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 2026
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

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TESTING

ISO/IEC 17025 Accreditation Granted: **24 July 2024**

Certificate Number: **AT-1340** Certificate Expiry Date: **24 July 2026**

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, water bath

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
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, water bath
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);	Medical Devices	Animal systems, thermometer readings, clinical observations, incubators,

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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
	USP <151>; 43-NF38:2020 (FDA Registration No. 2-295) ISO 10993-12 Fifth edition, 2021-01-01 (FDA Registration No. 2-289)		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 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 Water bath Incubators

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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 Interaction with Blood	ISO 10993-4 In Vitro Hemocompatibility (SOP 6.1.153, 3.8.211) WBC. RBC, Platelet Counts, Erythrocyte Indices UPTT /PTT (ASTM F2382-18) (SOP 6.1.152) Platelet and Leukocyte Count(ASTM F2888-19) (SOP 6.1.205) Time for Platelet Aggregation (SOP 6.1.156) Complement Activation (SOP 6.1.150) Thrombogenicity (SOP 6.2.32) Hemolysis (ASTM F756-17) (SOP 6.1.169)	Finished Medical Devices and Components / Drugs	Advia & hematology counter Water bath Start4 Hemostasis Analyzer Packs 4 Aggregometer ELISA, plate reader Spectrophotometer
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

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 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) In Vitro Skin Irritation (SOP 6.1.208)	Finished Medical Devices and Components / Drugs	Animal systems-Clinical observations and tissue evaluations Plate reader Incubator
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

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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 and Compendial Testing	ISO 10993-18 GC (SOPs, 3.7.41, 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 1100/1260/1290 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 Spectrophotometer, Balance

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 Water bath
Sterility Testing	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

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Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Endotoxin Testing	USP 85 USP 161 ANSI/AAMI ST72 SOP 6.1.143, SOP 6.1.44	Finished Medical Devices and Components / Drugs	Heat Block, Plate Reader, HEPA Hood, Depyrogenation Oven, Incubators
Reusable Medical Device Testing	ISO 17664-1 ISO/TS 17665-2 ISO 10993-1 AAMI TIR12 ANSI/AAMI ST98 ANSI/AAMI ST108 AAMI ST79 ASTM F3208 ISO 15883 EU 2017/745 SOP 6.1.196, SOP 6.1.197, SOP 6.1.198	Medical Devices	Autoclave, incubators, HEPA hood. Spectrophotometer, Plate reader, Balance

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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.

Jason Stine, Vice President

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