



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

PACIFIC BIOLABS
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BIOLOGICAL

Valid To: April 30, 2025

Certificate Number: 7312.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on medical devices, pharmaceuticals, and water:

<u>Test(s):</u>	<u>Test Method(s):</u>
Biocompatibility	
Intramuscular Implant Test	ISO 10993-6; USP <88>
Acute Systemic Toxicity Test	ISO 10993-11; USP <88>
Intracutaneous (Intradermal) Reactivity Test	ISO 10993-23; USP <88>
Rabbit Pyrogen Test	ISO 10993-11; <USP 151>, European Pharmacopoeia
Safety Test for Biological Products	USP <88>
Closed Patch Test for Delayed-Type Hypersensitivity	ISO 10993-10; OECD 406
Maximization Test for Delayed-Type Hypersensitivity Sken Sensitization-Buehler Method	ISO 10993-10
Mucosa, Ocular, Dermal Irritation	ISO 10993-23; EPA/OPPTS 870.2500; EPA/OPPTS 870.2400; FHSA/16 CFR 1500.41, FSHA/16 CFR 1500.42; OECD 404, OECD 405
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
Bioassay	
Glucagon Assay	USP <123>
Insulin Assay for Human Insulin - Bioidentity	USP <121>
Cleaning and Disinfection Studies	
Medical Device Cleaning Validations	AAMI TIR12; AAMI TIR30
Steam Sterilization, Biological Indicators	ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO 14161
Cytotoxicity	
Agar Diffusion	USP <87>; ANSI/AAMI/ISO 10993-5

<u>Test(s):</u>	<u>Test Method(s):</u>
Elution	USP <87>; ASNSI/AAMI/ISO 10993-5
Biological	
Direct Contact	USP <87>; ANSI/ AAMI/ISO 10993-5
LAL Bacterial Endotoxins	USP <85> and <161>; ANSI/AAMI ST72:2011. EP 2.6.14, Bacterial Endo toxins
Microbiological	
Antimicrobial Effectiveness	USP <51>
Bacteriostasis / Fungistasis Sterility	USP <71>
Bioburden	USP <61>; ANSI/AAMI/ISO 11737-1
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
Microbial Enumeration Testing for Specified Microorganisms	USP <61>; USP <62>; USP <1111> EP/BP

CHEMICAL

<u>Test(s):</u>	<u>Test Method(s):</u>
Chemical	
Conductivity	USP <645>
Toxic Organic Carbon	USP <643>
Extractable Leachable Testing	ISO 10993-18



Accredited Laboratory

A2LA has accredited

PACIFIC BIOLABS

Hercules, CA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. 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).



Presented this 15th day of May 2024.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7312.01
Valid to April 30, 2025
Revised on January 21, 2025

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.