Nelson Labs® | Bozeman
A Sotera Health company

Certification and Documentation Packet

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1765 S. 19th Avenue
Bozeman, MT 59718
+1 (406) 587-5735 | nelsonlabsbozeman.com

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES BOZEMAN, LLC
1765 South 19th 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, 2026 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)*) *and Environmental Protection Agency GLP (Good Laboratory Practices (40CFR160)*, 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.

Test Technology	**Test Method**
Clinical Bactericidal Tests - *In Vivo*[1]	
Chemical Disinfectants and Antiseptics - Hygienic Hand Rub - Test Method and Requirements (Phase 2/Step 2)	EN1500
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

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8398 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Test Technology	**Test Method**
Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations	ASTM E1174
Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products	ASTM E2752
Clinical Virucidal Tests - *In Vivo*[1]	
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
Bactericidal Tests and Fungicidal - *In Vitro*[1]	
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 Suspension Test for the Evaluation of Bactericidal Activity in the Medical Area - Test Method and Requirements (Phase 2, Step 1)	EN 13727
Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Mycobactericidal Activity of Chemical Disinfectants in the Medical Area including Instrument Disinfectants - Test Method and Requirements (Phase 2, Step 1)	EN 14348
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Fungicidal or Yeasticidal Activity in the Medical Area. Test Method and Requirements (Phase 2, Step 1)	EN 13624
Chemical Disinfectants and Antiseptics. Quantitative Suspension Test for the Evaluation of Basic Fungicidal or Basic Yeasticidal Activity of Disinfectants and Antiseptics. Test Method and Requirements (Phase 1)	EN 1275
Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Fungicidal or Yeasticidal Activity of Chemical Disinfectants and Antiseptics used in Food, Industrial, Domestic and Institutional Areas - Test Method and Requirements (Phase 2, Step 1)	EN 1650

Test Technology	**Test Method**
Chemical Disinfectants and Antiseptics. Quantitative Test for the Evaluation of Bactericidal and Yeasticidal and/or Fungicidal Activity of Chemical Disinfectants in the Medical Area on Non-Porous Surfaces without Mechanical Action. Test method and requirements (Phase 2, Step 2)	EN 17387
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
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)	EN 13697
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
Antimicrobial Effectiveness Testing	USP <51>
Virucidal Suspension Tests (Non-Clinical) - *In Vitro*[1]	
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
Chemical Disinfectants and Antiseptics. Quantitative Non-Porous Surface Test without Mechanical Action for the Evaluation of Virucidal Activity of Chemical Disinfectants used in the Medical Area. Test Method and Requirements (Phase 2, Step 2)	EN 16777
Measurement of Antiviral Activity on Plastics and Other Non-porous Surfaces	ISO 21702
Textiles - Determination of Antiviral Activity of Textile Products	ISO 18184
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

Test Technology	**Test Method**
Neutralization Evaluation[1]	
Standard Practices for Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054
Wound Dressing Evaluation – *In Vitro*[1]	
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

[1]This scope meets the A2LA P112 Flexible Scope Policy.

Below does not fall under A2LA P112 Flexible Scope Policy:

Clinical Respirator Fit Test - *In Vivo*	
Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators	ASTM F3407

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) & Environmental Protection Agency GLP (Good Laboratory Practices (40CFR160). 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 17th day of April 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3945.01
Valid to May 31, 2026

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

Registrant - Nelson Laboratories Bozeman, LLC (787813161)

Contact	Address	Telephone Number	Email Address
Danielle Goveia	Address: 1765 S. 19th Avenue City, State, Zip: Bozeman, MT, 59718 Country: USA	+406-587-5735;ext=136	dgoveia@nelsonlabs.com

Facility

Name	Address	ID/FEI	Business Operations
Nelson Laboratories Bozeman, LLC	Address: 1765 S. 19th Avenue City, State, Zip: Bozeman, MT, 59718 Country: USA	787813161/1000221600	clinical bioequivalence or bioavailability study, in vitro bioequivalence or bioanalytical testing

Contact	Address	Telephone Number	Email Address
Danielle Goveia	Address: 1765 S. 19th Avenue City, State, Zip: Bozeman, MT, 59718 Country: USA	+406-587-5735;ext=136	dgoveia@nelsonlabs.com

Revised: 12/2023

Registrant - Nelson Laboratories Bozeman, LLC (787813161)

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Danielle Goveia	Address: 1765 S. 19th Avenue City, State, Zip: Bozeman, MT, 59718 Country: USA	+406-587-5735;ext=136	dgoveia@nelsonlabs.com

Establishment

Name	Address	ID/FEI	Business Operations
Nelson Laboratories Bozeman, LLC	Address: PO Box 190 City, State, Zip: Bozeman, MT, 59718 Country: USA	787813161/1000221600	analysis

Contact	Address	Telephone Number	Email Address
Danielle Goveia	Address: 1765 S. 19th Avenue City, State, Zip: Bozeman, MT, 59718 Country: USA	+406-587-5735;ext=136	dgoveia@nelsonlabs.com

Revised: 12/2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3026934915

Other FDA Registrations:
Blood:
Devices:
Drugs: FEI: 1000221600

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 12/22/2023
Summary Report Print Date: 01/05/2024

Legal Name and Location:

Nelson Laboratories Bozeman, LLC
1765 S. 19th Ave

Bozeman, Montana 59718
USA

Phone: 406-587-5735 **Ext.:**

Reporting Official:

Robert Thoreson, Director of Quality Assurance
6280 South Redwood Road
Salt Lake City, Utah 84123
USA
Phone: 801-290-7618 Ext.
rthoreson@nelsonlabs.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: 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)).

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						

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3026934915

Legal Name: Nelson Laboratories Bozeman, LLC

IRB Organization Information

IORG0004971 - Nelson Laboratories Bozeman, LLC (Active)

Located at: Bozeman, MONTANA
Expires: 05/05/2025

IRBs for this Organization: 1
Agency Only Access

IRB#	IRB Name	City	State/Country	Status	IRB Type
IRB00005939	Gallatin IRB #1	Bozeman	MONTANA	Active	OHRP/FDA

Nelson Labs
A Sotera Health company

07 MAY 2024

Regulatory Inspection History, GMP, GCP, GTP, and GLP Compliance, and Debarment Statement

Dear Sponsor,

Nelson Laboratories Bozeman (NLB) located at 1755 South 19th Avenue (Admin Building) & 1765 South 19th Avenue (Lab Building) Bozeman, MT 59718, is audited by the Environmental Protection Agency (EPA) and U.S. Food and Drug Administration (FDA) according to current good manufacturing practices (GMP), Good Clinical Practices (GCP), good laboratory practices (GLP), and good tissue practices (GTP), as applicable. We are also currently ISO 17025:2017 accredited by the American Association for Laboratory Accreditation (A2LA) as a testing laboratory in the field of Biological Testing.

We certify that the facility, tests, and controls that are used in the analysis of your products are compliant with the following:

- Current Good Manufacturing Practices, as codified in 21 CFR 210/211 and 820
- Good Clinical Practices 21 CFR Parts 50, 56, 312, and 314
- Current Good Tissue Practices, as codified in 21 CFR 1270/1271
- Current Good Laboratory Practices, as codified in 21 CFR 58 or 40 CFR 160, when requested

Regulatory Inspection History

AGENCY	SCOPE	YEAR	DATES
FDA	GLP	2005	21-24 MAR
	GLP	2006	24-26 JAN
	GCP	2015	30 NOV-10 DEC
	GCP	2016	25-29 JUL
	GTP	2023	13-14 NOV
EPA	GLP	2001	28-31 AUG
	GLP	2009	01-02 SEP
	GLP	2015	28-29 JUL
	GLP	2019	12-13 JUN
	GLP	2023	06-08 JUN

Pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 D.S.C. 335a (k), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), NLB certifies that it did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of the Generic Drug Enforcement Act of 1992. No person employed by NLB has currently or in the past five (5) years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. NLB has not been debarred by the FDA and is not currently involved in any debarment proceeding with the FDA.

Sincerely,

DocuSigned by:
Robert Thoreson
Signer Name: Robert Thoreson
Signing Reason: I approve this document
Signing Time: May 7, 2024 | 12:33 PM MDT
6D561BC75E97432B9FF4CF3EF4893377

Rob Thoreson
Director of Quality Assurance
801-290-7618
RThoreson@nelsonlabs.com