



# 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;<br>USP <85>;<br>USP <161>;<br>ANSI/AAMI ST72                    | Medical Devices,<br>Pharmaceuticals    | Microplate Reader   |
| Bioburden  | STP0036;<br>ISO 11737-1  | Medical Devices,<br>Pharmaceuticals    | Biosafety Cabinet,<br>Incubators, Laminar Flow<br>Hood  |
| Biological Indicator Sterility   | STP0079;<br>ISO 11138-1 to -4;<br>USP <55>;<br>ISO 11135;<br>AAMI TIR 14 | BIs, PCDs                              | BI Sterility Suite<br>ISO Class 5 Hoods<br>Incubator  |
| Product Sterility<br>Bacteriostasis / Fungistasis  | STP0077;<br>STP0078;<br>ISO 11737-2;<br>USP <71>                         | Medical Devices,<br>Pharmaceuticals    | Product Sterility Suite<br>ISO Class 5 Hoods<br>Incubators                                      |
| Biological Indicator<br>Population Verification<br>(Enumeration and Specified<br>Organisms, USP 61/62) | STP0045;<br>USP <55>;<br>ISO 11138-1                                     | Medical Devices,<br>Pharmaceuticals    | Incubators  |
| Organism Identification<br>(Genetic and Gram Stain)  | STP0173;<br>STP0105;<br>USP <1113>                                       | Medical Devices and<br>Pharmaceuticals | Genetic Sequencer,<br>Thermocycler, Automated<br>Gram Stainer, Biosafety<br>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)<br>Residual Analysis  | G-WI-LB-CHM-008;<br>ISO 10993-7;<br>USP <1225>;<br>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

