

# CERTIFICATE OF ACCREDITATION

# The ANSI National Accreditation Board

Hereby attests that

Infinity Laboratories 1127 N. McDowell Blvd. Petaluma, CA 94954

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 <a href="https://www.anab.org">www.anab.org</a>.

Jason Stine, Vice President

Expiry Date: 12 October 2025 Certificate Number: AT-3247





#### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

### **Infinity Laboratories**

1127 N. McDowell Blvd. Petaluma, CA 94954

Kerlene Grounder 707-520-4500 Ext. 3

<u>kgounder@infinitylaboratories.com</u> <u>www.infinitylaboratories.com</u> Jordan Fujioka 510-673-5159 <u>jfujioka@infinitylaboratories.com</u>

### **TESTING**

Valid to: October 12, 2025 Certificate Number: AT-3247

#### Microbiological

Version 001 Issued: October 12, 2023

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Environmental Monitoring	ISO 14644-4; ISO 14644-2; ISO 14698-1; ISO 14698-2	Controlled Areas & Utilities	Particle Counters, Air Samplers, Gas Detector Tubes, Hygrometers, Incubators, Drager Tubes
Incubation and Enumeration	ISO 11737-1; ISO 14644-1	Viable Air, Viable Surface, Personnel, Utilities	Incubators
Bacterial Endotoxin Testing	ANSI/AAMI ST72; USP <85>; USP <161>	Medical Devices, Liquids, Raw Materials, Laboratory Products	Depyrogenation Oven, Shakers, Incubator, Bio-Tek ELx 808
Bioburden	ISO 11737-1	Medical Devices, Liquids, Raw Materials, Laboratory Products	Autoclave, LFH, Vacuum Pump and Filtration Pump Manifold, Incubators
Method Suitability Testing	ISO 11737-2; USP <71>	Medical Devices, Liquids, Raw Materials, Laboratory Products	Autoclave, LFH, Vacuum Pump and Filtration Pump Manifold, Incubators
Bacteriostasis and Fungistasis Testing	ISO 11737-2; USP <71>	Medical Devices, Liquids, Raw Materials, Laboratory Products	Autoclave, LFH, Vacuum Pump and Filtration Pump Manifold, Incubators
Product Sterility	ISO 11737-2; ISO 11135; ISO 11137-1; AAMI TIR33; 21 CFR 610.12; USP <71>	Medical Devices, Liquids, Raw Materials, Laboratory Products	ISO Class 7 CER and BSC, Incubators
Biological Indicator Sterility	ISO 11138	Biological Indicators	LFH, BSC, Incubators





#### Microbiological

Specific Tests and/or	Specification, Standard,	Items, Materials or	Key Equipment or
Properties Measured	Method, or Test Technique	Product Tested	Technology
DNase / RNase Testing	Ambion DNase and RNase	Liquid <mark>s</mark> , Raw Materials,	Biotek Synergy HT Plate
	Alert QC System	Labo <mark>ra</mark> tory Products	Reader

#### Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-3247.

Jason Stine, Vice President



