



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Pacific BioLabs
551 Linus Pauling Dr.
Hercules, CA 94547

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.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 25 March 2023
Certificate Number: AT-2661



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

Pacific BioLabs

551 Linus Pauling Dr.
Hercules, CA 94547

Thomas Chambers 510-964-9000
thomaschambers@pacificbiolabs.com
www.pacificbiolabs.com

TESTING

Valid to: **March 25, 2023**

Certificate Number: **AT-2661**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Biocompatibility			
Intramuscular Implant Test	ISO 10993-6 USP <88>	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Balance
Acute Systemic Toxicity Test	ISO 10993-11 USP <88>	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators and Ovens Balance
Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10 USP <88>	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators and Ovens
Rabbit Pyrogen Test	ISO 10993-11; USP <151>, European Pharmacopoeia	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Thermometer
Safety Test for Biological Products	USP <88>	Biologics	Balance



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Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Closed Patch Test for Delayed-Type Hypersensitivity Maximization Test for Delayed-Type Hypersensitivity Skin Sensitization-Buehler Method	ISO 10993-10 OECD 406	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators and Ovens
Mucosa, Ocular, Dermal Irritation	ISO 10993-10, EPA/OPPTS 870.2500, EPA/OPPTS 870.2400, FHSA/16 CFR 1500.41, FSHA/16 CFR 1500.42, OECD 404, OECD 405	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators and Ovens
Acute, Dermal, Oral Toxicity	ISO 10993-11, Iron Dextran Injection USP Monograph, EPA/OPPTS 870.1200, EPA/OPPTS 870.1100, FHSA, OECD 402, OECD 420, European Pharmacopoeia	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators and Ovens
Bioassay			
Glucagon Assay	USP <123>	Pharmaceutical, Biologics	Clinical Chemistry Analyzer
Insulin Assay for Human Insulin – Bioidentity	USP <121>	Pharmaceutical, Biologics	Clinical Chemistry Analyzer
Cleaning & Disinfection Studies			
Medical Device Cleaning Validations	AAMI TIR12; AAMI TIR30	Medical Devices, Combination Devices,	Microplate Reader Spectrophotometer
Steam Sterilization Validation, Biological Indicators	ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 14161	Medical Devices, Combination Devices,	Incubators
Cytotoxicity			
Agar Diffusion	USP <87>; ANSI/AAMI/ISO 10993-5	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators, Microscope

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Elution	USP <87>; ANSI/AAMI/ISO 10993-5	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators, Microscope
Direct Contact	USP <87>; ANSI/AAMI/ISO 10993-5	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubators, Microscope
LAL Bacterial Endotoxins	USP <85> and <161>; ANSI/AAMI ST72:2011; EP 2.6.14, Bacterial Endotoxins	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Incubating Absorbance Microplate Reader

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>	Chemicals, Pharmaceuticals, Biologics	ISO Class 5 Biosafety Cabinets
Bacteriostasis / Fungistasis Sterility	USP <71>	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Membrane Filtration/Direct Transfer
Bioburden	USP <61>; ANSI/AAMI/ISO 11737-1	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	Laminar Air Flow Hood
Sterility Assurance	Sterility AAMI TIR 33, Sterility ANSI/AAMI/ISO 11137-2 Method 1, Sterility ANSI/AAMI/ISO 11137-2, Sterility AAMI/ISO TIR 15844, ANSI/AAMI/ISO 11737-2	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	ISO Class 5 Biosafety Cabinets, ISO 5 through 8 Areas
Microbial Enumeration Testing for Specified Microorganisms	USP <61>; USP <62>; USP <1111> EP/BP	Medical Devices, Combination Devices, Chemicals, Pharmaceuticals, Biologics	ISO Class 5 Biosafety Cabinets, Incubators

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Conductivity	USP <645>	Pharmaceutical Water	Conductivity Analyzer
Total Organic Carbon	USP <643>	Pharmaceutical Water	Total Organic Carbon Analyzer
Extractable Leachable Testing	ISO 10993-18	Medical Devices, Combination Medical Devices	ICP-MS HPLC GC-MS

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2661.



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