SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

PACIFIC BIOLABS
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BIOLOGICAL

Valid To: January 31, 2027 Certificate Number: 7312.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance to the requirements of A2LA *R256 - Specific Requirements - FDA ASCA Program*), accreditation is granted to this laboratory to perform the following tests on medical devices, pharmaceuticals, and water:

| **Test(s):** | **Test Method(s):** |
|---|---|
| **Biocompatibility** | |
| Sample Preparation | 10993-12 |
| Intramuscular Implantation 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 |
| Maximization Test for Delayed-Type Hypersensitivity Sken Sensitization-Buehler Method | ISO 10993-10 |
| Mucosa, Ocular, Dermal Irritation | ISO 10993-23 |
| Iron Dextran Injection | USP Monograph |
| Acute Oral Toxicity - Limit Test | EPA/OPPTS 870.1100 |
| **Bioassay** | |
| Glucagon Assay | USP <123> |
| Insulin Assay for Human Insulin - Bioidentity | USP <121> |
| **Cleaning and Disinfection Studies** | |
| Medical Device Cleaning Validations | AAMI TIR12 |
| Steam Sterilization, Biological Indicators | ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO 14161 |
| **Cytotoxicity** | |
| Agar Diffusion | USP <87>; ANSI/AAMI/ISO 10993-5 |
| Direct Contact | USP <87>; ANSI/ AAMI/ISO 10993-5; ANSI/AAMI/ISO 10993-12 |

| **Test(s):** | **Test Method(s):** |
|---|---|
| Elution | USP <87> USP <88>; ASNSI/AAMI/ISO 10993-5; ISO 10993-1; ANSI/AAMI/ISO 10993-12 |
| **Biological** | |
| 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; USP<71> |
| Microbial Enumeration Testing for Specified Microorganisms | USP <61>; USP <62>; USP <1111> EP/BP |

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA *R256 Specific Requirements - FDA ASCA Program*

| **FDA Recognition Number** | **Standard Method(s)[1]** | **Test Method & Procedure** | **Exclusions** |
|---|---|---|---|
| 2-255; 2-295 | ISO 10993-11 Third Edition 2017-09; USP<151> | Material-Mediated Pyrogenicity (SOP 16E-02) | N/A |
| 2-255 | 10993-11 Third edition 2017-09 | Acute Systemic Toxicity (SOP 16E-03 and 16G-63) | N/A |
| 2-245 | 10993-5 Third edition 2009-06-01; USP<87> | MEM Elution Cytotoxicity (SOP 15B-01 and 15B-10) | N/A |
| 2-191 | 10993-12 Fifth edition 2021-01 | Sample Preparation(SOP 16G-61 and 16E-14) | N/A |

[1]These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA. A list of approved laboratories can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm.

CHEMICAL

| **Test(s):** | **Test Method(s):** |
|---|---|
| **Chemical** | |
| Conductivity | USP <645> |
| Total 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 laboratory also meets the requirements of A2LA *R256 - Specific Requirements - FDA ASCA Program*. 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 28th day of March 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7312.01
Valid to January 31, 2027

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