

Re: ISO 17025 Accreditation

Dear Sponsor,

**Nelson Laboratories, Inc. (NLI) maintains accreditation to ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."**

Because NLI is a testing laboratory, ISO 17025 is the most appropriate quality management system standard to be used for accreditation. ISO 17025 is aligned with ISO 9001, "Quality Management System – Requirements," with the addition of requirements for technical competency. ISO 13485, "Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes," is based on ISO 9001 and is intended to demonstrate the ability to design, develop, produce, and service medical devices and related services. ISO 13485 excludes some elements of ISO 9001 and includes requirements specific to the design and manufacture of medical devices. While ISO 13485 is written for the quality management system of medical device manufacturers, ISO 17025 is written for independent testing laboratories.

The ISO 17025 standard is comprised of the following 5 elements:

- |                          |   |
|--------------------------|---|
| 1) Scope                 | 4) Management requirements <sup>1</sup> |
| 2) Normative references  | 5) Technical requirements <sup>2</sup>  |
| 3) Terms and definitions |   |

<sup>1</sup>Management Requirements

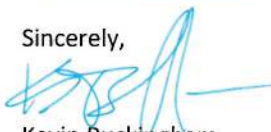
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|--|---|
| 1) Organization                              | 9) Control of nonconforming testing and/or calibration work |
| 2) Quality system                            | 10) Corrective action                                       |
| 3) Document control                          | 11) Preventative action                                     |
| 4) Review of requests, tenders and contracts | 12) Control of records                                      |
| 5) Subcontracting of tests and calibrations  | 13) Internal audits   |
| 6) Purchasing of services and supplies       | 14) Management reviews                                      |
| 7) Services to client                        |   |
| 8) Complaints                                |   |

<sup>2</sup>Technical Requirements:

- |   |   |
|---|---|
| 1) General  | 6) Measurement traceability                             |
| 2) Personnel  | 7) Sampling   |
| 3) Accommodation and environmental conditions         | 8) Handling of test and calibration items               |
| 4) Test and calibration methods and method validation | 9) Assuring the quality of test and calibration results |
| 5) Equipment  | 10) Reporting the results                               |

Our current Accreditation Certificate and Scope of Accreditation can always be found on our website at [www.nelsonlabs.com](http://www.nelsonlabs.com). Please do not hesitate to let us know if you have any additional questions or concerns.

Sincerely,



Kevin Buckingham  
Regulatory Affairs Manager