



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: 02/01/2018-08/15/2019
Version No. 004 Issued: 02/01/2018



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).



ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Nelson Laboratories, LLC

1500 West Thorndale Avenue

Itasca, IL 60143

Michael Rahn

630-285-9121

TESTING

Valid to: **August 15, 2019**

Certificate Number: **AT-2490**

Microbiological

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 11737-1:2006	Medical Devices, Pharmaceuticals	Biosafety Cabinet Incubators
Biological Indicator Sterility	STP0079 ISO 11138-1 and 2 ISO 14161 USP 71	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubator
Product Sterility Bacteriostasis / Fungistasis	STP0077 STP0078 ISO 11737-2:2009 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 ISO 11138	Medical Devices, Pharmaceuticals	Incubators

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	G-WI-LB-CHM-008 ISO 10993-7:2008 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

