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

& Meets the Requirements of the FDA

Accreditation Scheme for Conformity Assessment (ASCA) Program*

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:	*Issue Date:*	*Expiration Date:*
September 15, 2016	September 19, 2022	December 31, 2024

Accreditation No.:	*Certificate No.:*
78413	L22-625

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.pjlabs.com

Certificate of Accreditation: Supplement

PJLA

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[F]	Environmental Monitoring	Incubation and Enumeration of Fallout Plates, RODAC® Plates or Air Sample Media	ISO 14698-1, USP <1116>	Presence/Absence
Biological[F]	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[F]		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>	
Biological[F]		Class VI: -Intracutaneous -Systemic -Intramuscular -Implantation	USP <88>	
		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 [F]	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[F]		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[F] would mean that the laboratory performs this testing at its fixed location.
2. Methods noted with an (*) meet the assessment requirements of the ASCA Program