



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

North American Science Associates, Inc. (NAMSA)

6750 Wales Road

Northwood, OH 43619

has been assessed by ANAB and meets the requirements of international standard

ISO/IEC 17025:2017

and the

**Good Laboratory Practice for Nonclinical Laboratory Studies,
Title 21 CFR Part 58 Accreditation Program**

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

AT-2561

Certificate Number



ANAB Approval

Certificate Valid Through: 03/09/2020
Version No. 004 Issued: 06/06/2019



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 AND GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES, TITLE 21 CFR PART 58 ACCREDITATION PROGRAM

North American Science Associates, Inc. (NAMSA)

6750 Wales Road
Northwood, OH 43619

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TESTING

Valid to: **March 09, 2020**

Certificate Number: **AT-2561**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ultra Performance Liquid Chromatography-Mass Spectrometry (UPLC-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Ultra Performance Liquid Chromatograph (UPLC – qTOF)
Gas Chromatography-Mass Spectrometry (GC-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Gas Chromatograph - Mass Spectrometer (GC-MS)
Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Inductively Coupled Plasma - Mass Spectrometer (ICP-MS)
Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES)	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Inductively Coupled Plasma-Optical Emission Spectrometer (ICP-OES)
Infrared Analysis (IR)	USP <197>; USP <854>	Polymers, Non-Volatile Residue, Particulates	FTIR Spectrophotometer
Exhaustive and Exaggerated Extraction	ISO 10993-18	Polymers, Metals, Assembled Devices, Materials	Balances, Rotary Evaporator, Incubators
Preliminary and Exaggerated Extraction	MHLW	Finished Medical Devices	Balances, Rotary Evaporator, Incubators
Characterization of Plastic Materials of Construction and Elastomeric Closures (including Physicochemical Testing)	USP38-NF33 <661>; USP <381>; USP <661.1>; USP <661.2>	Polymers, Containers, Closures	FTIR Spectrophotometer, Balances, Rotary Evaporator, Incubators, pH Meter, UV-Vis Spectrophotometer, ICP-MS, Differential Scanning Calorimeter, Chromatography, GC-MS, ICP-MS, UPLC-MS

Biological ¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chromosomal Aberration Study in Mammalian Cells	ISO 10993-3; OECD 473; MHLW	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Lymphoma Assay	ISO 10993-3; OECD 490	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Cell Counters
Bacterial Reverse Mutation (Ames Test)	ISO 10993-3; OECD 471; MHLW	Polymers, Metals, Assembled Devices, Materials	Bacterial Culture Equipment
<i>In Vivo</i> Thromboresistance Study: Jugular or Carotid	ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Test System, Scoring
C3a Complement Activation Assay	ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Spectrophotometer, Elisa
SC5b-9 Complement Activation Assay	ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Spectrophotometer, Elisa
Hemolysis Study	ISO 10993-4; ASTM F756; MHLW Part 8	Polymers, Metals, Assembled Devices, Materials	Spectrophotometer
Partial Thromboplastin Time	ISO 10993-4; ASTM F2382	Polymers, Metals, Assembled Devices, Materials	Coagulation Analyzer
Cytotoxicity Assay, Elution Method	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Agarose Overlay	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Direct Contact	ISO 10993-5	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity, Colony Assay	MHLW Part 1	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, MTT	ISO 10993-5	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope, Spectrophotometer
Cytotoxicity Study using a modified ISO and USP Method	NAMSA TM_00205; TM_00210: Modified ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Subcutaneous Implantation Study	ISO 10993-6	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Muscle Implantation Study	ISO 10993-6; USP <88>; MHLW Part 4	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology

Biological ¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bone Implantation Study	ISO 10993-6	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Intracutaneous Reactivity Study	ISO 10993-10; USP <88>; MHLW Part 5	Polymers, Metals, Assembled Devices, Materials	Test System, Clinical Observations, Scoring
Skin Irritation Study	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Oral Mucosal Irritation Study	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Vaginal Irritation Study	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Urinary Bladder Irritation Study	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Penile Irritation Study	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Sensitization Study, Maximization Method	ISO 10993-11; USP <88>; MHLW Part 6	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Sensitization Study, Murine Local Lymph Node Assay	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Liquid Scintillation Counter
Sensitization Study, Closed Patch Method	ISO 10993-10	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Systemic Toxicity Study	ISO 10993-11; USP <88>; MHLW Part 6	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring
Pyrogen or Material Mediated Pyrogen Study	ISO 10993-11; USP <151>; MHLW Part 7; EP 6.0 Section 2.6.8; JP 4.04; 7.03	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Thermometer Readings

Biological ¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Subchronic/Chronic Toxicity Study, Subcutaneous	ISO 10993-11	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Subchronic Toxicity Study	ISO 10993-11	Polymers, Metals, Medical Devices, Materials	Test System, Clinical Observations, Tissue Evaluation, Histopathology

Note:

1. Biological testing is in conformance to the U.S. FDA GLP (Good Laboratory Practice) Regulations per 21 CFR Part 58.

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Gram Stain and Colony Morphology	ASM 1981, Manual Of Methods for General Bacteriology, Pg. 26-27 Methods In Clinical Bacteriology, 1972, pg. 164-66, ATCC Standards	Medical Devices, Biologics, Materials	ISO Class 5 Hoods, Biosafety Cabinets, Macroscopic Observations, Microscope
Bioburden Testing of Medical Products	ISO 11737-1	Medical Devices, Materials	ISO Class 5 Hoods, Incubators
Bacteriostasis/Fungistasis Testing	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Materials	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
Bioburden Recovery Validation	ISO 11737-1	Medical Devices, Materials	ISO Class 5 Hoods, Incubators
Incubation and Enumeration on Fallout Plates, RODAC® Plates, or Air Sampler Media	ISO 14698-1; USP <1116>	Environmental Monitoring	Incubators, Macroscopic Observations
Total Viable Spore Count	USP <55>	Biologics, Process Challenge Devices (PCDs)	ISO Class 5 Hoods, Incubators



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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
Sterility Testing	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Biologics, Materials	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators

Note:

- This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2561.



Vice President