



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

PACIFIC BIOLABS
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BIOLOGICAL

Valid To: January 31, 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 13th day of May 2024.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7312.01
Valid to January 31, 2025