



# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## *Certificate of Accreditation*

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

### ***FOCUS Laboratories***

***177 North Commerce Way, Bethlehem, PA 18017***

*(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):

***Chemical, Biological & Microbiological 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:*

August 26, 2014

*Issue Date:*

January 31, 2023

*Expiration Date:*

March 31, 2025

*Accreditation No.:*

77499

*Certificate No.:*

L23-77

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



# Certificate of Accreditation: Supplement

## FOCUS Laboratories

177 North Commerce Way, Bethlehem, PA 18017

Contact Name: Mel Homik Phone: 610-866-7272

*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
Chemical <sup>F</sup>	Water and Solutions	USP <643> Total Organic Carbon	FOCUS SOP 2302	D.L. = 50 ppb
		USP <644>, <645> Conductivity	FOCUS SOP 3510	D.L. = 1 µS/cm
Microbiological <sup>F</sup>	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	USP <51> Antimicrobial Effectiveness Testing	FOCUS Protocols 020, 030 / SOP 3470	1 LOG to 3 LOG reduction; D.L. = 0.5 LOG
		USP <60> Microbiological Examination of Non-sterile Products Tests for Burkholderia cepacia complex	FOCUS SOP 3451	D.L. = 1 CFU/g
		USP <61> Microbiological Examination of Non-sterile Products Microbial Enumeration Tests	FOCUS Protocol 004 / SOP 3410	D.L. = 10 CFU/g (Aerobic Plate Count); D.L. = 1 CFU/g (Membrane Filtration)
		USP <62> Microbiological Examination of Non-sterile Products Tests for Specified Microorganisms	FOCUS Protocol 005 / SOP 3450	Presence/Absence
	Water for Pharmaceutical Purposes	Microbial Enumeration and Identification USP <1231>, SMEWW	FOCUS Protocol 001 / SOP 3850	D.L. = < 1 CFU/100 mL by Membrane Filtration
	Medical Devices, Health and Beauty, and consumer products and materials	ANSI/AAMI/ISO 11737-1 Determination of a Population of Microorganisms (Bioburden)	FOCUS Protocol 014 / SOP 3411	D.L. = 1 CFU/device
	Environmental (Air & Surface Sampling)* (*Typically collected in Clean Rooms and Controlled Environments)	USP <797>, USP <1116>, ISO 14698-1 Microbial Enumeration and Identification	FOCUS Protocols 021 / SOP 3431, 010 / SOP 3430, 023 / SOP 3432	D.L. = 1 CFU/plate or swab Range = 1 CFU/plate or swab to 250 CFU/plate or swab
Biological <sup>F</sup>	Pharmaceutical Medical Devices, Health, and Beauty Products and Materials	USP <85> Bacterial Endotoxins	FOCUS SOP 3444	D.L. = 0.002 EU/mL or g of Product

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.
2. \* Typically collected in Clean Rooms and Controlled Environments as outlined in methods.