



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

Initial Accreditation Date:

September 15, 2016

Issue Date:

October 15, 2020

Expiration Date:

December 31, 2022

Accreditation No.:

78413

Certificate No.:

L20-649

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

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.pjlab.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:

1001 Proctor Drive, Elkhorn, WI 53121

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	Medical devices, Pharmaceutical Products and Personal Care Products	Cytotoxicity	ISO 10993-5	Presence/Absence
		Bacterial Endotoxin	USP <85>	
		Particle Count	USP <788>	
		Package Integrity	ASTM F1929	
Biological ^F		Intracutaneous	ISO 10993-10	
		Acute Systemic Toxicity	ISO10993-11	
		Ocular Irritation	ISO 10993-10	
		Penile Mucosa Irritation	ISO 10993-10	
		Closed Patch Sensitization	ISO 10993-10	
		Dermal Sensitization (GPMT)	ISO 10993-10	
		Class VI: -Intracutaneous -Systemic -Intramuscular -Implantation	USP <88>	
		Oral Mucosa Irritation	ISO 10993-10	
		Vaginal Mucosa Irritation	ISO 10993-10	
		Primary Skin Irritation	ISO 10993-10	
		Muscle Implantation	ISO 10993-6	



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Microbiological ^F	Medical devices, Pharmaceutical Products and Personal Care Products	Hemolysis	ISO 10993-4	Presence/Absence
		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>	
	Environmental Monitoring	Incubation and Enumeration of Fallout Plates, RODAC® Plates or Air Sample Media	ISO 14698-1, USP <1116>	
Chemical ^F	Water-USP	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

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.