



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

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

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-2490

Certificate Number



ANAB Approval

Certificate Valid: 04/20/2018-08/15/2019
Version No. 005 Issued: 04/20/2018



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 17025:2005

Nelson Laboratories, LLC

1500 West Thorndale Avenue

Itasca, IL 60143

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TESTING

Valid to: August 15, 2019

Certificate Number: AT-2490

Microbiology

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

Chemistry

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	G-WI-LB-CHM-008; ISO 10993-7; USP <1225>; USP <621>	Medical Devices	Gas Chromatograph (GC)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2490.



Vice President

