



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Canyon Rush, LLC
7500 West Henrietta Rd.
Rush, NY 14543

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: 24 August 2026

Certificate Number: AT-2068



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 ¹

Canyon Rush, LLC

7500 West Henrietta Rd.
Rush, NY 14543

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TESTING

ISO/IEC 17025 Accreditation Granted: 24 August 2024

Certificate Number: AT-2068

Certificate Expiry Date: 24 August 2026

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cytotoxic Reactivity ¹	CYT-3 based on USP <87> and ISO 10993-5	Textiles, Medical Devices	Incubator ISO Class 5 Hood CO2 incubator, Microscope
Biological Reactivity ¹	CYT-2 based on USP <87>, and ISO 10993-5	Textiles, Medical Devices	Incubator ISO Class 5 Hood CO2 incubator, Microscope
Bacterial Endotoxins (LAL) ¹	PYT-10 based on ANSI/AAMI ST72, ISO-11737-3	Medical Devices, Pharmaceuticals, Biologics	Incubator ISO Class 5 Hood Microplate Reader
MEM Elution ¹	CYT-1 based on USP <87>, ISO 10993-5, ISO 10993-12	Medical Devices, Pharmaceuticals, Biologics	ISO Class 5 Hoods Microscope Incubators
Acute Systemic Toxicity ¹	CLE-2 based on USP <88>, ISO 10993-11, ISO 10993-12, JP<7.03>	Medical Devices	Balance Incubator
Intracutaneous ¹	CLE-4 based on USP< 88>, CLE-5 based on ISO 10993-12, ISO 10993-23	Medical Devices, Pharmaceuticals, Biologics	Balance Incubator

This Scope of Accreditation, version 014, was last updated on: 28 July 2025 and is valid only when accompanied by the Certificate.

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1899 L Street NW, Suite 1100-A, Washington, DC 20036

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Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sensitization ¹	SST-1 based on ISO 10993-10, ISO 10993-12	Medical Devices, Pharmaceuticals, Biologics	Balance Incubator
Muscle Implantation ¹	CLE 6 based on USP <88>, CLE-8 based on ISO 10993-6	Medical Devices, Pharmaceuticals	Anesthesia Machine Calipers
Buehler Patch Sensitization Test ¹	SST-3 based on ISO 10993-12, ISO 10993-10	Medical Devices, Pharmaceuticals	Balance Incubator
Ocular Irritation Test ¹	CLE-7 based on ISO 10993-12, ISO 10993-23	Medical Devices, Pharmaceuticals	Slit Lamp Scale Incubator
General Safety Test	MDT-1 based on USP <88>	Medical Devices, Pharmaceuticals	Scale
Rabbit Pyrogen Test ¹	PYT-1 based on USP <151>, ISO 10993-11, ISO 10993-12 PYT-2 based on EP <2.6.8>	Medical Devices, Pharmaceuticals	Scale Incubator Temperature Probe
Hemolysis Test ¹	BCT-2 based on ISO 10993-4, ISO 10993-12, ASTM 756, ASTM F619	Medical Devices, Pharmaceuticals	Spectrophotometer Scale Incubator Centrifuge
Primary Skin Irritation Test ¹	SST-2 based on ISO 10993-12, ISO 10993-23	Medical Devices, Pharmaceuticals	Scale Incubator

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden	M-8 based on ANSI/AMMI/ISO 11737-1 M-9 based on ANSI/AAMI/ISO 11737-1	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicator Sterility	S-2 based on ANSI/AAMI/ISO 11737-2	BI's, PCD's	Sterility Suite ISO Class 5 Hoods Incubator
Product Sterility	S-2 based on USP <71>, ANSI/AAMI/ISO 11737-2, ANSI/AAMI/ISO 11137-1 and 11137-2, AAMI TIR33	Medical Devices, Pharmaceuticals, Biologics, Tissues	Sterility Suite ISO Class 5 Hoods Incubator

Microbiological

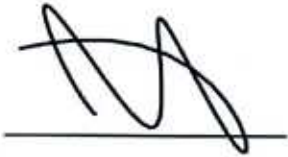
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacteriostasis / Fungistasis	M-12, based on USP <71>	Medical Devices, Pharmaceuticals, Biologics, Tissues	Incubator
Population Determination	M-6 based on USP <55>	BI's	Incubator, Colony Counter
Heterotrophic Plate Count (Water) Test	M-1 based on USP <1231>	Water	Incubator, Colony Counter

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	CA-2 based on ANSI/AAMI/ISO 10993-7	Medical Devices	Gas Chromatograph, FID Balance Incubator

Note:

1. Biological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.



Jason Stine, Vice President