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 PROGRAM[1]

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Simon Jones sajones@nelsonlabs.com
Kevyn House khouse@nelsonlabs.com
www.nelsonlabs.com 801-290-7500

TESTING

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

Certificate Number: **AT-1382** Certificate Expiry Date: **16 March 2027**

Microbiological[1]

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

Microbiological[1]

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	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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

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 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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

Microbiological[1]

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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

Microbiological[1]

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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

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 27and 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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

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 EN 29073-3	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

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org

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

ANAB Supplemental Requirements SR 2438, Biocompatibility Testing of Medical Devices

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-1382.03

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

AND

Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21 CFR Part 58 Accreditation Program

Nelson Laboratories, LLC

6280 S. Redwood Road
Salt Lake City, UT 84123

Simon Jones sajones@nelsonlabs.com
Kevyn House khouse@nelsonlabs.com
www.nelsonlabs.com 801-290-7500

TESTING

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

Certificate Number: **AT-1382.03** Certificate Expiry Date: **16 March 2027**

Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, Biocompatibility Testing of Medical Devices [1]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
MEM Elution Cytotoxicity	ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices – Part 5 (FDA Recognition No.2-245); ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices -part 12 (FDA Recognition No. 2-191)	Medical Devices	ISO Class 5 Hoods, Microscope, Incubators

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Biocompatibility Laboratories meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories. .

Jason Stine, Vice President

1899 L Street NW, Suite 1100-A, Washington, DC 20036
414-501-5494
www.anab.org