



# CERTIFICATE OF ACCREDITATION

## ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

**iuvo BioScience, LLC**  
**7500 West Henrietta Rd.**  
**Rush, NY 14543**

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

## ISO/IEC 17025:2005

while demonstrating technical competence in the field of

## TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-2068

Certificate Number



ANAB Approval

Certificate Valid: 10/02/2017-08/24/2018  
Version No. 003 Issued: 10/02/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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 17025:2005**

**iuvo BioScience, LLC**

7500 West Henrietta Rd.  
Rush, NY 14543  
Deborah Sorochty  
585-533-1672

**TESTING**

Valid to: **August 24, 2018**

Certificate Number: **AT-2068**

**Biological**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Cytotoxic Reactivity	CYT-005 based on USP <87> and ISO 10993-5:2009	Textiles, Medical Devices	CO2 incubator, Microscope
Biological Reactivity	CYT-002 based on USP <87>, <381>, <1031> and ISO 10993-5:2009	Textiles, Medical Devices	CO2 incubator, Microscope
Bacterial Endotoxins (LAL)	PYT-011 based on ANSI/AAMI ST72:2011	Medical Devices, Pharmaceuticals, Biologics	Microplate Reader
MEM Elution	CYT-001 based on USP <87>, ISO 10993-5:2009, ANSI/AAMI/ISO 10993-12:2012.	Medical Devices, Pharmaceuticals, Biologics	ISO Class 5 Hoods Microscope Incubators
Colony Forming Assay	CYT-009, based on JP <7.02> and <7.03>	Medical Devices, Pharmaceuticals, Biologics, Tissues	CO2 incubator, Microscope
Acute Systemic Toxicity	CLE-003 based on <USP> 88, 2.12 ANSI/AAMI/ISO 10993-11:2006, JP XVI, <7.03>, JP XVI, Supplement II, <7.03>	Medical Devices	
Intracutaneous	CLE-016 based on <USP> 88 CLE-016.1 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals, Biologics	
Sensitization	SST-001.1 based on ISO 10993-10:2010(E)	Medical Devices, Pharmaceuticals, Biologics	

**Biological**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Muscle Implantation	CLE-017 based on <USP> 88, ANSI/AAMI/ISO 10993-6:2007	Medical Devices, Pharmaceuticals	
Buehler Patch Sensitization Test	SST-004 based on ISO 10993-10:2010	Medical Devices, Pharmaceuticals	Scale Incubator
Ocular Irritation Test	CLE-018 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals	Slit Lamp Scale Incubator
General Safety Test/Abnormal Toxicity Test	MDT-002, MDT-004 based on USP <88>, EP <2.6.9>	Medical Devices, Pharmaceuticals	Scale
Rabbit Pyrogen Test	PYT-001, PYT-001.11, PYT-010 based on USP <151>, EP <2.6.8>, JP <4.04>	Medical Devices, Pharmaceuticals	Scale Incubator Temperature Probe
Hemolysis Test	BCT-004 based on ASTM 756	Medical Devices, Pharmaceuticals	Spectrophotometer Scale Incubator
Primary Skin Irritation Test	SST-002.1 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals	Scale Incubator

**Microbiological**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Bioburden	M-009 based on ANSI/AMMI/ISO 11737-1:2006.	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicator Sterility	S-045 based on ANSI/AAMI/ISO 11737-2:2009.	BI's, PCD's	Sterility Suite Class 5 Hoods Incubator
Product Sterility	S-045 based on USP <71>, ANSI/AAMI/ISO 11737-2:2009, 1137-01 and -02, ANSI/AAMI/ISO 11137-2:2013, AAMI TIR33:2005	Medical Devices, Pharmaceuticals, Biologics, Tissues	Sterility Suite Class 5 Hoods Incubator
Bacteriostasis / Fungistasis	M-017, based on USP <71>	Medical Devices, Pharmaceuticals, Biologics, Tissues	Incubator, Membrane Filtration

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
D Value Determination	M-004, M-004.1, M-004.2, M-004.3, based on USP <55>	BI's	Resistometer, Incubator
Population Determination	M-005 based on USP <55>	BI's	Incubator, Colony Counter
Heterotrophic Plate Count (Water) Test	M-001 based on USP <1231>	Water	Incubator. Colony Counter

**Chemical**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	CA-003.1 based on ANSI/AAMI/ISO 10993-7:2008/(R)2012	Medical Devices	Gas Chromatograph, FID

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2068



Vice President