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.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 16 March 2023
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

1500 West Thorndale Avenue
Itasca, IL 60143

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TESTING

Valid to: **March 16, 2023** Certificate Number: **AT-1382.01**

Microbiological[1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	STP0046; USP <85>; USP <161>; ANSI/AAMI ST72	Medical Devices, Pharmaceuticals	Microplate Reader
Bioburden	STP0036; ISO 11737-1	Medical Devices, Pharmaceuticals	Biosafety Cabinet, Incubators, Laminar Flow Hood
Biological Indicator Sterility	STP0079; ISO 11138-1 to -4; USP <55>; ISO 11135; AAMI TIR 14	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubator
Product Sterility Bacteriostasis / Fungistasis	STP0077; STP0078; ISO 11737-2; USP <71>	Medical Devices, Pharmaceuticals	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms, USP 61/62)	STP0045; USP <55>; ISO 11138-1	Medical Devices, Pharmaceuticals	Incubators
Organism Identification (Genetic and Gram Stain)	STP0173; STP0105; USP <1113>	Medical Devices and Pharmaceuticals	Genetic Sequencer, Thermocycler, Automated Gram Stainer, Biosafety Cabinet, Microscope

Microbiological[1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cleaning, Disinfection, Sterilization Including the following subanalyses (separately accredited): Hemoglobin Protein TOC	Template 122 and Template 202 based on AAMI TIR 12,30, ASTM E1837, ISO 17664 STP0086 based on ANSI/AAMI ST79, AAMITIR12, AAMI/ISO 17665, USP <1211> Template 98 and Template 124 based on ISO 17664, ANSI/AAMI ST79, ANSI/AAMI ST77, ANSI/AAMI/ISO 11135, AAMI TIR30	Medical Devices, Reusable Devices	Washer/Disinfectors Sterilizers (Steam) UV/VIS Spectrophotometer
Radiation Dose Audit	STP0044	Medical Devices	Biosafety Cabinet, Laminar Flow Hood Product Sterility Suite ISO Class 5 Hoods Incubators

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Particulates	STP0011 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

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	STP0016 based on ANSI/AMMI/ISO 10993-7, 2008; USP <621>	Medical Devices	Gas Chromatograph (GC)
Water Purity Analysis TOC	STP0028 based on USP <643>	Water – USP	TOC Analyzer

Chemical

Biological Marker Analysis Hemoglobin Protein	STP0087, STP0183 based on ASTM F756-13, AAMI TIR30 and Cleaning, Disinfection, Sterilization references previously listed	Medical Devices, Reusable Devices	Spectrophotometer

Note:

1. Microbiological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1382.01.

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