

Registrations, Licenses and Accreditations

Organization / Agency	Description	Identification #	Expiration Date
ANSI National Accreditation Board (ANAB)	ISO 17025 Accreditation AT-3031		October 25, 2023
FDA Center for Drug Evaluation and Research (CDER)	n and Establishment Registration 3021085128		December 31, 2022
FDA Center for Biologics Evaluation and Research (CBER)	Human Cells, Tissues and Cellular Based Products (HCTP) Establishment Registration	3021085128	December 31, 2022
FDA Office of Human Research Protections (OHRP)	Institutional Review Board (IRB) Registration	IRB00013374	December 31, 2022
Generic Drug User Fee Amendments (GDUFA)	Generic Drug Self Identification Letter (FY 2022)	Self-Identification Letter	December 31, 2022
State of Utah Division of Occupational & Professional Licensing (DOPL)	Class E Pharmacy License	12389808-1714	September 30, 2023
State of Utah Division of Occupational & Professional Licensing (DOPL)	Controlled Substance License	12389808-8915	September 30, 2023
Centers for Medicare and Medicaid Services (CMS)	l (TIA Certificate of Waiver		January 24, 2024



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Canyon Labs LLC 505 West Ultradent Drive South Jordan, UT 84095

Fulfills the requirements of

ISO/IEC 17025:2017

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.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 25 October 2023 Certificate Number: AT-3031





SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Canyon Labs LLC

505 West Ultradent Drive South Jordan, UT 84095

Marianne Brady 358-337-6311

marianne.brady@canyonlabs.com www.canyonlabs.com

TESTING

Valid to: October 25,2023 Certificate Number: AT-3031

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, ISO Class 5 Hood, Pour Plating
 Escherichia coli Salmonella sp. Staphylococcus aureus Pseudomonas aeruginosa 	USP <62>	Pharmaceutical, Medical Device	Incubator, BSC Class II, ISO Class 5 Hood, Direct Plating



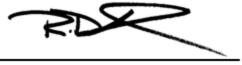


Chemical

Specific Tests and/or	Specification, Standard,	Items, Materials or	Key Equipment or
Properties Measured	Method, or Test Technique	Product Tested	Technology
Identification	USP <197A>	Pharmaceutical, Cosmetic, Medical Device, Environment	

Note:

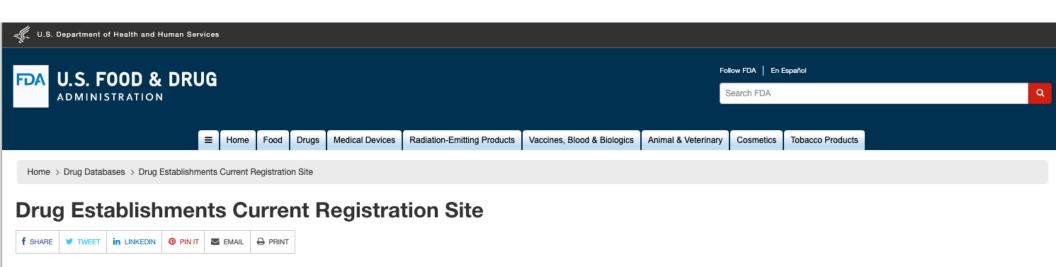
1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT -3031.



R. Douglas Leonard Jr., VP, PILR SBU







New Search

Search Results for canyon



Previous

Next

Showing 1 to 1 of 1 entries

Data Current through: Wednesday, Jan 26, 2022

Return to Drug Firm Annual Registration Status Home Page

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

Ext.:

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

Legal Name and Location:

Canyon Laboratories, LLC

Bluffdale, Utah 84065

Phone: 385-337-6311

USA

16217 S. Bringhurst Blvd Suite 600

FEI: 3021085128

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Initial Registration/Listing Last Annual Registration Year: 2022 Last Registration Receipt Date: 01/27/2022 Summary Report Print Date: 01/27/2022

Reporting Official:

Marianne Brady, Head of Quality & Regulatory Compliance

16217 S. Bringhurst Blvd Suite 600

Bluffdale, Utah 84065

Phone: 385-337-6311 Ext. marianne.brady@canyonlabs.com Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

Establishment Functions Date of Date of Proprietary Name(s) HCT/P(s) Donor Type(s) Screen Donor Testina Package Process Store Distribute Label Resumption Discontinuance Amniotic Membrane Blood Vessel Bone Cardiac Tissue - non-valved Cartilage Cornea Dura Mater Embryo Fascia Heart Valve **HPC Apheresis** HPC Cord Blood Ligament Nerve Tissue Oocyte Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid Pericardium Peripheral Blood Mononuclear Cells Peritoneal Membrane Sclera Semen Skin Tendon Testicular Tissue Χ Tooth Pulp Χ **Umbilical Cord Tissue**



New Search

Return to: Search Results

IRB Organization Information

IORG0011272 - Canyon Labs (Active)

Located at: Bluffdale, UTAH Expires: 01/12/2025

IRBs for this Organization: 1

Agency Only Access

IRB#	IRB Name	<u>City</u>	State/Country	<u>Status</u>	IRB Type
IRB00013374	Canyon Labs IRB #1 - Behavioral, Biomedical	Bluffdale	UTAH	Active	OHRP/FDA



Generic Drug User Fee Amendments (GDUFA) Generic Drug Self Identification FY 2022

Canyon Laboratories, LLC performs laboratory testing services for the medical device, pharmaceutical, cosmetic, dietary supplement, natural products, food, and beverage industries.

This document confirms Canyon Labs has electronically self-identified with the United States Food and Drug Administration (FDA) for FY 2022 and complies with requirements for testing human generic drugs, identified within the Generic Drug User Fee Amendments (GDUFA) of 2012.

Establishment	Address	DUNS #	FEI#
Canyon Laboratories, LLC	16217 S. Bringhurst Blvd Suite 600 Bluffdale, UT 84065	117919762	3021085128

Marianne Brady

Director of Quality & Compliance

Canyon Laboratories, LLC

Marianne Brady

STATE OF UTAH DEPARTMENT OF COMMERCE ACTIVE LIMITED LICENSE

Canyon Laboratories, LLC

EFFECTIVE EXPIRATION 08/17/2021 09/30/2023

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

12389808-1714 Pharmacy - Class E Business 12389808-8915 Limited Controlled Substance-Business

12387808-8713 Ellinea Controllea Sub

Analytical Laboratory

DBA: CANYON LABS

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

CANYON LABORATORIES, LLC 16217 S BRINGHURST BLVD STE 600 RIVERTON UT 84065 Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LIMITED LICENSE

EFFECTIVE DATE: 08/17/2021

EXPIRATION DATE: 09/30/2023

ISSUED TO: Canyon Laboratories, LLC

16217 S Bringhurst Blvd Ste 600

Riverton UT 84065



REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

12389808-1714 Pharmacy - Class E Business 12389808-8915 Limited Controlled Substance-Business

Analytical Laboratory

DBA: CANYON LABS



SPENCER J. COX Governor

DEIDRE HENDERSON Lieutenant Governor

Utah Department of Health Richard G. Saunders Executive Director

Division of Disease Control and Prevention Andreas Rohrwasser, PhD, MBA Director, Utah Public Health Laboratory

January 25, 2022

Canyon Labs 16217 S. Bringhurst Boulevard, Suite 600 Bluffdale, Utah 84065

CLIA #46D2250085

Dear Director:

I received your application for a CLIA Certificate of Waiver. Your application, has been processed. You certificate will expire on 1/24/2024.

With a Certificate of Waiver, you may perform any or all CLIA waived tests. A list of CLIA waived tests is available at www.cms.gov/clia. You must follow the manufacturer's instructions for use exactly as written and keep a current package insert on file. You will be billed by the Centers for Medicare and Medicaid Services (CMS) for your certificate in a few days. You may begin patient testing as soon as CMS receives your payment.

I have also attached a Quality Assurance aid for Certificate of Waiver laboratories. Please notify me at 801-965-2588 or by email at cmitchell@utah.gov if you have questions.

Respectfully,

Office Specialist II

Certification & Approval Section

