



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

American Preclinical Services
8945 Evergreen Boulevard
Minneapolis, MN 55433

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 tests to which this accreditation applies.

L2348

Certificate Number



ANAB Approval

Certificate Valid: 12/19/2018-12/21/2021
Version No. 002 Issued: 12/19/2018



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

American Preclinical Services

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 Minneapolis, MN 55433
 Sarah Bronstad 763-951-8087
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TESTING

Valid to: **December 21, 2021**

Certificate Number: **L2348**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mammalian Erythrocyte Micronucleus Test	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 474)	Finished Medical Devices, and Drugs	Genotoxicity
Guinea Pig Maximization Test	ISO 10993-10 BS/EN/ISO 10993-10 PFSB/ELD/OMDE Notification No. 0301-20, Part 5	Finished Medical Devices, and Drugs	Sensitization
Closed-Patch Test (Buehler)	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Sensitization
Animal Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Intracutaneous Reactivity Test	ISO 10993-10 BS/EN/ISO 10993-10 USP 88 PFSB/ELD/OMDE Notification No. 0301-20, Part 5	Finished Medical Devices, and Drugs	Irritation
Vaginal Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Primary Buccal (mucosal) Irritation Test	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Irritation
Acute Systemic Toxicity Test	ISO 10993-11 BS/EN/ISO 10993-11 USP 88 PFSB/EDL/OMDE Notification	Finished Medical Devices, and Drugs	Systemic Toxicity

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Materials Mediated Pyrogenicity Test; Rabbits	ISO 10993-11 BS/EN/ISO 10993-11 USP 151	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Implant Method)	ISO10993-11 BS/EN/ISO 10993-11 ISO10993- 6 BS/EN/ISO 10993-6	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Repeated Exposure Method)	ISO10993- 11 BS/EN/ISO 10993-11	Finished Medical Devices, and Drugs	Systemic Toxicity
Thrombogenicity Test	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Implantation Test	ISO 10993-6 BS/EN/ISO 10993-6	Finished Medical Devices, and Drugs	Local Tissue Effects
Agar Overlay; Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
Direct Contact Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MEM Elution Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MTT Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Neutral Red Uptake Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Colony Formation Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 PFSB/ELD/OMDE Notification No. 0301-20, Part 1	Finished Medical Devices, and Drugs	Cytotoxicity
In-Vitro Skin Sensitization Assay; Human Cell Line Activation Test	OECD 442E	Drugs	Sensitization
Direct Peptide Reactivity Assay	OECD 422C	Finished Medical Devices, and Drugs	Sensitization
In-Vitro Skin Irritation Assay	OECD 439	Finished Medical Devices Drugs	Irritation

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Hemolysis Assay Extract Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756 PFSB/ELD/OMDE Notification No. 0301-20, Part 8	Finished Medical Devices, and Drugs	Hemocompatibility
Hemolysis Assay; Direct Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756 NIH	Finished Medical Devices, and Drugs	Hemocompatibility
Partial Thromboplastin Time (PPT) Assay	ISO 10993-4 EN/SIO 10993-4 ASTM F2382	Finished Medical Devices, and Drugs	Hemocompatibility
Prothrombin Time Assay	ISO 10993-4 BS/EN/ISO10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; SC5b-9 Method	ISO 10993-4 BS/EN/ISO10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; C3a Method	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
ASTM Platelet and Leukocyte Count Assay	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F2888	Finished Medical Devices and Drugs	Hemocompatibility
Heparinized Blood Platelet and Leukocyte Count Assay	ISO10993- 4 BS/EN/ISO 10993-4 ASTM F2888	Finished Medical Devices, and Drugs	Hemocompatibility
In Vitro Blood Loop Assay (Ovine Blood)	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices and Drugs	Hemocompatibility
In Vitro Human Blood Loop Assay	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Bacterial Endotoxin: Kinetic Chromogenic LAL Method	USP 85 USP 161	Finished Medical Devices, and Drugs	Endotoxin
Ames Bacterial Reverse Mutation Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 471) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mouse Lymphoma Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 476) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity
Chromosome Aberration Assay	ISO 10993-3 BS/EN/ISO 10993-3 (OECD 473) PFSB/ELD/OMDE Notification No. 0301-20, Part 3	Finished Medical Devices, and Drugs	Genotoxicity

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	High-Performance Liquid Chromatography (HPLC)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Inductively Coupled Plasma Mass Spectrometry (ICPMS)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Fourier Transform Infrared Spectroscopy (FTIR)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Gas Chromatography Mass Spectrometry (GCMS)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2348.



Vice President