CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Labcorp Bedford, LLC
15-25 Wiggins Avenue
Bedford, MA 01730
(and satellite location as listed on the scope)

Fulfills the requirements of

ISO/IEC 17025:2017
and
FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices
and
Good Laboratory Practice for Nonclinical Laboratory Studies, Title 21 CFR Part 58 Accreditation Program

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President
Expiry Date: 24 July 2024
Certificate Number: AT-1340

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

FDA ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT PROGRAM – BIOCOMPATIBILITY TESTING OF MEDICAL DEVICES[1]

GOOD LABORATORY PRACTICE for NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM[2]

Labcorp Bedford, LLC

15-25 Wiggins Avenue
Bedford, MA 01730

781-275-3330
Randi LaMadeleine felice.lamadeleine@labcorp.com
Christopher Parker christopher.parker1@labcorp.com

TESTING

Valid to: **July 24, 2024** Certificate Number: **AT-1340**

Testing to meet the requirements of ANAB supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Biocompatibility Testing of Medical Devices [1,2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Complement Activation using a U.S. marketed ELISA kit	ISO 10993-4 Third edition, 2017-04 (FDA Registration No. 2-248); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	ELISA, plate reader, incubators, laminar hood, balance, calipers, waterbath
Direct and Indirect Hemolysis	ISO 10993-4 Third edition, 2017-04 (FDA Registration No. 2-248); ASTM F756-17 (FDA Registration No. 2-250); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Spectrophotometer, incubators, laminar hood, balance, calipers, waterbath

Testing to meet the requirements of ANAB supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Biocompatibility Testing of Medical Devices [1,2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
MEM Elution Cytotoxicity	ISO 10993-5 Third edition 2009-06-01 (FDA Registration No. 2-245); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Incubators, microscope, laminar hood, balance, calipers
Dermal Irritation, and Intracutaneous Reactivity Irritation	ISO 10993-23 First edition 2021-01-01 (FDA Registration No. 2-291); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Animal systems – clinical observations, incubators, laminar hood, balance, calipers
Guinea Pig Maximization (Kligman) Sensitization and Closed Patch Sensitization	ISO 10993-10 Fourth edition 2021-11-01 (FDA Registration No. 2-147); ASTM F720-17 (FDA Registration No. 2-256); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Animal systems – clinical observations, incubators, laminar hood, balance, calipers
Acute Systemic Toxicity	ISO 10993-11 Third edition 2017-09 (FDA Registration No. 2-255); ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Animal systems – clinical observations, incubators, laminar hood, balance, calipers
Material-Mediated Pyrogenicity	ISO 10993-11; Third edition 2017-09 (FDA Registration No. 2-255); USP <151>; 43-NF38:2020 (FDA Registration No. 2-295) ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)	Medical Devices	Animal systems, thermometer readings, clinical observations, incubators, laminar hood, balance, calipers

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for Genotoxicity	ISO 10993-3 Bacterial Reverse Mutation (Ames) Test (OECD 471) SOP 6.1.11 In Vitro Mammalian Chromosome Aberration Test (OECD 473) SOP 6.1.32; 6.1.32.1 Mammalian Erythrocyte Micronucleus Test (OECD 474) SOP 6.1.192 In vitro Mammalian Cell Gene Mutation Test-Mouse Lymphoma Assay (OECD 476) SOP 6.1.142	Finished Medical Devices and Components / Drugs	Colony Counters Microscopes Semi-quantitative BD FACS Flow Cytometer Waterbath Incubators
Tests for Interaction with Blood	ISO 10993-4 In Vitro Hemocompatibility (SOP 6.1.153, 3.8.211) WBC. RBC, Platelet Counts, Erythrocyte Indices UPTT /PTT (SOP 6.1.152) Platelet and Leukocyte Count (SOP 6.1.205) Time for Platelet Aggregation (SOP 6.1.156) Complement Activation (SOP 6.1.150) Thrombogenicity (SOP 6.2.32) Hemolysis (SOP 6.1.169)	Finished Medical Devices and Components / Drugs	Advia & hematology counter Waterbath Start4 Hemostasis Analyzer Packs 4 Aggregometer ELISA, plate reader Spectrophotometer

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for In vitro Cytotoxicity	ISO 10993-5 Mem Elution / Cytotoxicity or Direct Contact (SOP 6.1.53, SOP 6.1.185)) Agar Diffusion (SOP 6.1.54) MTT Cytotoxicity Assay (SOP 6.1.177) Neutral Red Uptake (NRU) Cytotoxicity Assay (SOP 6.1.178) V79 Colony Formation (SOP 6.1.163)	Finished Medical Devices and Components / Drugs	Cell culture equipment / microscope Plate reader Incubator
Tests for Local Effects after Implantation	ISO 10993-6 Muscle Implant Test (SOP 6.2.13.5) Subcutaneous Implant (SOP) 6.2.13.4) Bone Implant (SOP 6.2.46)	Finished Medical Devices and Components / Drugs	Animal system Explant and histological evaluation / pathology
Tests for Irritation and Sensitization	ISO 10993-10 and ISO 10993-23 Kligman Sensitization (SOP 6.2.20) Buehler Sensitization (SOP 6.2.25.3) Ocular, Vaginal, Buccal, Skin, Penile Irritation (SOPs 6.2.16, 6.2.28, 6.2.27, 6.2.23. 6.2.29) Intracutaneous (SOP 6.2.13.2)	Finished Medical Devices and Components / Drugs	Animal systems-Clinical observations and tissue evaluations

Biological [2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for Systemic Toxicity	ISO 10993-11 Pyrogen Test (SOP 6.2.14) Systemic Injection Test (SOP 6.2.13.1) 14/28 Day Intravenous Toxicity (SOP 6.2.40) 21/28 Day Repeat Dose Study (SOP 6.2.37) Systemic Toxicity via Intramuscular or Subcutaneous Implantation (SOP 6.2.62)	Finished Medical Devices and Components / Drugs	Animal Systems Thermometer readings Clinical observations Scoring, balance Tissue Evaluations Advia automatic hematology counter Cobas automatic clinical chemistry analyzer

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide Sterilization Residuals	ISO 10993-7 SOP 3.7.38 and 11.2	Finished Medical Devices and Components / Drugs	Agilent 6890 GC-FID
Leachables and Extractables Testing	ISO 10993-18 GC (SOPs, 3.7.38, 11.67, 11.68) GC/MS (SOP 3.7.30, 11.67, 11.68, 11.95) HPLC (SOP 3.8.88) LC/MS (SOP 10.15, 10.19,11.94) TOC and TIC (SOP 3.8.250 11.9) ICP (SOP 3.8.189, 11.96, 11.97, 11.100) ICP/MS (SOP 3.8.201,11.96, 11.97) FTIR (SOP 3.8.115)	Finished Medical Devices and Components / Drugs	(Detection limits vary with analyte & matrix) Agilent 6890/7890 GC and GC/MS Agilent 1100/g1260/1290 HPLC and LC/MS systems Tekmar TOC Fusion Thermo Fisher 6300 ICP Thermo Fisher iCAP-Q, iCAP-RQ and ICP w/MS Perkin Elmer IR

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden Testing	ISO 11737-1 Sterilization of Medical Devices – Estimation of Organisms on Products SOP 6.1.49 / USP, AAMI	Finished Medical Devices and Components / Drugs	Autoclave, incubators, HEPA hood
Sterility Test Methods	ISO 11737-2 Sterilization of Medical Devices – Validation of a Sterilization Process USP, AAMI 6.1.47 and 6.1.2	Finished Medical Devices and Components / Drugs	Sterile Room Autoclave, incubators, HEPA hood

Satellite Location
Labcorp

3301 Kinsman Blvd.
Madison, WI 53704

Deb Olszewski 608-230-1764
Tana Derringer 608-210-7521
deb.olszewski@labcorp.com tana.derringer@labcorp.com

TESTING

Biological[2]

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Histology processing of tissues	P-0274 Post Life Necropsy and Histology; SOP-3123 Histology Procedures-All Species; SOP-3503 Preparation and Labelling of Solutions; P-0322 Special Staining of Histology Slides; SOP-2735 Automated IHC/ISH Stainer; SOP-3154 Immunohistochemistry – Method Approval and Staining; SOP-3002 Embedding Tissues in Epoxy Resin; SOP-3838 Tissue Processing for Epoxy Resin; SOP-7221 Sectioning of Tissue(s) Embedded in Epoxy Resin	Medical Devices	Embedding Center, Microtome, Tissue Processor, Stainer, Coverslipper

Note:

1. Testing is in conformance to the FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Biocompatibility Testing of Medical Devices and according to the FDA Biocompatibility Recognized Consensus Standards.
2. Biological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.
3. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1340.

Jason Stine, Vice President