



# 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 Insert April 2017):

### ***Biological and Chemical 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

*Issue Date:*

October 13, 2024

*Expiration Date:*

December 31, 2026

*Accreditation No.:*

78413

*Certificate No.:*

L24-775

*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.pjilabs.com](http://www.pjilabs.com)*



# Certificate of Accreditation: Supplement

## Geneva Laboratories, Inc.

1001 Proctor Drive, Elkhorn, WI 53121

980 Proctor Drive, Elkhorn, WI 53121

Contact Name: Jodie Moore Phone: 262-723-5669

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

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED			
F1, F2	Biological <sup>F</sup>	Environmental Monitoring	Incubation and Enumeration of Fallout Plates, RODAC® Plates or Air Sample Media	ISO 14698-1, USP <1116>	Incubators, Macroscopic Observation			
F1, F2						Medical devices, Pharmaceutical Products and Personal Care Products	Cytotoxicity	ISO 10993-5
F1, F2		Bacterial Endotoxin	USP <85> ANSI/AAMI ST72	Gel Clot, Kinetic Turbimetry				
F1, F2		Particle Count	USP <788>	Particle Count Apparatus, Class 6 Cleanroom, Microscope				
F1, F2		Package Integrity	ASTM F1929	Dye Penetration				
F1, F2		Antimicrobial Effectiveness	USP <51>	Incubators				
F1, F2		Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	USP <60> USP <61> USP <62>					
F1, F2		Sterility Test	USP <71> ISO 11137-2 ISO 11737-2	ISO Class 5 Cleanroom, Incubators, Steritest				
F1, F2		Bioburden Test	ISO 11737-1, USP <1231>	ISO Class 5 Cleanroom, Incubators				
F1, F2		Primary Skin Irritation	ISO 10993-23	Macroscopic Observation				
F1, F2		Muscle Implantation	ISO 10993-6					
F1, F2		Direct and Indirect Hemolysis	ISO 10993-4 ASTM F756-17	Incubators, Spectrophotometer				
F1, F2		Acute Systemic Toxicity	ISO 10993-11	Macroscopic Observation				
F1, F2		Closed Patch Sensitization	ISO 10993-10					
F1, F2		Guinea Pig Maximization Test (GPMT)	ISO 10993-10 ASTM F720-17					
F1, F2		Chemical <sup>F</sup>	Medical devices, Pharmaceutical Products and Personal Care Products	Intracutaneous Reactivity Irritation	ISO 10993-23		TOC meter, Conductivity meter pH meter	
F1, F2				Water Purity Analysis Total Organic Carbon (TOC), Conductivity, pH	USP <1231>, (USP <643>- TOC, USP<645> Conductivity, USP <791> pH			
F1, F2				Purity	USP <621>			HPLC
F1, F2				Residue on Ignition	USP <281>			Furnace, Balance
F1, F2				Water Determination	USP <921>	Karl Fisher Titration		
F1, F2	Identity			USP <197>	FTIR			



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Contact Name: Jodie Moore Phone: 262-723-5669

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

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.
2. Flex Code:
  - F0-Fixed scope item. No deviations allowed to the line item as identified, except for updating to the most recent version of an accredited standard method after verification
  - F1-Laboratory has the capability to test a new item, material, matrix, or product similar in composition to item, material, matrix, or product identified on the scope
  - F2-Laboratory has the capability to introduce the newest revision of an accredited authoritative standard method (with no modifications) identified on the scope
  - F3-Laboratory has the capability to introduce a parameter/component/analyte to an accredited test method identified on the scope
  - F4-Laboratory has the capability to introduce a new revision of an accredited non-standard method using the same technology or technique identified on the scope
  - F5-Laboratory has the capability to introduce a validated method that is equivalent to an accredited method (using same technology or technique) identified on the scope

