



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

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.

Jason Stine, Vice President

Expiry Date: 16 March 2027

Certificate Number: AT-1382



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 PROGRAM¹

Nelson Laboratories, LLC

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TESTING

ISO/IEC 17025 Accreditation Granted: **16 March 2025**

Certificate Number: **AT-1382** 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
Agar Overlay	NEL-STP-0031 based on ANSI/AAMI/ISO 10993-1,5,12 USP <87>, USP<1031>	Medical Devices, Raw Materials	ISO Class 5 Hoods Microscope Incubators
Antimicrobial Preservative Effectiveness	NEL-STP-0131 based on USP <51>, NEL-STP-0132 based on USP <51> and EP 5.1.3	Antimicrobial Preservatives	Incubators
Bacterial Endotoxins	NEL-STP-0046 based on USP <85>, USP<161>, ISO11737-3, EP 2.6.14, JP 4.01 and ANSI/AAMI ST72	Medical Devices, Drugs	Microplate Reader
Bacterial Endotoxins	NEL-STP-0038 ISO 11737-3	Medical Devices, Drugs	Gel Clot Technique
Bacterial Filtration Efficiency (BFE)	NEL-STP-0004 based on ASTM F2101, EN14683, ASTM F2100	Medical & Surgical Face Masks	Andersen Sampler

Microbiological¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Viral Penetration Testing	NEL-STP-0062, and NEL-STP-0174 based on ASTM F1671, AAMI PB70, ISO16604, and NFPA 1999	Textiles, Gloves	ISO Class 5 Hoods Incubators
Bioburden	NEL-STP-0036 based on ISO 11737-1 and BS/EN 14683	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Radiation Sterilization Validations and Dose Audits	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. NEL-STP-0044 based on ISO11137-01 and -02, AAMI TIR 33, 35	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicators (Population verification, BI Sterility)	NEL-STP-0045, and NEL-STP-0079, based on USP<55>, ISO 11138-1 to -4, ISO 11135-1 to -2, ISO 11138-7 ISO 14937, ISO 17665-2, AAMI TIR 13, 14, 16, BS EN 550	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubator

Microbiological¹

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 sub-analyses (separately accredited): - Hemoglobin - Protein - Carbohydrates - MEM elution - TOC - Bioburden	Template 122, Template 251 and Template 202 based on AAMI TIR 12, AAMI ST98, ASTM F3208, ASTM E1837, ISO17664, ISO 15883 NEL-STP-0086 and NEL-STP-0202 based on ANSI/AAMI ST79, AAMITIR12, ANSI/AAMI/ISO 17665, USP <1211> NEL-STP-0152 based on AAMI TIR 12, USP<1211>, ANSI/AAMI/ISO 11135-1, Template 124, based on ISO 17664, ANSI/AAMI ST79, ANSI/AAMI ST77, ANSI/AAMI/ISO 11135	Medical Devices, Reusable Devices	Washer/Disinfectors Sterilizers (Steam, EO, VHP) UV/VIS Spectrophotometer
Hemolysis	NEL-STP-0093 based on ANSI/AAMI/ISO 10993-1,4,12 and ASTM F756-08	Medical Devices, Raw Materials	Spectrophotometer Incubators
MEM Elution	NEL-STP-0032 based on ANSI/AAMI/ ISO 10993-1,5,12 USP <87>, USP<1031>	Medical Devices, Raw Materials	ISO Class 5 Hoods Microscope Incubators
Bacterial Reverse Mutation Assay (Ames Test)	NEL-STP-0097 and NEL-STP-0098 based on ISO 10993-1,3,12,33 OECD 471	Medical Devices, Raw Materials	Incubators, Automated Plate Counter
Chromosome Aberration Assay	NEL-STP-0101 and NEL-STP-0102 based on ISO 10993-1,3,12,33 OECD 473	Medical Devices, Raw Materials	ISO Class 5 Hoods, Microscope, Incubators
MTT Quantitative Cytotoxicity Test	NEL-STP-0207 based on ISO10993-5 and ISO10993-12	Medical Devices	Incubator, Microscope, Spectrophotometer
Complement Activation	NEL-STP-0092 based on ISO 10993-1,4,12	Medical Devices	Spectrophotometer
Partial Thromboplastin Time Test - PTT	NEL-STP-0094 based on ISO 10993-4, 12 and ASTM F2382	Medical Devices	Incubator

Microbiological¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Microbial Retention (Including Filter Bubble Point/Integrity Test)	NEL-STP-0103 based on ASTM F838-15	Filters	Flow Meter Pressure Gauge ISO Class 5 Hood Incubators
Microbiological Examination of NonSterile Products (Enumeration and Specified Organisms, USP 61/62)	NEL-STP-0165 based on USP<61> and USP<62>	Medical Devices, Pharmaceuticals	ISO Class 5 Hoods Incubators
Organism Identification (Genetic and Gram Stain)	NEL-STP-0105, and NEL-STP-0173 based on USP<1113>	Medical Devices, Pharmaceuticals	Genetic Sequencers Thermocyclers Automatic Gram Stainer ISO Class 5 Hoods Incubators Microscopes
Product Sterility (Cleanroom and Isolator), MPN Method Suitability (Bacteriostasis /Fungistasis), and Isolator Package Validation	NEL-STP-0077, NEL-STP-0081, NEL-STP-0082 and NEL-STP-0078 based on USP<71>, USP<161>, USP<797>, ISO 11737-2, 11137-01 and -02, PIC/S PI 012-3, EP 2.6.1, JP XV 4.06, ISO 17665, AAMI TIR 33	Medical Devices, Pharmaceuticals, Biologics, Tissues	ISO Class 6 Cleanrooms and ISO Class 5 Hoods Incubators Isolator
Standard Plate Counts	NEL-STP-0035 based on USP <71> NEL-STP-0165 based on USP<61>	Water, Food, Cosmetics, Pharmaceuticals	ISO Class 5 Hoods Incubators
Antimicrobial Potency Assay	NEL-STP-0085 based on USP <81> and 21 CFR Part 436 Subpart D – Microbiological Assay Methods	Antibiotics	Incubator Calipers Waterbath pH meter
Rapid Sterility Assurance and BI Sterility Testing using the Celsis Advance II™ System	NEL-STP-0371 based on USP<1223>, AAMI TIR 33, USP<71>, USP<161>, USP<797>, ISO 11737-2, 11137-01 and -02, PIC/S PI 012-3, EP 2.6.1, JP XV 4.06, ISO 17665, USP<1229.52>, ISO 11138-1 and -7, AAMI TIR16, PDA TR 33	Medical Devices, Pharmaceuticals, Biologics, Tissues, BIs, PCDs	Celsis Advance II System, AMPiScreen AP, ISO Class 5 Hood

Microbiological¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
MALDI-TOF Microbial Identification	NEL-STP-0119 based on USP<1113>	Medical Devices, Pharmaceuticals	MALDI-TOF

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	GC
FTIR, Material Characterization	NEL-STP-0021 based on USP<851> and USP<197>	Polymers, Non-volatile Residue, Materials	FTIR, Microscope
Water Purity Analysis • TOC • Conductivity • pH	NEL-STP-0024 and NEL-STP-0099 based on USP<1231>, USP<1230> And All USP monographs waters, NEL-STP-0028 based on USP<643>, NEL-STP-0029 based on USP<791>, NEL-STP-0147 based on USP<645>	Water – USP, Water - EP	TOC Analyzer, Conductivity Meter, pH Meter
Biological Marker Analysis • Hemoglobin • Protein • Carbohydrates	NEL-STP-0087, NEL-STP-0088 and NEL-STP-0183 based on ASTM F756-13, AAMI ST98, ASTM F3208 and Cleaning, Disinfection, Sterilization references previously listed.	Medical Devices, Reusable Devices	Spectrophotometer
Metals Analysis via Inductively Coupled Plasma – Mass Spectrometry	NEL-STP-0190 based on USP<233>, and EPA Method 200.8	Medical Devices	Inductively Coupled Plasma – Mass Spectrometer (ICP-MS)
Particulates Testing and VOC Sampling	NEL-STP-0104 based on ISO 18562-2 and ISO 18562-3	Breathing systems, intubation tubing, other gas pathway devices	DustTrak, Flow meters, Nitrogen source

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification of Non-Volatile Organic Compounds	NEL-STP-0166 (APCI) and NEL-STP-0215 (ESI) based on ISO-10993-12, 18, USP<621> and EP 2.2.29	Medical devices and general plastics used in packaging final pharmaceutical products	Liquid Chromatography/ Mass Spectrometry (LC/MS)
Identification of Semi-Volatile Organic Compounds	NEL-STP-0314 based on ISO-10993-12, 18, USP<621> and EP 2.2.28	Medical devices and general plastics used in packaging final pharmaceutical products	Gas Chromatography/ Mass Spectrometry (GC/MS)

Mechanical / Microbiological

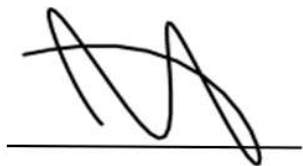
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Barrier Testing: Synthetic Blood and Water Resistance (Hydrostatic Pressure, Impact Penetration)	NEL-STP-0061, NEL-STP-0071 and NEL-STP-0072 based on ASTM F1670, AAMI PB70, ISO 16603, AATCC 42 and 127	Textiles, Gloves	Hydrostatic Head Tester, Incubators
Synthetic Blood Resistance	NEL-STP-0012 based on ASTM F1862 and ISO 22609	Medical facemasks and surgical respirators	Blood testing apparatus
Flammability	NEL-STP-0073 based on 16 CFR Part 1610	Face masks, surgical gowns, and surgical drapes	Flammability tester
Differential Pressure Testing	NEL-STP-0217 based on EN14683	Surgical Face masks and comparable porous materials	Differential Pressure Apparatus, Air Flow Apparatus, Flow Meter
Container Closure Integrity (Dye Ingress)	NEL-STP-0149 based on ANSI/AAMI/ISO 11607-1,2, ASTM D4491-07, PDA TR 27 and FDA Guidance for Industry: Container and Closure Integrity Testing	Packaging Materials for Medical Device & Pharmaceutical	Vacuum Vessel, Spectrophotometer
Container Closure Integrity (Mass Extraction)	NEL-STP-0140 based on ASTM F3287-17	Nonporous rigid containers	ME2 Mass Extraction Leak Test Instrument, Calibrated Leak Orifices
Particulates	NEL-STP-0011 based on USP<787>, <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

Mechanical / Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Respirator Pre-Certification Testing (NIOSH N95/N99) and Barrier Face Coverings - Sodium Chloride Aerosol and Air Resistance Test (Respirator and barrier face covering) - Inhalation/Exhalation (Respirator) - Valve Lead (Respirator)	NEL-STP-0145 based on 42 CFR Part 84 and NIOSH TEB – APR-STP-007, RCT- APR-STP-003 NEL-STP-0143 based on 42 CFR Part 84 and NIOSH TEB-APR-STP-0004 NEL-STP-0014 based on 42 CFR Part 84, NIOSH TEB-ARP-STP-0058, and 0059, and ASTM F3502	Respirators and Barrier Face Coverings	Differential Pressure Apparatus, Air Flow Apparatus, Automated Filter Tester, Sodium Chloride Tester, Valve Leak Tester
EN 13795: Performance requirements for surgical gowns and drapes - Microbial penetration resistance (wet and dry) - Microbial evaluation (bioburden) - Particle evaluation - Liquid penetration resistance - Burst strength - Tensile Strength	NEL-STP-0191 and NEL-STP-0188 based on EN ISO22610:2006 and EN ISO 22612 NEL-STP-0036 based on ISO 11737-1 (Bioburden method) NEL-STP-0144 based on EN ISO 9073-10 NEL-STP-0071 based on AATCC 127 and EN 20811 NEL-STP-0192 based on EN ISO 13938-2 NEL-STP-0066 based on ISO 9073	Medical & Surgical Gowns and Drapes	ISO Class 6 Hoods Incubators Gelbo Flex Unit Particle counter Burst tester Instron (Tensile) tester Rulla II testers

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