



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, Inc.
6280 S. Redwood Road
Salt Lake City, UT 84123

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

ISO/IEC 17025:2005

while demonstrating technical competence in the field(s) of

TESTING

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

AT-1382

Certificate Number

ANAB Approval

Certificate Valid: 03/16/2015-03/16/2017

Version No. 001 Issued: 02/10/2015



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 January 2009*).



ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Nelson Laboratories, Inc.

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TESTING

Valid to: March 16, 2017

Certificate Number: AT - 1382

I. Microbiological

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
Medical Devices, Raw Materials	Agar Overlay	STP0031 based on ANSI/AAMI/ISO 10993-1,5,12 USP <87>, USP<1031>	ISO Class 5 Hoods Microscope Incubators
Antimicrobial Preservatives	Antimicrobial Preservative Effectiveness	STP0131 based on USP <51>, STP0132 based on USP <51> and EP 5.1.3	Incubators
Medical Devices, Drugs	Bacterial Endotoxins	STP0046 based on USP <85>, USP<161>, USP<797>, AAMI ST72, EP 2.6.14, ASTM D7102-04, BS EN 455-3	Microplate Reader
Medical & Surgical Face Masks	Bacterial Filtration Efficiency (BFE) Viral Filtration Efficiency (VFE)	STP00004 and STP0007 based on ASTM F2101, EN14683, ASTM F2100	Andersen Sampler
Textiles, Gloves	Barrier Testing (Viral Penetration)	STP0062 and STP0174 based on ASTM F1671, AAMI PB70, ISO16604	ISO Class 5 Hoods Incubators
Textiles, Medical Devices, Tissues, Pharmaceuticals	Bioburden	STP0036 based on ISO 11737-1, STP0050 based on ISO11737-2, 11137-01 and -02, AAMI TIR 17, 35, 37, STP0051 based on ISO 11737-01 and -02, 11137-01 and -02, AAMI TIR 17, 33, 37 and STP0044 based on ISO11137-01 and -02, AAMI TIR 33, 35	ISO Class 5 Hoods Incubators

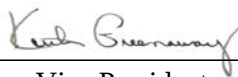
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BIs, PCDs	Biological Indicator Sterility	STP0045 based on USP<55> and ISO 11138-1, STP0079 based on USP<55>, ISO 11138-1 to -4, ISO 11135-1 to -2, ISO 14161, ISO 14937, ISO 17665-2, AAMI TIR 13, 14, 16, BS EN 550	BI Sterility Suite Class 5 Hoods Incubator
Medical Devices, Reusable Devices	Cleaning, Disinfection, Sterilization	STP0083and STP0129 based on AAMI TIR 12, 30, ASTM E1837, ISO17664 STP0086 based on ANSI/AAMI ST79, AAMI TIR12, ANSI/AAMI/ISO 17665, USP <1211> STP0152 based on AAMI TIR 12, USP<1211>, ANSI/AAMI/ ISO 11135-1 STP0153 based on ANSI/AAMI/ISO 14937, AAMI TIR12, USP <1211> STP0159 based on ISO 17664, ANSI/AAMI ST79, ANSI/AAMI ST77, ANSI/AAMI/ISO 11135, AAMI TIR30	Washer/Disinfectors Sterilizers (Steam, EO, VHP)
Packaging Materials for Medical Device & Pharmaceutical	Container Closure (Bacterial Ingress)	STP0164 based on PDA TR 27 and FDA Guidance for Industry: Container and Closure Integrity Testing	Pressure/Vacuum Vessel Incubators
Medical Devices, Raw Materials	Hemolysis	STP0033 based on ANSI/AAMI/ ISO 10993-1,4,12 STP0155 based on ASTM F756-08, STP0093 based on ANSI/AAMI/ISO 10993-1,4,12 and ASTM F756-08	Spectrophotometer Incubators
Medical Devices, Raw Materials	MEM Elution	STP0032 based on ANSI/AAMI/ ISO 10993-1,5,12 USP <87>, USP<1031>	ISO Class 5 Hoods Microscope Incubators
Filters	Microbial Retention (Including Filter Bubble Point/Integrity Test)	STP0103 based on ASTM F838-05	Flow Meter Pressure Gauge ISO Class 5 Hood Incubators
Medical Devices, Pharmaceuticals	Microbiological Examination of NonSterile Products (Enumeration and Specified Organisms, USP 61/62)	STP0169 and STP0165 based on USP<61> and USP<62>	ISO Class 5 Hoods Incubators

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*KEY EQUIPMENT OR TECHNOLOGY
Medical Devices, Pharmaceuticals	Organism Identification (Genetic and Gram Stain)	STP0105, STP0173 and STP0037 based on USP<1113>	Genetic Sequencers Thermocyclers Automatic Gram Stainer ISO Class 5 Hoods Incubators Microscopes
Medical Devices, Pharmaceuticals, Biologics, Tissues	Product Sterility Bacteriostasis / Fungistasis	STP0077 and STP0078 based on USP<71>, USP<161>, USP<797>, ISO 11737-2, 1137-01 and -02, PIC/S PI 012-3, EP 2.6.1, JP XV 4.06, ISO 17665, AAMI TIR 33	ISO Class 5 Cleanrooms and Hoods Incubators
Water, Food, Cosmetics, Pharmaceuticals	Standard Plate Counts	STP-0035 based on USP <71> STP0169 based on USP<61>	ISO Class 5 Hoods Incubators
Textiles, Gloves	Barrier Testing: Synthetic Blood and Water Resistance (Hydrostatic Pressure, Impact Penetration)	STP0061, STP0071 and STP0072 based on ASTM F1670, AAMI PB70, ISO 16603, AATCC 42 and 127	Hydrostatic Head Tester Incubators
Packaging Materials for Medical Device & Pharmaceutical	Container Closure (Dye Ingress)	STP0149 based on ANSI/AAMI/ISO 11607-1,2, ASTM D4491-07, PDA TR 27 and FDA Guidance for Industry: Container and Closure Integrity Testing	Vacuum Vessel UV/Vis Spectrophotometer
Medical Devices	Ethylene Oxide (EO) Residual Analysis	STP0016 based on ANSI/AMMI/ISO10993-7, 2008, USP <621>	Gas Chromatograph (GC)
Medical Devices, Injectables and Ophthalmic Solutions, Pharmaceutical Products	Particulates	STP0011 based on USP <788>, <789>, EP 2.9.19, 2.9.31, BP Appendix XIII A, BH EN 45502-1, 45502-2-1 ISO 8536-4	Liquid Particle Counting System Microscope system
Medical & Surgical Face Masks	Particulate Filtration Efficiency (PFE)	STP0005 based on ASTM F2299	Particle Generator Particle Counter
Water – USP, Water – EP	Water Purity Analysis • TOC • Conductivity pH	STP-0024 based on USP<1231>, USP<1230> and all USP monograph waters, STP0028 based on USP<643> STP0029 based on USP<791> STP0147 based on USP<645>	Ion Analyzer TOC Analyzer

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Polymers, Non-volatile Residue, Materials	FTIR, Material Characterization	STP0021 based on USP <851> and USP <197>	FTIR Spectrophotometer

Notes:

1. * = As Applicable
2. This scope is formatted as part of a single document including the Certificate of Accreditation No. AT-1382



Vice President