



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

Pacific BioLabs
551 Linus Pauling Dr.
Hercules, CA 94547

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

ISO/IEC 17025:2017

while demonstrating technical competence in the field of

TESTING

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

AT-2661

Certificate Number


ANAB Approval

Certificate Valid Through: 03/25/2021
Version No. 001 Issued: 03/25/2019



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).



ANSI National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Pacific BioLabs

551 Linus Pauling Dr.
Hercules, CA 94547

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TESTING

Valid to: **March 25, 2021**

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

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 ²	USP <121>	Pharmaceutical, Biologics	Clinical Chemistry Analyzer
Cleaning & Disinfection Studies			
Medical Device Cleaning Validations	AAMI TIR12:2010; AAMI TIR30:2011	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- 1:2006	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	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

Note:

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



Vice President

