

# Certification and Documentation Packet

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SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES BOZEMAN, LLC<sup>1</sup>

1765 South 19<sup>th</sup> Avenue

Bozeman, MT 59718

Dr. Margret Butler Phone: 406-587-5735 ext. 163

Danielle Goveia Phone: 406-587-5735 ext. 136

BIOLOGICAL

Valid To: May 31, 2024

Certificate Number: 3945.01

In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the laboratory's compliance to *U.S. Food and Drug Administration's GLP (Good Laboratory Practices Act) requirements as specified in the Code of Federal Regulations Title 21 part 58 (21CFR58)*), accreditation is granted to this laboratory to perform *In Vivo* and *In Vitro* testing for qualitative and quantitative analysis of medical devices, textiles, wound dressings, respirators, gloves, condoms, and sanitizing substances, including the antimicrobial properties of soaps, hand sanitizers, preoperative skin preparations, and disinfectants.

<b><u>Test Technology</u></b>	<b><u>Test Method</u></b>
<b>Clinical Bactericidal Tests - <i>In Vivo</i></b>	
Chemical Disinfectants and Antiseptics - Hygienic Hand Rub - Test Method and Requirements (Phase 2/Step 2)	EN 1500
Chemical Disinfectants and Antiseptics - Hygienic Handwash - Test Method and Requirements (Phase 2/Step 2)	EN 1499
Standard Test Method for Determining the Bacteria - Eliminating Effectiveness of Hygienic Handwash and Hand Rub Agents Using the Finger Pads of Adults	ASTM E2276
Standard Test Method for Determining the Bacteria - Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults	ASTM E2755
Standard Test Method for Evaluation of Pre-operative, Pre-catheterization, or Pre-injection Skin Preparations	ASTM E1173
Standard Test Method for Evaluation of Surgical Hand Scrub Formulations	ASTM E1115
Standard Test Method for Evaluation of the Effectiveness of Handwash Formulations Using the Paper Towel (Palmar) Method of Hand Contamination	ASTM E2784
Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations	ASTM E1174

<b><u>Test Technology</u></b>	<b><u>Test Method</u></b>
<b>Clinical Bactericidal Tests - <i>In Vivo</i> (cont.)</b>	
Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products	ASTM E2752
<b>Clinical Virucidal Tests - <i>In Vivo</i></b>	
Standard Test Method for Determining the Virus - Eliminating Effectiveness of Hygienic Handwash and Hand Rub Gents Using the FingerPads of Adults	ASTM E1838
Standard Test Method for Evaluation of Hygienic Handwash and Hand Rub Formulations for Virus - Eliminating Activity Using the Entire Hand	ASTM E2011
<b>Clinical Respirator Fit Test - <i>In Vivo</i></b>	
Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators	ASTM F3407
<b>Bactericidal Tests - <i>In Vitro</i></b>	
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Basic Bactericidal Activity of Chemical Disinfectants and Antiseptics. Test Method and Requirements (Phase 1)	EN 1040
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Bactericidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic and Institutional Areas. Test Method and Requirements (Phase 2, Step 1)	EN 1276
Chemical Disinfectants and Antiseptics-Quantitative Test Method for the Evaluation of Bactericidal and Yeasticidal Activity on Non-porous Surfaces with Mechanical Action Employing Wipes in the Medical Area (4 - field test) - Test Method and Requirements (Phase 2, Step 2)	EN 16615
Measurement of Antibacterial Activity on Plastics and Other Non-porous Surfaces	ISO 22196
Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time - Kill Procedure	ASTM E2783
Germicidal and Detergent Sanitizing Action of Disinfectants	AOAC 960.09
Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic, and institutional areas-Test method, and requirements without mechanical action (phase 2, step 2)	BS EN 13697

<b><u>Test Technology</u></b>	<b><u>Test Method</u></b>
<b>Virucidal Tests - <i>In Vitro</i></b>	
Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Virucidal Activity in the Medical Area - Test Method and Requirements (Phase 2/Step 1) (Includes Amendment :2019)	EN 14476
Measurement of Antiviral Activity on Plastics and Other Non-porous Surfaces	ISO 21702
Standard Practice to Assess the Activity of Microbicides Against Viruses in Suspension	ASTM E1052
Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Non-porous Environmental Surface	ASTM E1053
Textiles - Determination of Antiviral Activity of Textile Products	ISO 18184
<b>Neutralization of Antimicrobial Activity - <i>In Vitro</i></b>	
Standard Practices for Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054
<b>Wound Dressing Evaluation – <i>In Vitro</i></b>	
Test Method for Primary Wound Dressings – Part 1: Aspects of Absorbency	EN 13726-1 Section 3.2 & 3.3
Test Methods for Primary Wound Dressings – Part 2: Moisture Vapor Transmission Rate of Permeable Film Dressings	EN 13726-2

<sup>1</sup>This scope meets the A2LA P112 Flexible Scope Policy.



# Accredited Laboratory

A2LA has accredited

## NELSON LABORATORIES BOZEMAN, LLC

Bozeman, MT

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 laboratory also meets the U.S. Food and Drug Administration's GLP (*Good Laboratory Practices Act*) requirements as specified in the Code of Federal Regulations Title 21 part 58 (21CFR58). 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 19<sup>th</sup> day of July 2022.

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

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3945.01  
Valid to May 31, 2024

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



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**Document Type:** \* GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION ▼

**Set ID:** \* 112ceaa4-b787-60b3-e054-00144ff8d46c

**Version Number:** \* 13

**Root ID:** \* ecabf532-0f87-107e-e053-2a95a90a69f4

**Effective Date:** \* 11-04-2022

**Registrant Details**

**Registrant Name:** \* Nelson Laboratories Bozeman, LLC

**Registrant DUNS:** \* 787813161

**Registrant Contact Details**

**Contact Name:** \* Danielle Goveia

**Contact Email:** \* dgoveia@nelsonlabs.com

**Contact Phone:** \* 406-587-5735

**Phone Extension:** 136

**Contact Fax:**

**Registrant Contact Address**

**Country:** \* United States ▼  
**Street Address:** \* 1765 S. 19th Avenue

**City:** \* Bozeman

**State:** \* Montana ▼

**Postal Code:** \* 59718

**Facilities**

row(s) 1 - 1 of 1

FACILITY DUNS	FACILITY FEI NUMBER	FACILITY NAME
787813161	1000221600	BioScience Laboratories, Inc.

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Header Details

**Document Type:** \* ESTABLISHMENT REGISTRATION

**Set ID:** \* 1130a1f8-bcc3-72ec-e054-00144ff8d46c

**Root ID:** \* ecabad49-efa5-0003-e053-2995a90a7835

**Version Number:** \* 13

**Effective Date:** \* 11-04-2022

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**Registrant Name:** \* Nelson Laboratories Bozeman, LLC

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Registrant Contact Address

**Country:** \* United States

**Street Address:** \* 1765 S. 19th Avenue

**City:** \* Bozeman

**State:** \* Montana

**Postal Code:** \* 59718

Establishments

row(s) 1 - 1 of 1

ESTABLISHMENT DUNSE	ESTABLISHMENT FEI	ESTABLISHMENT NAME
787813161	1000221600	BioScience Laboratories

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3026934915	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b> FEI: 1000221600	Reason For Last Submission: Initial Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 05/11/2023 Summary Report Print Date: 05/11/2023
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<b>Legal Name and Location:</b>  Nelson Laboratories Bozeman, LLC 1765 S. 19th Ave  Bozeman, Montana 59718 USA  Phone: 406-587-5735 <b>Ext.:</b>	<b>Reporting Official:</b>  Robert Thoreson, Director of Quality Assurance 6280 South Redwood Road Salt Lake City, Utah 84123 USA Phone: 801-290-7618 Ext. rthoreson@nelsonlabs.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> Yes  Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane						X						
Blood Vessel						X						
Bone						X						
Cardiac Tissue - non-valved						X						
Cartilage						X						
Cornea						X						
Dura Mater						X						
Embryo												
Fascia						X						
Heart Valve						X						
HPC Apheresis												
HPC Cord Blood												
Ligament						X						
Nerve Tissue						X						
Oocyte												
Ovarian Tissue						X						
Pancreatic Islet Cells - autologous						X						
Parathyroid						X						
Pericardium						X						
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane						X						
Sclera						X						
Semen												
Skin						X						
Tendon						X						
Testicular Tissue						X						
Tooth Pulp						X						
Umbilical Cord Tissue						X						



**Additional Information:** No additional information provided.

**Proprietary Name(s):**

FEI: 3026934915

Legal Name:

Nelson Laboratories Bozeman, LLC

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## IRB Organization Information

**IORG0004971 - Nelson Laboratories Bozeman, LLC (Active)**

**Located at:** Bozeman, MONTANA

**Expires:** 05/05/2025

**IRBs for this Organization: 1**

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IRB#	IRB Name	City	State/Country	Status	IRB Type
IRB00005939	<a href="#">Gallatin IRB #1</a>	Bozeman	MONTANA	Active	OHRP/FDA