



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

North American Science Associates, LLC (NAMSA)

8945 Evergreen Boulevard
Minneapolis, MN 55433

Fulfills the requirements of

ISO/IEC 17025:2017

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: 09 March 2026

Certificate Number: AT-2561.02



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

North American Science Associates, LLC (NAMSA)

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Minneapolis, MN 55433

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TESTING

Valid to: **March 9, 2026**

Certificate Number: **AT-2561.02**

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 ISO 10993-12 BS/EN/ISO 10993-12 OECD 474	Polymers, Metals, Assembled Devices, Materials	Genotoxicity – Test System, Clinical Observations, Flow Cytometry
Guinea Pig Maximization Test	ISO 10993-10 BS/EN/ISO 10993-10 ISO 10993-12 BS/EN/ISO 10993-12 MHLW Part 2	Polymers, Metals, Assembled Devices, Materials	Sensitization – Test System, Clinical Observations, Scoring
Closed-Patch Test (Buehler)	ISO 10993-10 BS/EN/ISO 10993-10 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Sensitization – Test System, Clinical Observations, Scoring
Animal Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Irritation – Test System, Clinical Observations, Scoring
Intracutaneous Reactivity Test	ISO 10993-23 BS/EN/ISO 10993-23 ISO 10993-12 BS/EN/ISO 10993-12 USP 88 MHLW Part 5	Polymers, Metals, Assembled Devices, Materials	Irritation – Test System, Clinical Observations, Scoring

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Vaginal Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Irritation – Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Primary Buccal (mucosal) Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Irritation – Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Ocular Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Irritation – Test System, Clinical Observations, Scoring
Acute Systemic Toxicity Test	ISO 10993-11 BS/EN/ISO 10993-11 ISO 10993-12 BS/EN/ISO 10993-12 USP 88 MHLW Part 6	Polymers, Metals, Assembled Devices, Materials	Systemic Toxicity – Test System, Clinical Observations, Scoring
Materials Mediated Pyrogenicity Test; Rabbits	ISO 10993-11 BS/EN/ISO 10993-11 USP 151	Polymers, Metals, Assembled Devices, Materials	Systemic Toxicity – Test System, Clinical Observations, Thermometer Readings
Systemic Toxicity Test (Implant Method)	ISO10993-11 BS/EN/ISO 10993-11 ISO10993-6 BS/EN/ISO 10993-6 ISO 10993-12 BS/EN/ISO 10993-12 MHLW Part 4 MHLW Part 6	Polymers, Metals, Assembled Devices, Materials	Systemic Toxicity – Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
Systemic Toxicity Test (Repeated Exposure Method)	ISO10993-11 BS/EN/ISO 10993-11 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Systemic Toxicity – Test System, Clinical Observations, Scoring, Tissue Evaluation, Histopathology
In Vivo Thrombogenicity Test	ISO 10993-4 BS/EN/ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Test System, Scoring
Implantation Test	ISO 10993-6 BS/EN/ISO 10993-6 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Local Tissue Effects – Test System, Clinical Observations, Scoring

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Agar Overlay Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12 USP 87	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope
Direct Contact Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12 USP 87	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope
MEM Elution Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12 USP 87	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope
MTT Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope, Spectrophotometer
Neutral Red Uptake Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope, Spectrophotometer
Colony Formation Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 ISO 10993-12 BS/EN/ISO 10993-12 MHLW Part 1	Polymers, Metals, Assembled Devices, Materials	Cytotoxicity – Cell Culture Equipment, Microscope
Hemolysis Assay Extract Method	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12 ASTM F756 MHLW Part 8	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, Centrifuge
Hemolysis Assay Direct Method	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12 ASTM F756	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, Centrifuge

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Partial Thromboplastin Time (PTT) Assay	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12 ASTM F2382	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Coagulation Analyzer
Thrombin Antithrombin Assay	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, ELISA
Beta-Thromboglobulin (β -TG) Assay	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, ELISA
Complement Activation Assay; SC5b-9 Method	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, ELISA
Complement Activation Assay; C3a Method	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Spectrophotometer, ELISA
Heparinized Blood Platelet and Leukocyte Count Assay	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12 ASTM F2888	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Hematology Analyzer
Heparinized Blood Count Assay	ISO 10993-4 BS/EN/ISO 10993-4 ISO 10993-12 BS/EN/ISO 10993-12 ASTM F2888	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Hematology Analyzer
In Vitro Blood Loop Assay (Ovine Blood)	ISO 10993-4 BS/EN/ISO 10993-4	Polymers, Metals, Assembled Devices, Materials	Hemocompatibility – Roller Pumps, Scoring
Ames Bacterial Reverse Mutation Assay	ISO 10993-3 BS/EN/ISO 10993-3 ISO 10993-12 BS/EN/ISO 10993-12 OECD 471 MHLW Part 3	Polymers, Metals, Assembled Devices, Materials	Genotoxicity – Bacterial Culture Equipment, Colony Counter

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 ISO 10993-12 BS/EN/ISO 10993-12 OECD 490 MHLW Part 3	Polymers, Metals, Assembled Devices, Materials	Genotoxicity – Bacterial Culture Equipment, Colony Counter

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2561.02.



Jason Stine, Vice President

