



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES FAIRFIELD, INC.
16 Montesano Rd
Fairfield, NJ 07004
Chuck Weibel Phone: 973 227 6882

BIOLOGICAL

Valid To: February 28, 2021

Certificate Number: 0056.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following biological tests on raw materials, excipients, intermediate and finished product pharmaceuticals, dietary supplements, human cells, tissues, tissue products and medical devices:

Monograph Testing Employing the Following:

<u>Technology</u>	<u>Reference Method(s)</u>
Antibiotics – Microbial Assays	USP <81>
Antimicrobial Effectiveness Test (AET)	USP <51>; EP 5.01.03 CTFA M3, M6
Antiviral Efficacy	9CFR 113.47; 40CFR 158
Bacterial Endotoxins Test (Gel Clot and Kinetic Chromogenic LAL)	USP <85>; EP 2.06.14; ANSI/AAMI ST 72
Bioburden	ISO 11737-1, -2, -3; ISO 11137-1, -2, -3
Cytotoxicity - Elution, Agar Overlay and Agar Diffusion Methods	USP <87>; ISO 10993-5
Detection Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	ASTM F2096-11
Disinfectant Testing: - Virucidal - Tuberculocidal - Bactericidal - Available Chlorine - Germicidal - Fungicidal - Sporicidal	AOAC Chapter 6, 21 CFR 610.12; ANSI/AAMI ST 58; 9 CFR 113; AOAC, EPA 40 CFR 158
Dye Penetration Testing	ASTM F1929-15
Enumeration of Organisms in Water: - Total Heterotrophic Plate Count - Coliforms	USP<1231>; Standard Methods for the Examination of Water and Wastewater

<u>Technology</u>	<u>Reference Method(s)</u>
Environmental Monitoring	USP <1116>; ISO 14644-1, -2; ISO 14698-1; ISO 8573
Identification of Organisms	Vitek 2 Compact Systems
Immunological Test Method – Enzyme Linked Immunosorbent Assay (ELISA)	USP<1103>
Microbial Aerosol Challenge Test for Packages	ISO 11607
Microbial Content (Qualitative Tests) <ul style="list-style-type: none"> - <i>Klebsiella</i> spp. - <i>Listeria monocytogenes</i> and <i>Listeria</i> spp. - <i>Shigella</i> - <i>Cronobacter Sakazakii</i> - <i>Enterobacteriaceae</i> - <i>Salmoenlla</i> spp. - Coagulase Positive <i>Staphylococcus</i> 	BAM CMMEF; ISO 11290 BAM ISO/TS 22964 ISO 21528 ISO 6579 ISO 6888
Microbial Limits. Microbiological Examination of Nonsterile Products, Microbial Enumeration Tests	USP <61>, <62>, <2021>, <2022>; EP 2.06.12; EP 2.06.13
Mycoplasma Tests	USP<63>; EP 2.06.07; 9 CFR 113.28; 21 CFR 610
Nucleic Acid Based Technique – Polymerase Chain Reaction (PCR)	USP<1127>
Protein Analysis by SDS-PAGE and Western Blot	USP<1045>; USP<1049>
Quantitative Analysis for Hemoglobin, Protein, and Carbohydrate Residue on Reusable Medical Devices	ANSI/AAMI TIR 30; ANSI/AAMI TIR 12; ANSI/AAMI ST 70; ISO 10995-5, 10993-12
Sterility Tests	USP <71>; EP 2.06.01; ANSI/AAMI ST 77, ST 79; ISO 11137-1, -2, -3; ISO 11737-1, -2, -3; ISO 17665
Validation of Microbial Recovery from Pharmacopeial Articles	USP <1227>



Accredited Laboratory

A2LA has accredited

NELSON LABORATORIES FAIRFIELD, INC.

Fairfield, NJ

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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).



Presented this 10th day of December 2018.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 56.01
Valid to February 28, 2021
Revised December 16, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Nelson Laboratories Fairfield, INC.
122 Fairfield Road
Fairfield, NJ 07004
Pharaoh Accilien Phone: 973 227 6882

CHEMICAL

Valid To: February 28, 2021

Certificate Number: 0056.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following chemical tests on raw materials, excipients, intermediate and finished product pharmaceuticals, dietary supplements, human cells, tissues, tissue products and medical devices:

Monograph Testing Employing the Following:

<u>Test/Technology</u>	<u>Reference Method</u>
Arsenic Limit Test	USP <211>
Chloride and Sulfate Limit Test	USP <221>
Chromatography (GC and HPLC)	USP <621>
Dissolution	USP <711>
Ethylene Oxide Sterilization Residuals	ISO 10993 Part 7
Heavy Metals Limit Test	USP <231>
Identification Tests - General	USP <191>
Iron Limit Test	USP <241>
Lead Limit Test	USP <251>
Loss on Drying	USP <731>
Loss on Ignition	USP <733>
Melting Range	USP <741>
Nitrogen and Oxygen Determination in Nitrogen	USP-NF
Optical Rotation	USP <781>
Particulate Matter in Injections	USP <788>
pH	USP <791>
Readily Carbonizable Substances Limit Test	USP <271>
Refractive Index	USP <831>
Residual Solvents (Organic Volatile Impurities)	USP <467>
Residue on Ignition Limit Test	USP <281>
Specific Gravity	USP <841>
Spectrophotometric Identification Tests (FTIR, UV/VIS)	USP <197>
Thin Layer Chromatography Identification Tests	USP <201>
Total Organic Carbon	USP <643>
Validation of Compendial Methods, GC/HPLC	USP <1225>
Water Conductivity	USP <645>
Water Determination by Karl Fischer	USP <921>



Accredited Laboratory

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NELSON LABORATORIES FAIRFIELD, INC.

Fairfield, NJ

for technical competence in the field of

Chemical Testing

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Presented this 10th day of December 2018.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 56.02
Valid to February 28, 2021
Revised December 16, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.