ANAB

ANSI National Accreditation Board

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

ANAB

ANSI National Accreditation Board

ilac-MRA

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).

ANSI National Accreditation Board

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

Nancy Rakiewicz 585-233-1354
Nancy.Rakiewicz@canyonlabs.com

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

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414-501-5494
www.anab.org

ANSI National Accreditation Board ilac-MRA

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-1based 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

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