



# 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](http://www.anab.org).

A handwritten signature in black ink, appearing to be 'J. Stine', is positioned above a horizontal line.

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)

8945 Evergreen Boulevard  
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 OECD 474	Finished Medical Devices, and Drugs	Genotoxicity
Guinea Pig Maximization Test	ISO 10993-10 BS/EN/ISO 10993-10 MHLW Part 2	Finished Medical Devices, and Drugs	Sensitization
Closed-Patch Test (Buehler)	ISO 10993-10 BS/EN/ISO 10993-10	Finished Medical Devices, and Drugs	Sensitization
Animal Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23	Finished Medical Devices, and Drugs	Irritation
Intracutaneous Reactivity Test	ISO 10993-23 BS/EN/ISO 10993-23 USP 88 MHLW Part 5	Finished Medical Devices, and Drugs	Irritation
Vaginal Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23	Finished Medical Devices, and Drugs	Irritation
Primary Buccal (mucosal) Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23	Finished Medical Devices, and Drugs	Irritation
Ocular Irritation Test	ISO 10993-23 BS/EN/ISO 10993-23	Finished Medical Devices, and Drugs	Irritation
Acute Systemic Toxicity Test	ISO 10993-11 BS/EN/ISO 10993-11 USP 88 MHLW Part 6	Finished Medical Devices, and Drugs	Systemic Toxicity

## Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Materials Mediated Pyrogenicity Test; Rabbits	ISO 10993-11 BS/EN/ISO 10993-11 USP 151	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Implant Method)	ISO10993-11 BS/EN/ISO 10993-11 ISO10993-6 BS/EN/ISO 10993-6 MHLW Part 4 MHLW Part 6	Finished Medical Devices, and Drugs	Systemic Toxicity
Systemic Toxicity Test (Repeated Exposure Method)	ISO10993-11 BS/EN/ISO 10993-11	Finished Medical Devices, and Drugs	Systemic Toxicity
Thrombogenicity Test	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Implantation Test	ISO 10993-6 BS/EN/ISO 10993-6	Finished Medical Devices, and Drugs	Local Tissue Effects
Agar Overlay Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
Direct Contact Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MEM Elution Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 USP 87	Finished Medical Devices, and Drugs	Cytotoxicity
MTT Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Neutral Red Uptake Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5	Finished Medical Devices, and Drugs	Cytotoxicity
Colony Formation Cytotoxicity Assay	ISO 10993-5 BS/EN/ISO 10993-5 MHLW Part 1	Finished Medical Devices, and Drugs	Cytotoxicity
In-Vitro Skin Irritation Assay	OECD 439	Finished Medical Devices and Drugs	Irritation
Hemolysis Assay Extract Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756 MHLW Part 8	Finished Medical Devices, and Drugs	Hemocompatibility
Hemolysis Assay Direct Method	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F756	Finished Medical Devices, and Drugs	Hemocompatibility

### 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 ASTM F2382	Finished Medical Devices, and Drugs	Hemocompatibility
Thrombin Antithrombin Assay	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; SC5b-9 Method	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Complement Activation Assay; C3a Method	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Heparinized Blood Platelet and Leukocyte Count Assay	ISO 10993-4 BS/EN/ISO 10993-4 ASTM F2888	Finished Medical Devices, and Drugs	Hemocompatibility
In Vitro Blood Loop Assay (Ovine Blood)	ISO 10993-4 BS/EN/ISO 10993-4	Finished Medical Devices, and Drugs	Hemocompatibility
Bacterial Endotoxin: Kinetic Chromogenic LAL Method	USP 85 USP 161	Finished Medical Devices, and Drugs	Endotoxin
Ames Bacterial Reverse Mutation Assay	ISO 10993-3 BS/EN/ISO 10993-3 OECD 471 MHLW Part 3	Finished Medical Devices, and Drugs	Genotoxicity
Mouse Lymphoma Assay	ISO 10993-3 BS/EN/ISO 10993-3 OECD 490 MHLW Part 3	Finished Medical Devices, and Drugs	Genotoxicity

### Chemical

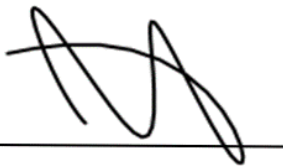
Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	High-Performance Liquid Chromatography (HPLC/UV/MS)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Inductively Coupled Plasma Mass Spectrometry (ICPMS)
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Fourier Transform Infrared Spectroscopy (FTIR)

**Chemical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Chemical Characterization; Extractables / Leachables Analysis	ISO 10993-18 BS/EN/ISO 10993-18	Finished Medical Devices, Drugs, and Packaging	Gas Chromatography Mass Spectrometry (GCMS)

Note:

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



Jason Stine, Vice President

