



The American Association for Laboratory Accreditation

World Class Accreditation

Accredited Laboratory

A2LA has accredited

NORTH AMERICAN SCIENCE ASSOCIATES (NAMSA™)

Northwood, OH


for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. 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 8 January 2009).

Presented this 1st day of April 2010.




President & CEO
For the Accreditation Council
Certificate Number 2419.01
Valid to May 31, 2012

For the tests or types of tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.



World Class Accreditation

American Association for Laboratory Accreditation

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005*

NORTH AMERICAN SCIENCE ASSOCIATES (NAMSA™)
6750 Wales Road
Northwood, OH 43619

BIOLOGICAL

Valid To: May 31, 2012

Certificate Number: 2419.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on biological samples:

Test Method	Test
ISO 10993:4	<i>In Vivo</i> Thromboresistance Study: Jugular/Carotid Dog In-Life, Implant, Termination
ISO 10993:10	ISO Maximization Sensitization Study: Guinea Pig
ISO 10993:10	Murine Local Lymph Node Assay (Sensitization): Mouse Subchronic/Chronic Toxicity Study
ISO 10993:11	Subcutaneous: Rat In-Life, Implant, Necropsy, Histology/Pathology
ISO 10993:11	Subchronic Toxicity Study: Rat In-Life, Necropsy, Histology/Pathology
ISO 10993:10	Urinary Bladder Irritation Study: Rabbit In-Life, Necropsy, Histology/Pathology
ISO 10993:10	ISO Skin Irritation Study: Rabbit
ISO 10993:11, USP <88>	Systemic Toxicity Study: Mouse
ISO 10993:11, MHLW Part 6	Systemic Toxicity Study, Japanese, MHLW: Mouse In-Life, Necropsy
ISO 10993:10, USP <88>, MHLW Part 5	ISO Intracutaneous Study: Rabbit ISO Subcutaneous Implantation Study: Rabbit

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Test Method	Test
ISO 10993:6	In-Life, Implant, Necropsy, Histology/Pathology
ISO 10993:6, USP <88>, MHLW Part 4	Muscle Implantation Study: Rabbit In-Life, Implant, Necropsy, Histology/Pathology
ISO 10993:6	Bone Implant: Rabbit In-Life, Implant, Necropsy, Histology/Pathology
ISO 10993:10	Oral Mucosal Irritation Study: Hamster In-Life, Dose, Necropsy, Histology/Pathology
ISO 10993:10	ISO Vaginal Irritation Study: Rabbit In-Life, Necropsy, Histology/Pathology
ISO 10993:10	ISO Penile Irritation Study: Rabbit In-Life, Necropsy, Histology/Pathology
ISO 10993:4	Lee-White Clotting Time Study: Dog
ISO 10993:10	ISO Closed Patch Sensitization Study: Guinea Pig
ISO 10993:10	Maximization Sensitization Study, Japanese MHLW: Method 1 & 2: Guinea Pig
ISO 10993:1, ISO 10993:11, USP <151>, MHLW Part 7, EP 6.0, Section 2.6.8, JP 4.04; 7.03	USP Pyrogen Study (or Material Mediated): Rabbit
ISO 10993:3, OECD 473	In Vitro Chromosomal Aberration, Study in Mammalian Cells: Chinese Hamster Ovary Cells
ISO 10993:3, ASTM E1280, OECD 476	Mouse Lymphoma Assay In Vitro, L5178Y TK ^{+/+} Cells
ISO 10993:3, OECD 471	Bacterial Reverse Mutation (AMES Test): TA98, TA100, TA1535, TA1537, WP2uvrA
ISO 10993:5, USP <87>	Cytotoxicity Assay – Elution Method (48-hour Exposure): L929 Cells
ISO 10993:5, USP <87>	Cytotoxicity Assay – Agarose Overlay: L929 Cells
MHLW, Japan	Cytotoxicity Study Using the Colony Assay: V- 79 Cells
ASTM D6499	Latex Protein Assay by ASTM Method
ISO 10993:4	C3a Complement Activation Assay
ISO 10993:4	SC5b-9 Complement Activation Assay
MHLW, Japan	In Vitro Hemolysis Study, Japanese MHLW
ASTM F756, ISO 10993:4	ASTM Hemolysis
ASTM F2382, ISO 10993:4	ASTM Partial Thromboplastin Time
ASM 1981, Manual Of Methods for General Bacteriology, Pg. 26-27	Gram Stain and Colony Morphology
Methods In Clinical Bacteriology, 1972, pg. 164-66, ATCC Standards	
ISO 11737:1	Bioburden Testing of Medical Products

Peter M. Meyer

Test Method	Test
ISO 11737-2, ISO 11137-2, ISO 11135, and USP <71> ISO 11737:1	Bacteriostasis/Fungistasis Testing Test Method
ISO 14698:1 and USP <1116>	Bioburden Recovery Validation
USP <55>	Incubation and Enumeration on Fallout Plates, RODAC® Plates, or Air Sampler Media
ISO 11737-2, ISO 11137-2, ISO 11135 and USP <71>	USP Total Viable Sport Count
	Sterility Testing

* The laboratory was also evaluated to U.S. FDA GLP (Good Laboratory Practice) Regulations per 21CFR Part 58 and found to be in conformance with the standard.

