



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES FAIRFIELD, INC.

122 Fairfield Road  
Fairfield, NJ 07004

Dan Carrino Phone: 973 227 6882

BIOLOGICAL

Valid To: December 31, 2024

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 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(s)</u>	<u>In-House SOP(s)</u>
Antibiotics – Microbial Assays	USP <81>	STP0302, STP0300
Antimicrobial Effectiveness Test (AET)	USP <51>; EP 5.01.03; CTFA M3, M6	STP0216
Antiviral Efficacy	9CFR 113.47; 40CFR 158	STP0254, STP0261, SOP0598
Bacterial Endotoxins Test (Gel Clot and Kinetic Chromogenic LAL)	USP <85>; EP 2.06.14; ANSI/AAMI ST 72	STP0046
Bioburden	ISO 11737-1, -2, -3; ISO 11137-1, -2, -3	STP0036
Cytotoxicity – Elution, Agar Overlay and Agar Diffusion Methods	USP <87>; ISO 10993-5	STP0295
Disinfectant Testing: <ul style="list-style-type: none"><li>- Available Chlorine</li><li>- Bactericidal</li><li>- Fungicidal</li><li>- Germicidal</li><li>- Sporicidal</li><li>- Tuberculocidal</li><li>- Virucidal</li></ul>	AOAC Chapter 6; 21 CFR 610.12; ANSI/AAMI ST 58; 9 CFR 113; EPA 40 CFR 158	STP0261, STP0250, STP0226, STP0219, STP0239, STP0251
Enumeration of Organisms in Water: <ul style="list-style-type: none"><li>- Coliforms</li><li>- Total Heterotrophic Plate Count</li></ul>	USP<1231>; Standard Methods for the Examination of Water and Wastewater	STP0057, STP0040
Environmental Monitoring	USP <1116>; ISO 14644-1, - 2; ISO 14698-1; ISO 8573	STP0297, STP0034, SOP0606
Identification of Organisms	Vitek 2 Compact Systems	STP0105, STP0298

<b><u>Test/Technology</u></b>	<b><u>Reference Method(s)</u></b>	<b><u>In-House SOP(s)</u></b>
Microbial Content (Qualitative Tests) <ul style="list-style-type: none"> <li>- Coagulase Positive <i>Staphylococcus</i></li> <li>- <i>Cronobacter sakazakii</i></li> <li>- Enterobacteriaceae</li> <li>- <i>Klebsiella</i> spp.</li> <li>- <i>Listeria monocytogenes</i> and <i>Listeria</i> spp.</li> <li>- <i>Salmonella</i> spp.</li> <li>- <i>Shigella</i></li> </ul>	ISO 6888; ISO/TS 22964; ISO 21528; FDA/BAM; CMMEF; ISO 11290; ISO 6579	STP0228
Microbial Limits – Microbiological Examination of Nonsterile Products, Microbial Enumeration Tests	USP <61>, <62>, <2021>, <2022>; EP 2.06.12; EP 2.06.13	STP0165
Microbiological Examination of Nonsterile Products – Tests for <i>Burkholderia cepacia</i> Complex	USP<60>	STP0312
Mycoplasma Tests	USP<63>; EP 2.06.07; 9 CFR 113.28; 21 CFR 610	STP0220
Nucleic Acid Based Technique – Polymerase Chain Reaction (PCR)	USP<1127>	STP0304
Protein Analysis by SDS-PAGE and Western Blot	USP<1045>; USP<1049>	STP0305
Sterility Tests	USP<71>; EP 2.06.01; ANSI/AAMI ST 77, ST79; ISO 11137-1, -2 -3; ISO 117371, -2, -3; ISO 17665	STP0077, STP0078
Validation of Microbial Recovery from Pharmacopeial Articles	USP <1227>	N/A



## 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 27<sup>th</sup> day of February 2023.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 0056.01  
Valid to December 31, 2024

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