CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Canyon Labs Holdings, LLC
16217 South Bringhurst Drive, Suite 600
Bluffdale, UT 84065

Fulfills the requirements of

ISO/IEC 17025:2017
and
Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21 CFR Part 58 Accreditation Program

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 25 October 2027

Certificate Number: AT-3031

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. 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).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM

Canyon Labs Holdings, LLC

16217 S Bringhurst Drive Suite 600
Bluffdale, UT 84065

Bo Rich 1-801-740-4253
bo.rich@canyonlabs.com

TESTING

ISO/IEC 17025 Accreditation Granted: **24 October 2025**

Certificate Number: **AT-3031** Certificate Expiry Date: **25 October 2027**

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
• Total Aerobic Count • Yeast Count • Mold Count • Standard Plate Count	USP <61>	Pharmaceutical, Medical Device, Environment	Incubator, BSC Class II, Plating
• Escherichia coli • Salmonella sp. • Staphylococcus aureus • Pseudomonas aeruginosa	USP <62>	Pharmaceutical, Medical Device	Incubator, BSC Class II, Plating
• Total Aerobic Count • Yeast Count • Mold Count • Standard Plate Count	USP <2021>	Cosmetics, Nutraceuticals	Incubator, BSC Class II, Plating

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
• Escherichia coli • Salmonella sp. • Staphylococcus aureus	USP <2022>	Cosmetics, Nutraceuticals	Incubator, BSC Class II, Plating
Biological Indicators (Population verification, BI sterility)	USP <55>, ISO 11138-1 to -4, ISO 11135, ISO 11138-7, ISO 14937, AAMI 17665, AAMI TIR 13, 14, 16	BIs, PCDs	BI Sterility Suite, ISO Class 5 Hoods, Incubator
Bacterial Endotoxins	AAMI ST72, USP <85>, USP<161>, USP<797>	Medical Devices, Pharmaceuticals	Cartridge technology
Bioburden	ISO 11737-1; USP <1227>	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods, Incubators
Product Sterility (Cleanroom and Isolator), MPN Method Suitability (Bacteriostatis/Fungistatis)	USP <71>, USP <797>, ISO 11737-2, ISO 11137-1 and –2, ISO 17665, AAMI TIR33, ISO 11135	Medical Devices, Pharmaceuticals, Biologics, Tissues	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
Gram Stain and Colony Morphology	FDA Bacteriological Analytical Manual Method R32	Medical Device, Materials, Pharmaceuticals	ISO Class 5 Hoods, Incubator, Microscopes
Incubation and Enumeration of Settle Plates, Surface Sampling Plates, or Active Air Plates	ISO 14698-1 USP<1116>	Environmental Monitoring	Incubators Macroscopic Observations

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Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Identification	USP <197A>	Pharmaceutical, Cosmetic, Medical Device, Environment, Foods, Nutraceuticals	FTIR
Ethylene Oxide (EO) Residual Analysis	ISO 10993-7	Medical Device	GC-FID

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Dye Penetration Testing Porous Materials	ASTM F1929 ISO 11607-1	Medical Device, Pharmaceutical	Dye Penetrant Solution
Dye Penetration Testing Nonporous Materials	ASTM F3039 ISO 11607-1	Medical Device, Pharmaceutical	
Gross Leak Testing with Internal Pressurization Testing (Bubble Test)	ASTM F2096 ISO 11607-1	Medical Device, Pharmaceutical	Bubble Tester
Leaks in Flexible Packaging by Bubble Emission Testing (Vacuum)	ASTM F3078	Medical Device, Pharmaceutical	Bubble Vacuum Tester
Internal Pressurization Failure Resistance Testing (Burst)	ASTM F1140	Medical Device, Pharmaceutical	Burst Tester
Visual Inspection	ASTM F1886	Medical Device, Pharmaceutical	Macroscopic Observations
Seal Strength of Flexible Barrier Materials (horizontal and vertical)	ASTM F88	Medical Device, Pharmaceutical	Tensile Tester
Sealable Pouches and Reels of Porous Materials and Plastic Film Construction	EN 868-5	Medical Device, Pharmaceutical	Tensile Tester
Test Method for Verifying Nonporous Flexible Barrier Material Resistance to the Passage of Air	ASTM F2981	Medical Device, Pharmaceutical	Densometer
Paper and board – Determination of air permeance (medium range) – Part 5: Gurley method	ISO 5636-5	Medical Device, Pharmaceutical	

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Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Abrasion Resistance of Printed Materials by the Sutherland Rub Tester	ASTM D5264	Medical Device, Pharmaceutical	Rub Tester
Practice for Conditioning Containers, Package, or Packaging Components for Testing	ASTM D4332	Medical Device, Pharmaceutical	Environmental Chamber
Conditioning and Testing Flexible Barrier Packaging	ASTM E171	Medical Device, Pharmaceutical	
Climatic Stressing of Packaging Systems for Single Parcel Delivery	ASTM F2825	Medical Device, Pharmaceutical	
Accelerated Aging of Sterile Barrier Systems and Medical Devices	ASTM F1980	Medical Device, Pharmaceutical	
Altitude Testing	ASTM D6653 ASTM D4169 ASTM D7386 ISTA 3A	Medical Device, Pharmaceutical	
Drop/Shock Testing	ASTM D5276 ASTM D4169 ASTM D7386 ISTA 1A / ISTA 1B ISTA 1C / ISTA 1D ISTA 1G / ISTA 1H ISTA 2A / ISTA 2B ISTA 2C / ISTA 3A ISTA 3B / ISTA 3F ISTA 3K / ISTA 3L ISTA 6-AMAZON.COM-OVERBOXING ISTA 6-AMAZON.COM-SIOC FEDEX A & B ISTA 6 SAMSCLUB	Medical Device, Pharmaceutical	Drop Tester

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Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Test Method for Bridge Impact Testing	ASTM D5265 ASTM D4169 ASTM D7386 ISTA 3A / ISTA 3B ISTA 3K ISTA 3L ISTA 6-AMAZON.COM-SIOC FEDEX A & B ISTA 6 SAMACLUB	Medical Device, Pharmaceutical	
Random Vibration Testing of Shipping Containers	ASTM D4728 ASTM D4169 ISTA 1C / ISTA 1D ISTA 1E / ISTA 1G ISTA 1H / ISTA 2A ISTA 2B / ISTA 2C ISTA 3A / ISTA 3B ISTA 3E / ISTA 3F ISTA 3H / ISTA 3K ISTA 3L ISTA 6-AMAZON.COM-OVERBOXING ISTA 6-AMAZON.COM-SIOC FEDEX A & B ISTA 6 SAMSCLUB	Medical Device, Pharmaceutical	Vibe Table
Vibration Testing of Shipping Containers	ASTM D999 ASTM D4169 ISTA 1A / ISTA 1B ISTA 1C / ISTA 1D ISTA 1E / ISTA 2A ISTA 2B	Medical Device, Pharmaceutical	

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Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads	ASTM D642 ASTM D4169 ISTA 1C / ISTA 1D ISTA 2A / ISTA 2B ISTA 3E / ISTA 3F ISTA 3H / ISTA 3L ISTA 6-AMAZON.COM_SIOC FEDEX A & B ISTA 6 SAMSCLUB	Medical Device, Pharmaceutical	Compressional Tester
Impact Testing for Shipping Containers and Systems	ASTM D880 ASTM D4169 ISTA 1 A/ ISTA 1B ISTA 1C / ISTA 1D ISTA 1E / ISTA 1G ISTA 1H / ISTA 2A ISTA 2B / ISTA 2C ISTA 3B / ISTA 3E ISTA 3K / ISTA 3L ISTA 6-AMAZON.COM_SIOC FEDEX B ISTA 6 SAMSCLUB	Medical Device, Pharmaceutical	Incline Impact Tester
Programmed Horizontal Impacts Using an Inclined Impact Tester	ASTM D5277	Medical Device, Pharmaceutical	

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Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Test Methods for Mechanical Handling of Unitized Loads and Large Shipping Cases and Crates	ASTM D6055 ASTM D 4169 ISTA 2F / ISTA 3 B ISTA 3L ISTA 6-AMAZON.COM-SIOC ISTA 6 SAMSCLUB	Medical Device, Pharmaceutical	Fork Truck
Concentrated Impact	ASTM D6344 ASTM D4169 ASTM D7386	Medical Device, Pharmaceutical	Cylindrical Mass

Jason Stine, Vice President

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