

CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Eurofins Infinity Laboratory Group Inc.

10151 Pacific Mesa Blvd., Suite 107 San Diego, CA 92121

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.

Jason Stine, Vice President

Expiry Date: 19 October 2026 Certificate Number: AT-2916





SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Eurofins Infinity Laboratory Group Inc.

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TESTING

Valid to: October 19, 2026 Certificate Number: AT-2916

Chemical

Specific Tests and/or Properties Measured	Specificat <mark>ion, Standard,</mark> Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Total Organic Carbon	USP <643>	USP Water	TOC Analyzer
Conductivity	USP <645>	USP Water	Conductivity Meter
pН	USP <791>	USP Water	pH Meter
Nitrates Testing (Presence)	EP Chapter 5.0 Water, Purified	Purified Water	Fume Hood, Reagent, and Standards

Microbiological

Version 008 Issued: October 11, 2024

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	USP <85> USP <161> ISO 11737-3	Water, Laboratory Products Endotoxin Standard and Lysate Medical Devices	Portable Testing System Microplate Reader
Bioburden	ISO 11737-1	Medical Devices	Biological Safety Cabinets, Incubators
Biological Indicator Sterility	USP <55>	Biological Indicators	Biological Safety Cabinets, Incubators
Coliform Detection	SM 9222	Water	Biological Safety Cabinets, Incubators
Heterotrophic Plate Count	USP <1231> CLSI C3-A4	Water	Biological Safety Cabinets, Incubators
Method Suitability	ISO 11737-2	Medical Devices	Biological Safety Cabinets, Incubators





Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Microbiological Examination of Nonsterile Products (Enumeration)	USP <61>	Laboratory Products	Biological Safety Cabinets, Incubators
Mycoplasma Detection	USP <1223>	Seru <mark>m, M</mark> edia, Cells	PCR System, Biological Safety Cabinets
Microorganism Identification (Genetic and Gram Stain)	USP <1113>	Environmental Samples, Medical Devices, Pharmaceuticals	Genetic Analyzer, Thermal Cycler, Incubators, Microscope
Product Sterility	ISO 11737-2	Medical Devices	ISO Class 7 Cleanroom, ISO Class 5 Biological Safety Cabinets, Incubators

Sample Collection - Environmental

Items, Materials or Product Sampled	Component, Parameter or Characteristic Sampled	Specification, Standard, Method, or Sampling Technique
Controlled Environment	Nonviable Air	WI-SD-001 (based on USP <1116> and ISO 14644-1)
Controlled Environment	Viable Air	WI-SD-002 (based on USP <1116> and ISO 14644-1)
Controlled Environment	Viable Surface	WI-SD-003 (based on USP <1116> and ISO 14644-1)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2916.

Jason Stine, Vice President

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