



# CERTIFICATE OF ACCREDITATION

## ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

**Infinity Laboratories**  
**1585 South Perry Street, Suite B**  
**Castle Rock, CO 80104**

has been assessed by ANAB  
and meets the requirements of international standard

## ISO/IEC 17025:2005

while demonstrating technical competence in the field of

## TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-1982

Certificate Number



ANAB Approval

Certificate Valid: 08/31/2017-09/02/2019  
Version No. 004 Issued:08/31/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 17025:2005

Infinity Laboratories

1585 South Perry Street, Suite B

Castle Rock, CO 80104

Dan Henderson 303 730 7330

dhenderson@infinitylaboratories.com www.infinitylaboratories.com

TESTING

Valid to: September 2, 2019

Certificate Number: AT-1982

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Antimicrobial Agent Content	USP <341>	Pharmaceuticals	High Performance Liquid Chromatography, Gas Chromatography
Conductivity	USP <645>	USP Water	Conductivity Meter
Ethylene Oxide (EtO) Residual Analysis	USP <621> ISO 10993-7	Medical Devices	Gas Chromatography
pH	USP <791>	Pharmaceuticals	pH Meter
Potency/Purity	USP <621> USP <1225>	Pharmaceuticals	High Performance Liquid Chromatography, Gas Chromatography
Total Organic Carbon	USP <643>	USP Water	TOC Analyzer

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Antimicrobial Effectiveness	USP <51>	Pharmaceuticals	Biological Safety Cabinets, Incubators
Bacterial Endotoxins	USP <85>	Medical Devices, Pharmaceuticals, Tissue	Microplate Reader
Bioburden	ISO 11737-1 ISO 11737-2 ISO 11137-1 ISO 11137-2	Medical Devices, Pharmaceuticals, Tissue	Biological Safety Cabinets, Incubators

**Microbiological**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Biological Indicator Population Verification	USP <55>	Biological Indicators	Biological Safety Cabinets, Incubators
Biological Indicator Sterility	ISO 11135	Biological Indicators	Biological Safety Cabinets, Incubators
Coliform Detection	USP <1231> Standard Methods for the Examination of Water and Wastewater	Water	Biological Safety Cabinets, Incubators
Heterotrophic Plate Count	USP <1231> Standard Methods for the Examination of Water and Wastewater	Water	Biological Safety Cabinets, Incubators
Method Suitability	USP <71> ISO 11737-2	Medical Devices, Pharmaceuticals	Biological Safety Cabinets, Incubators
Microbiological Examination of Nonsterile Products (Enumeration and Specified Organisms)	USP <61> USP <62>	Pharmaceuticals	Biological Safety Cabinets, Incubators
Microorganism Identification (Genetic and Gram Stain)	USP <1113>	Environmental Samples, Medical Devices, Pharmaceuticals	Genetic Analyzer, Thermal Cycler, Incubators, Microscope
Product Sterility	USP <71> ISO 11737-2 ISO 11137-1	Medical Devices, Pharmaceuticals	ISO Class 7 Cleanroom, ISO Class 5 Biological Safety Cabinets, Incubators

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1982.



Vice President

