



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Nelson Laboratories, LLC

**6280 S. Redwood Road
Salt Lake City, UT 84123**

Fulfills the requirements of

ISO/IEC 17025:2017

and

**ANAB Supplemental Requirements SR 2438, Biocompatibility Testing of
Medical Devices**

and

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

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: 16 March 2027

Certificate Number: AT-1382.03



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

Nelson Laboratories, LLC

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Salt Lake City, UT 84123

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TESTING

ISO/IEC 17025 Accreditation Granted: **16 March 2025**

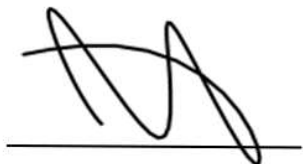
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Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, Biocompatibility Testing of Medical Devices ¹

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials, or Product Tested	Key Equipment or Technology
MEM Elution Cytotoxicity	ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices – Part 5 (FDA Recognition No.2-245); ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices -part 12 (FDA Recognition No. 2-191)	Medical Devices	ISO Class 5 Hoods, Microscope, Incubators

Note:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2438, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Biocompatibility Laboratories meeting these requirements are eligible to apply to participate in the FDA ASCA program. Participation in the FDA ASCA program can be confirmed by visiting their website <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories>.



Jason Stine, Vice President

