CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Labcorp Bedford, LLC

15-25 Wiggins Avenue
Bedford, MA 01730

Fulfills the requirements of

ISO/IEC 17025:2017

and

FDA ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT PROGRAM – BIOCOMPATIBILITY TESTING OF MEDIAL 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.

R. Douglas Leonard Jr., VP, PILR SBU

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 MEDIAL DEVICES[1]

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

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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 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	Medical Devices	ELISA, plate reader, incubators, laminar hood, balance, calipers
Direct and Indirect Hemolysis	ISO 10993-4 10993-4 Third edition, 2017-04 (FDA Registration No. 2-248); ASTM F756-17 (FDA Registration No. 2-250); ISO 10993-12 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	Medical Devices	Spectrophotometer, incubators, laminar hood, balance, calipers

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 10993-5 Third edition 2009-06-01 (FDA Registration No. 2-245); ISO 10993-12 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	Medical Devices	Incubators, microscope, laminar hood, balance, calipers
Dermal Irritation, and Intracutaneous Reactivity Irritation	ISO 10993-10 Third edition 2010-08-01 (FDA Registration No. 2-147); ISO 10993-12 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	Medical Devices	Animal systems – clinical observations, incubators, laminar hood, balance, calipers
Guinea Pig Maximization (Kligman) Sensitization and Closed Patch Sensitization	ISO 10993-10 Third edition 2010-08-01 (FDA Registration No. 2-147); ASTM F720-17 (FDA Registration No. 2-256); ISO 10993-12 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	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 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	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 ISO 10993-12 Fourth edition, 2012-07-01 (FDA Registration No. 2-191)	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 6.1.117 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
Tests for Interaction with Blood	ISO 10993-4 In Vitro Hemocompatibility (SOP 6.1.153, 3.8.211) WBC. RBC, Platelet Counts, Erythrocyte Indices PT / UPTT /APTT/ (SOP 6.1.63, SOP 6.1.152, and SOP 6.1.64) 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 6.1.51 and SOP 6.1.169)	Finished Medical Devices and Components / Drugs	Advia & hematology counter 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
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) Murine Lymph Node Assay (SOP 6.2.54)	Finished Medical Devices and Components / Drugs	Animal systems-Clinical observations and tissue evaluations Scintillation counter

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 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 3.8.201,10.15) FTIR (SOP 3.8.115)	Finished Medical Devices and Components / Drugs	(Detection limits vary with analyte & matrix) Agilent 5890 and 6890 GC and GC/MS Agilent 1100 HPLC and LC/MS systems Tekmar TOC Fusion Thermo Fisher 6300 ICP Thermo Fisher iCAP-Q, iCAP-RQ and X Series ICP w/MS Perkin Elmer IR

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology

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

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.

R. Douglas Leonard Jr., VP, PILR SBU