2018 to evaluate compliance with the following:

- CFR 210, 211, 820 and 1271
- ISO 17025:2005
- Nelson Labs (NL) Quality Manual – MAN0001 and quality policy

Purpose: The assessment was performed to determine the qualification status of the site based on the industry regulations and the high quality standards that Nelson Laboratories expects from qualified suppliers, subcontractors and its own testing labs.

This assessment was also performed on your behalf to determine if the site meets the high quality standards and regulatory requirements to perform testing as a qualified supplier for you and to assure you that Nelson Labs quality standards are maintained at this site.

Conclusion: APPROVED

As a result of this assessment the NL facilities located at 122 Fairfield Rd. and 16 Montesano Rd. in Fairfield, NJ are considered **APPROVED** for full use of services. The Fairfield locations meet and/or exceed the requirements of the NL quality manual (MAN0001), the NL supplier management program (SOP0106), as well as the applicable CFRs and ISO standards for a quality management system.

This documented approval is intended to be used as qualification documentation for your files in order for you to fulfill internal requirements for qualification of facility as a laboratory testing provider.

Ongoing Monitoring: In addition to meeting the requirements for qualification the Fairfield locations will be continuously monitored for quality performance through regular reporting/oversight, internal audits and site visits.

Evaluation date: 02-04 Oct 2018
Site evaluation performed by: Matt Cushing, Senior Director Global Quality

Matt Cushing

Matt Cushing, Senior Director Global Quality

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Quality Information – Gibraltar Laboratories (GBL)

Company Information		
Company Name	Gibraltar Laboratories (a Sotera Health Company) Established in 1970.	
Parent Company	Sotera Health	
Company Address	122 Fairfield Rd. Fairfield, NJ 07004	16 Montesano Rd. Fairfield, NJ 07004
Website	GibraltarLabsInc.com	
Telephone	973-227-6882	
Business Information		
Business Classification	ISO 17025 accredited, FDA Registered Testing Laboratories.	
Federal Tax ID	22-1906078	
Dun & Bradstreet Number	062032693	078394591
US SAM Entity/ DUNS/ CAGE Code	N/A	
Facilities		
Total Square Footage	19,520 ft^2	
Lab Space	10,000 ft^2	
Operating Hours	Two shifts, 8:30am-5:00pm and 2:30pm-11:00pm, 5 days a week. Small crew for receiving and testing on Saturdays.	
Number of employees	~ 80	
Quality Staff	9	
Equal Opportunity	GBL is an equal opportunity employer	
Critical Contacts		
Management	Daniel Prince, PhD – Chief Scientific Officer Jozef Mastej – VP of Operations	
Operations (Microbiology)	Zankhna Solanki – Microbiology Laboratory Manager	
Operations (Chemistry)	Shiri Hechter – Chemistry Laboratory Manager	
Quality	Chuck Weibel – Regulatory Affairs Manager Rupinder Puar – Quality Assurance Microbiology Manager	
Technical Services	Danina Rinaldi – Technical Services Manager	
Additional Contacts		
Technical Services	DRinaldi@GibraltarLabsInc.com or EHomenik@GibraltarLabsInc.com	
Audit Scheduling	CWeibel@GibraltarLabsInc.com or SKhalil@GibraltarLabsInc.com	
Proprietary Information		
References	GBL 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	GBL sales and financial information is proprietary, thus no sales or financial information is able to be provided	
Manufacturer Statement	GBL 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	A2LA, 0056.02	A2LA, 0056.01
FDA FEI Identifier	2219947	
Last FDA Audit	02/2017, No 483s	
Please note: Up to date certifications are available on the website.		
Payment Information		
Check Remittance / Billing Address	Gibraltar Laboratories, Inc. 734182 Network Place Chicago, IL 60673-1734	
Overnight Address	Gibraltar Laboratories, Inc. 734182 Network Place Chicago, IL 60673-1734	
Wire Transfers	Bank Name: JP Morgan Bank Address: New York, New York JP Morgan Bank Swift Code: CHASUS33 Customer Name (Recipient): Gibraltar Laboratories, Inc. Customer Address: 122 Fairfield Road, Fairfield, NJ 07004 Account #: 327858715 Routing #: 021000021 Please include your Name, full Address, account number and Country. Remittance Advice to: accounting@gibraltarlabsinc.com	
ACH Transactions	Bank Name: JP Morgan LockBox Address: 734182 Network Place Chicago, IL 60673-1734 U.S.A. Customer Name: Gibraltar Laboratories, Inc. Account #: 327858715 Routing #: 021202337 Remittance Advice: accounting@gibraltarlabsinc.com	
NL has procedures/processes including (but not limited to) the following:		
Quality Manual/Policy	SOP 40G, Quality Manual. The GBL Quality Manual provides the employees, auditors, and customers of Gibraltar Laboratories with a description of the Quality Management System and Quality Policy.	
Change Control and Change Notification	Change controls are maintained for processes, equipment, instrumentation, documentation, etc. per SOP 55G, Change Control. Each proposed change control is reviewed and pre-determined if the change is “Major”, requiring customer notification and possible approval. When required, customers are notified of the upcoming change in writing including rationale, description of change, scope of impact, implementation timing, supporting data, and internal tracking number.	
Document Control	Documents are controlled per SOP 32G, Document Control and Change Control. This SOP describes the process for Document Change Control, Raw Data Records, and Computerized control of documents, SOP Creation, Revision, Control, and Distribution are handled per SOP 30G, SOP on SOP. Document retention is handled in SOP 40G, Quality Manual, and SOP 68G, Document Scanning, Archiving, and Use of the Drivve Document Management System.	

Calibration and Maintenance	Calibrations and PMs are scheduled as listed in SOP 18G, Calibration, Preventative Maintenance, and Certification of General Instruments. The calibration and maintenance of equipment is primarily performed by GBL's Calibration 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	Upon receipt, Gibraltar makes every effort to respond immediately and to investigate, correct, and close within 30 days per SOP 59G, Complaint Handling.
Customer Feedback	SOP 34G, Quality Assurance Auditing Procedure. Includes details of the customer feedback process.
Control of Non-conforming Product	SOP 69G, Deviation Investigations, and SOP 12G, Laboratory Result Failure Investigations and Other Excursions. Out of Specification results are communicated to customers within one business day.
Corrective Action / Preventative Action	All CAPAs are handled per SOP 62G, Corrective and Preventative Actions. Management and Quality Assurance are responsible for determining the root cause, proper corrective action(s), possible preventative action(s), requirements of effectiveness checks, and effectiveness determination..
Deviations	All Deviations are handled per SOP 69G, Deviation Investigations. Management and Quality Assurance are responsible for determining the investigation review, and customer notification.
Out of Specification (OOS) Results	SOP 12G Laboratory Result Failure Investigations and Other Excursions. Out of Specification results are communicated to customers within one business day.
Training	SOP 11G, Training and Proficiency Testing of Technicians and New Employees. GBL includes an extensive, documented training program for all employees. All employees receive annual GMP, GLP, and GDP training. Additionally, proficiency and competency analyses are performed (where applicable).
Traceability	Process controls are in place to ensure traceability and to prevent contamination. Samples, reagents, and equipment are identified by a unique "GBL" asset number per SOP 7G, Receiving Login Procedure and Processing of Samples. Associated items used in testing are traceable to the batch record, lot number, or part number.
Data Integrity	SOP 70G, Data Integrity Policy, defines the roles and responsibilities of Gibraltar employees in assuring data integrity requirements are maintained. Many of current requirements are maintained in specific SOPs which are referred to inside of this SOP.
Internal Audits	The Quality Assurance Department performs an internal audit for each department at least once during the calendar year per SOP 34G, Quality Assurance Auditing Procedure. The only exception is the QA Department is not audited by a person determined by management.
Management Responsibilities	Management responsibilities are defined in SOP 40G, Quality Manual. Management review determines the effectiveness of the Quality System during Management Review per SOP 15G, Quality System / Management Review.
Study Documentation	Documentation is recorded per SOP 25G, Data Recording, Correction, Review, and Reporting. Document retention is handled in accordance with SOP 40G, Quality Manual, and SOP 68G, Document Scanning, Archiving, and Use of the Drivve Document Management System.
Supplier Management	All suppliers are qualified through our supplier management process per SOP 29G, Vendor and Service Provider Qualifications. The quality capabilities of vendors/subcontractors are reviewed prior to placing any orders. Supplier performance is assessed on an ongoing basis through incoming inspections documented in the Purchase Order System.
Test Data Review	Documentation is reviewed and approved per SOP 25G, Data Recording, Correction, Review, and Reporting. All data is peer reviewed before being submitted to Quality Assurance for a secondary full review.

Validation	Laboratory methods of analysis are validated before being used for routine testing per SOP 14C, Validation Analytical Methods, in accordance with ICH guidelines.
Equipment	Qualifications and Validations directed by SOP 6G, Validations, Qualifications, and Validations Master Plan, to ensure that equipment and instrumentation are properly qualified/validated in accordance to design criteria, manufacturer's specifications, industry and company standards, and all documentation is accurate and complete. The Calibration Department is responsible for ensuring equipment or instruments not in current qualified status are identified as such with a DO NOT USE sign.