



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)

9 Morgan

Irvine, CA 92618

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

ISO/IEC 17025:2017

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-2562

Certificate Number


ANAB Approval

Certificate Valid Through: 03/09/2022
Version No. 006 Issued: 03/09/2020



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).



ANSI National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

North American Science Associates, Inc. (NAMSA)

9 Morgan
Irvine, CA 92618

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TESTING

Valid to: **March 9, 2022**

Certificate Number: **AT-2562**

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
USP Physiochemical Testing – Polymers, Resins, Mixed Materials, Elastomeric Closures	USP <661>; USP <381>	Polymers, Non-Volatile Residue, Particulates	Balances, Incubators, pH Meter, UV-Vis Spectrophotometer
Infrared Analysis (IR)	ISO 10993-18; USP <197>	Polymers, Non-Volatile Residue, Particulates	FTIR Spectrophotometer
Particulate Analysis	USP <788>; USP <789>; ISO 14708-3	Medical Devices	Particle Counting Apparatus, LAF Hood, Microscope
Ethylene Oxide Residuals Analysis	ISO 10993:7	Medical Devices	Gas Chromatography
USP Total Organic Carbon	USP <643>	Medical Devices	TOC Analyzer

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cytotoxicity Assay, Elution Method (48-hour Exposure): L929 Cells	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope
Cytotoxicity Assay, Agarose Overlay: L929 Cells	ISO 10993-5; USP <87>	Polymers, Metals, Assembled Devices, Materials	Cell Culture Equipment, Microscope

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
USP Limulus Amebocyte Lysate (LAL) Kinetic Turbidimetric Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Spectrophotometer, Incubator
USP Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Spectrophotometer, Incubator
USP Limulus Amebocyte Lysate (LAL) Gel Clot Method	USP <85>	Polymers, Metals, Assembled Devices, Materials, Drug Products (Intermediates and Finished)	Incubator, Qualitative Observation

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden Testing of Medical Products	ISO 11737-1; USP<55>; USP<61>; USP<1231>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators
Identification of Microorganisms	Applied Biosystems MicroSEQ® Microbial Identification System Analysis and Interpretation	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Genetic Sequencer, Thermocyclers
Bacteriostasis/Fungistasis Testing	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
USP Antimicrobial Preservative Effectiveness	USP <51>	Medical Devices, Materials, Pharmaceuticals	ISO Class 5 Hoods, Incubators
Bioburden Recovery Validation	ISO 11737-1; USP<1227>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators
Incubation and Enumeration of Fallout Plates, RODAC® Plates, or Air Sampler Media	ISO 14698-1; USP<1116>	Environmental Monitoring	Incubators, Macroscopic Observations
Kirby-Bauer Standard Antimicrobial Susceptibility Test	American Journal of Clinical Pathologists, Volume 95	Medical Devices, Materials, Pharmaceuticals	ISO Class 5 Hoods, Incubators

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Determining Antimicrobial Activity of Immobilized Antimicrobial Agents	ASTM E2149	Medical Devices, Materials	ISO Class 5 Hoods, Incubators
Sterility	ISO 11737-2; ISO 11137-2; ISO 11135; USP <71>	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 6 Cleanroom, ISO Class 5 Hoods, Incubators
Gram Stain and Colony Morphology	FDA Microbiological Methods & Bacteriological Analytical Manual (BAM)	Medical Devices, Materials, Pharmaceuticals, Human Tissues	ISO Class 5 Hoods, Incubators, Microscopes

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2562.



Vice President