



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC
1500 West Thorndale Avenue
Itasca, IL 60143

Fulfills the requirements of

ISO/IEC 17025:2017

and

**Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21
CFR Part 58 Accreditation Program**

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to be 'Jason Stine', is positioned above a horizontal line.

Jason Stine, Vice President

Expiry Date: 16 March 2027

Certificate Number: AT-1382.01



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory
quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

**GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES,
TITLE 21 CFR PART 58 ACCREDITATION PROGRAM ¹**

Nelson Laboratories, LLC

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Itasca, IL 60143

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TESTING

ISO/IEC 17025 Accreditation Granted: **11 March 2026**

Certificate Number: **AT-1382.01** Certificate Expiry Date: **16 March 2027**

Microbiological¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	NEL-STP-0046; USP<85>; USP<161>; ISO 11737-3:2023 EP 2.6.14 , JP 4.01 ANSI/AAMI ST72 ASTM D7102-04, BS EN 455-3	Medical Devices, Pharmaceuticals, Tissues	Microplate Reader
Bioburden	NEL-STP-0036; ISO 11737-1	Medical Devices, Pharmaceuticals, Tissues	Biosafety Cabinet, Incubators, Laminar Flow Hood
Biological Indicator Sterility	NEL-STP-0079; ISO 11138-1 to -4; USP<55>; ISO 11135; AAMI TIR 14	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubators
Product Sterility (Cleanroom) MPN Method Suitability Bacteriostasis / Fungistasis	NEL-STP-0077; NEL-STP-0078; ISO 11737-1 and -2; USP<71> EP 2.6.1, JP 4.06, PIC/S PI 012-3 AAMI TIR 37	Medical Devices, Pharmaceuticals, Tissues	Product Sterility Suite ISO Class 5 Hoods Incubators

This Scope of Accreditation, version 021, was last updated on: 11 March 2026 and is valid only when accompanied by the Certificate.

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Microbiological¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Biological Indicator Population Verification (Enumeration and Specified Organisms)	NEL-STP-0045; USP<55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators
Organism Identification (Genetic and Gram Stain)	NEL-STP-0173; NEL-STP-0105; USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope
TOC	NEL-STP-0028 based on USP<643>	Medical Devices, Pharmaceuticals	Washer/Disinfectors Sterilizers (Steam) UV/VIS Spectrophotometer
Particulates	NEL-STP-0011 based on USP<788>,<789>, EP 2.9.19, 2.9.31, BP Appendix XIII A, BH EN 45502-1, 45502-2-1 ISO 8536-4	Medical Devices, Injectables and Ophthalmic Solutions, Pharmaceutical Products	Liquid Particle Counting System, Microscope
Radiation Sterilization Validation and Dose Units	NEL-STP-0044 ISO 11737-1 ISO 11737-2 11137-01 and -02 AAMI TIR 35 NEL-STP-0050 based on ISO 11737-2, 11137-01 and - 02, AAMI TIR 17, 35, 37. NEL-STP-0051 based on ISO 11737-01 and -02, 11137-01 and -02, AAMI TIR 17, 33, 37.	Medical Devices	Biosafety Cabinet, Laminar Flow Hood Product Sterility Suite ISO Class 5 Hoods Incubators
Rapid Sterility Assurance and BI Sterility Testing using the Celsis Advance II™ System	NEL-STP-0371 based on USP<71>, USP<73>, USP <1071>, USP <1116>, USP<1223>, USP<1229>; ISO 11137-01 and -02, ISO 11138-1 and -7, ISO 11737-2, ISO 17665 PIC/S PI 012-3, EP 2.6.1, JP XV 4.06 AAMI TIR16, AAMI TIR 33, PDA TR 33	Medical Devices, Pharmaceuticals, Biologics, Tissues, BIs, PCDs	Celsis Advance II System, AMPiScreen AP, ISO Class 5 Hood, Cleanroom

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	NEL-STP-0016 based on ANSI/AMMI/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	NEL-STP-0028 based on USP<643>	Water – USP	TOC Analyzer
Water Conductivity	NEL-STP-0147 USP <645>	Water – USP	Conductivity Meter
pH	NEL-STP-0029 USP <791>	Water – USP	pH Meter

Note:

1. Microbiological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.



Jason Stine, Vice President

