SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

NELSON LABORATORIES BOZEMAN, LLC[1]
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 *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*	
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

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

Test Technology	**Test Method**
Clinical Bactericidal Tests - *In Vivo* (cont.)	
Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products	ASTM E2752
Clinical Virucidal Tests - *In Vivo*	
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
Clinical Respirator Fit Test - *In Vivo*	
Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators	ASTM F3407
Bactericidal Tests - *In Vitro*	
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

Test Technology	**Test Method**
Virucidal Tests - *In Vitro*	
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 - *In Vitro*	
Standard Practices for Evaluation of Inactivators of Antimicrobial Agents	ASTM E1054
Wound Dressing Evaluation – *In Vitro*	
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.

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.

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.