



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## Certificate of Accreditation

*Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:*

***Geneva Laboratories, Inc.***  
***1001 Proctor Drive, Elkhorn, WI 53121***  
***980 Proctor Drive, Elkhorn, WI 53121***

*(Hereinafter called the Organization) and hereby declares that Organization 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  
 (as outlined by the joint ISO-ILAC-IAF Communiqué dated April 2017):

***Microbiological, Chemical, and Biological Testing***  
*(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen  
President

Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

*Initial Accreditation Date:*

September 15, 2016

*Accreditation No.:*

78413

*Issue Date:*

September 19, 2022

*Certificate No.:*

L22-625-R1

*Expiration Date:*

December 31, 2024

*Revision Date:*

September 27, 2023

*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjllabs.com](http://www.pjllabs.com)*



# Certificate of Accreditation: Supplement

## Geneva Laboratories, Inc.

1001 Proctor Drive, Elkhorn, WI 53121

980 Proctor Drive, Elkhorn, WI 53121

Contact Name: Paul Norland Phone: 262-723-5669

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT	
Microbiological <sup>F</sup>	Environmental Monitoring	Incubation and Enumeration of Fallout Plates, RODAC® Plates or Air Sample Media	ISO 14698-1, USP <1116>	Presence/Absence	
Biological <sup>F</sup>	Medical devices, Pharmaceutical Products and Personal Care Products	Cytotoxicity	ISO 10993-5		
		Bacterial Endotoxin	USP <85>		
		Particle Count	USP <788>		
		Package Integrity	ASTM F1929		
Microbiological <sup>F</sup>		Antimicrobial Effectiveness	USP <51>		
		Microbiological Examination of Nonsterile Products: Enumeration and Tests for Specified Microorganisms	USP <61> USP <62> USP <2021> USP <2022>		
		Sterility Test	USP <71> ISO 11137-2 ISO 11737-2		
		Bioburden Test	ISO 11737-1, USP <1231>		
		Class VI: -Intracutaneous -Systemic -Intramuscular -Implantation	USP <88>		
Biological <sup>F</sup>		Primary Skin Irritation	ISO 10993-10		
		Muscle Implantation	ISO 10993-6		
		Direct and Indirect Hemolysis	ISO 10993-4:2017, ASTM F756-17 MI1008 Rev. W		Hemolytic Index = 0 to 2
		MEM Elution Cytotoxicity	ISO 10993-5:2009/(R)2014 CC1001 Rev. N Add. ISO-1 Rev. I		≤ Grade 2
		Acute Systemic Toxicity	ISO 10993-11:2017 CL1026 Rev. H		Meets Requirements of Test
		Closed Patch Sensitization	ISO 10993-10:2021 CL1014 Rev. P		Non-Sensitizer



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Biological <sup>F</sup>	Medical devices, Pharmaceutical Products and Personal Care Products	Guinea Pig Maximization Test (GPMT)	ISO 10993-10:2021 ASTM F7207-17 CL1015 Rev. FF	Non-Sensitizer
		Intracutaneous Reactivity Irritation	ISO 10993-10:2021 CL1025 Rev. J	Non-Irritant
		Dermal Irritation	ISO 10993-10:2021 CL1024 Rev. P	Non-Irritant
		Sample Preparation for all test types	ISO 10993-12:2012 SP0095 Rev. F	N/A
Chemical <sup>F</sup>		Water Purity Analysis Total Organic Carbon (TOC), Conductivity, pH	USP <1231> and all water monographs, (USP <643>- TOC, USP<645> Conductivity, USP <791> pH)	N/A
		HPLC	USP <621>	% Purity
		Residue on Ignition	USP <281>	% Weight
		Water Determination	USP <921>	% Water
		FTIR	USP <197>	% Match

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer<sup>F</sup> would mean that the laboratory performs this testing at its fixed location.