

Certification and Documentation Packet

Table of Contents

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017	Pg. 1 – 3
ISO/IEC 17025:2017 Accreditation Certificate	Pg. 4
FDA: Generic Drug Facility Identification	Pg. 5
FDA: Drug Establishments Registration	Pg. 6
Active IRB Registration	Pg. 7



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, 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 the following tests on soaps, hand sanitizers, preoperative skin preparations, hard surface disinfectants, textiles, medical devices, gloves, and condoms:

<u>Test</u>	<u>Test Method</u>
Clinical Bactericidal Tests - <i>In Vivo</i>	
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
Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations	ASTM E1174

<u>Test</u>	<u>Test Method</u>
Clinical Bactericidal Tests - <i>In Vivo</i> (cont.)	
Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products	ASTM E2752
Clinical Virucidal Tests - <i>In Vivo</i>	
Standard Test Method for Determining the Virus - Eliminating Effectiveness of Hygienic Handwash and Hand Rub Gents Using the FingerPads of Adults	ASTM E1838
Clinical Respirator Fit Test - <i>In Vivo</i>	
Standard Test Method for Evaluation of Hygienic Handwash and Hand Rub Formulations for Virus - Eliminating Activity Using the Entire Hand	ASTM E2011
Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators	ASTM F3407
<i>In Vitro</i> Bactericidal Tests	
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

<u>Test</u>	<u>Test Method</u>
<i>In Vitro</i> Virucidal Tests	
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
Neutralization of Antimicrobial Activity - <i>In Vitro</i>	
Standard Practices for Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054



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 19th 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.

**CDER Direct**

Electronic Submissions Portal

[View SPL](#) [Download SPL](#)

Cre

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this GDUFA Self-Identification submission form. required fields.

Header Details**Document Type:** * GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION ▼**Set ID:** * 112ceaa4-b787-60b3-e054-00144ff8d46c**Version Number:** * 11**Root ID:** * de0bcd7d-dd9c-22cb-e053-2a95a90a4e98**Effective Date:** * 05-02-2022**Registrant Details****Registrant Name:** * Nelson Laboratories Bozeman, LLC**Registrant DUNS:** * 787813161**Registrant Contact Details****Contact Name:** * Amy Juhnke**Contact Email:** * ajuhnke@nelsonlabs.com**Contact Phone:** * 406-587-5735**Phone Extension:** 105**Contact Fax:** 406-586-7930**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

<input checked="" type="checkbox"/>	FACILITY DUNS	FACILITY FEI NUMBER	FACILITY NAME
<input checked="" type="checkbox"/>	787813161	1000221600	BioScience Laboratories, Inc.

[FDA Home](#) | [Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [Help Desk](#) | [FAQs](#)[Follow FDA](#) | [FDA Voice Blog](#) | [Privacy](#)

[View SPL](#)[Download SPL](#)[Create](#)

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form required fields.

Header Details

Document Type: [ESTABLISHMENT REGISTRATION](#) ▼

Set ID: * 1130a1f8-bcc3-72ec-e054-00144ff8d46c
Root ID: * de0bcd7d-dd9b-22cb-e053-2a95a90a4e98

Version Number: * 11
Effective Date: * 05-02-2022

Registrant Details

Registrant Name: * Nelson Laboratories Bozeman, LLC

Registrant DUNS: * 787813161

Registrant Contact Details

Contact Name: * Amy Juhnke
Contact Email: * ajuhnke@nelsonlabs.com
Contact Phone: * 406-587-5735
Phone Extension: 105

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

[FDA Home](#) | [Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [Help Desk](#) | [FAQs](#)
[Follow FDA](#) | [FDA Voice Blog](#) | [Privacy](#)

[New Search](#)

Return to: [Search Results](#)

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