



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
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 of

TESTING

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

AT-1382
Certificate Number


ANAB Approval

Certificate Valid: 03/14/2017-03/16/2019
Version No. 003 Issued: 03/14/2017



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, LLC

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TESTING

Valid to: March 16, 2019

Certificate Number: AT - 1382

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

Items, Materials or Products Tested	Specific tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
BIs, PCDs	Biological Indicators (Population verification, Process Challenge Device (PCD) Preparation, BI Sterility)	STP0045, STP0079, and SOP0180 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 ISO Class 5 Hoods Incubator
Medical Devices, Reusable Devices	Cleaning, Disinfection, Sterilization Including the following subanalyses (separately accredited): - Hemoglobin - Protein - Carbohydrates - MEM elution - TOC - Bioburden	STP0083 and 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) UV/VIS Spectrophotometer
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	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 F838-15	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
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

Items, Materials or Products Tested	Specific tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Medical Devices, Pharmaceuticals, Biologics, Tissues	Product Sterility & Bacteriostasis /Fungistasis (B/F)	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

Physical/ Chemical Testing

Items, Materials or Products Tested	Specific tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
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 27and 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)
Polymers, Non-volatile Residue, Materials	FTIR, Material Characterization	STP0021 based on USP<851>and USP<197>	FTIR Spectrophotometer
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 Counter Microscope
Medical & Surgical Face Masks	Particulate Filtration Efficiency (PFE)	STP0005 based on ASTM F2299	Particle Generator Particle Counter
Respirators	Respirator Certification Testing (NIOSH N95/N99) - Respirator Inhalation/Exhalation - Respirator Valve Leak	STP 145 based on 42 CFR Part 84 and NIOSH TEB – APR-STP-007, RCT- APR-STP-003 STP0143 based on 42 CFR Part 84 and NIOSH TEB-APR-STP-0004	Differential Pressure Apparatus Air Flow Apparatus Automated Filter Tester

Items, Materials or Products Tested	Specific tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
	Sodium Chloride Aerosol Test	STP0014 based on 42 CFR Part 84 and NIOSH TEB-ARP-STP-0058, TEB-ARP-STP-0059	
Water – USP, Water – EP	Water Purity Analysis - TOC - Conductivity - pH	STP0024 and STP0099 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
Medical Devices, Reusable Devices	Biological Marker Analysis - Hemoglobin - Protein - Carbohydrates	STP0087, STP0088, STP0089, and STP0183 based on ASTM F756-13, AAMI TIR30, and Cleaning, Disinfection, Sterilization references previously listed.	UV/VIS Spectrophotometer

Microbiological and Physical/Chemical Testing

Items, Materials or Products Tested	Specific tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Medical & Surgical Gowns and Drapes	EN 13795: Performance requirements for surgical gowns and drapes - Microbial penetration resistance - Microbial evaluation (bioburden) - Particle evaluation - Liquid penetration resistance - Burst strength - Tensile Strength	STP191 based on EN ISO22610 and EN ISO 22612 STP0036 based on ISO 11737-1 (Bioburden method) STP0144 based on EN ISO 9073-10 STP0071 based on AATCC 127 and EN 20811 STP0192 based on EN ISO 13938-1 STP0066 EN 29073-3	ISO Class 5 Hoods Incubators Gelbo Flex Unit Particle counter Burst tester Instron (Tensile) tester

Notes:

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


 Vice President