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)	Analytical Lab 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)	CLIA Certificate of Waiver	46D2250085	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

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

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 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	FTIR

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

Drug Establishments Current Registration Site

New Search

Search Results for **canyon**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Canyon Laboratories, LLC	3021085128	117919762	ANALYSIS;	16217 S. Bringhurst Blvd Suite 600, Bluffdale, Utah (UT) 84065, United States (USA)	12/31/2022

Showing 1 to 1 of 1 entries

Previous 1 Next

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

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

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

Legal Name and Location:

Canyon Laboratories, LLC
16217 S. Bringhurst Blvd Suite 600

Bluffdale, Utah 84065
USA

Phone: 385-337-6311 **Ext.:**

Reporting Official:

Marianne Brady, Head of Quality & Regulatory Compliance
16217 S. Bringhurst Blvd Suite 600
Bluffdale, Utah 84065
USA
Phone: 385-337-6311 Ext.
marianne.brady@canyonlabs.com

Satellite Recovery Establishment: No
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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
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												
Tooth Pulp							X					
Umbilical Cord Tissue							X					

FDA information collection OMB Control number: 0910-0543, expiration date: 07/31/2023

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	City	State/Country	Status	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

Marianne Brady
Director of Quality & Compliance
Canyon Laboratories, LLC

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Canyon Laboratories, LLC

EFFECTIVE **08/17/2021**

EXPIRATION **09/30/2023**

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

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

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

State of Utah
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,

Cathy Mitchell

Cathy Mitchell
Office Specialist II
Certification & Approval Section