



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

FOCUS Laboratories

894 Marcon Blvd., Suite 150, Allentown, PA 18109

*and hereby declares that the Organization is accredited in accordance with
the recognized International Standard:*

ISO/IEC 17025:2017

Whereby, technical competence has been confirmed for the associated scope supplement, in the fields of:

Biological and Chemical Testing (As detailed in the supplement)

Accreditation claims for conformity assessment activities shall only be made from the addresses referenced within this certificate and shall apply solely to those activities identified in the related scope. This Accreditation is granted subject to the Accreditation Body rules governing the Accreditation referred to above, and the Organization hereby commits to observing and complying with those rules in their entirety.

For PJLA:

Initial Accreditation Date:

Issue Date:

Expiration Date:

August 26, 2014

February 06, 2025

March 31, 2027

Accreditation No.:

Certificate No.:

77499

L25-101-1

Tracy Szerszen
President

*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*

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



Certificate of Accreditation: Supplement

FOCUS Laboratories

894 Marcon Blvd., Suite 150, Allentown, PA 18109

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

Accreditation is granted to the facility to perform the following conformity assessment activities:

FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Chemical	Water and Solutions	Total Organic Carbon	FOCUS SOP CHEM-3 USP <643>	Catalytic combustion oxidation	F1, F2, F4	F
Chemical	Water and Solutions	Conductivity	FOCUS SOP CHEM-1 USP <644>, USP <645>	Conductivity Meter	F1, F2, F4	F
Biological	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	Antimicrobial Effectiveness Testing	FOCUS SOP MICRO-16 USP <51>	Plating/Culture	F1, F2, F3, F4	F
Biological	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	Microbiological Examination of Non-sterile Products Tests for Burkholderia cepacia complex	FOCUS SOP MICRO-15 USP <60>	Plating/Culture	F1, F2, F4	F
Biological	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	Microbiological Examination of Non-sterile Products Microbial Enumeration Tests	FOCUS SOP MICRO-40 USP <61>	Plating/Culture	F1, F2, F3, F4	F
Biological	Nonsterile Pharmaceutical Health and Beauty Products materials and toys	Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	FOCUS SOP MICRO-40 ASTM F963-17 Section 4.3.6.3 USP <61>	Plating/Culture	F1, F2, F3, F4	F
Biological	Nonsterile Pharmaceutical Health and Beauty Products materials and toys	Microbiological Examination of Nonsterile Products: Tests for specified Microorganism	FOCUS SOP MICRO-41 ASTM F963-17 Section 4.3.6.3 USP <62>	Plating/Culture	F1, F2, F3, F4	F
Biological	Pharmaceutical Products and Materials, Medical Devices, Health and Beauty, and consumer products and material	Microbiological Examination of Non-sterile Products Tests for Specified Microorganisms	FOCUS SOP MICRO-41 USP <62>	Plating/Culture	F1, F2, F3, F4	F



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Biological	Water for Pharmaceutical Purposes	Microbial Enumeration and Identification	FOCUS SOP MICRO-63 USP <1231> SMEWW 9215B, 9215C, 9215D, 9222B, 9223B	Plating/Culture	F1, F2, F3, F4	F
Biological	Medical Devices, Health and Beauty, and consumer products and materials	Determination of a Population of Microorganisms (Bioburden)	FOCUS SOP MICRO-46 ANSI/AAMI/ISO 11737-1	Plating/Culture	F1, F2, F3, F4	F
Biological	Environmental (Air & Surface Sampling)* (*Typically collected in Clean Rooms and Controlled Environments)	Microbial Enumeration and Identification	FOCUS SOPs MICRO-48 MICRO-57 MICRO-45 MICRO-52 USP <797>, USP <1116>, ISO 14698-1	Plating, Culture, Biochemical and Genetic Identification	F1, F2, F3, F4	F
Biological	Pharmaceutical Medical Devices, Health, and Beauty Products and Materials	Bacterial Endotoxins	FOCUS SOPs MICRO-13 MICRO-54 MICRO-69 USP <85> USP <161>	Kinetic Turbidimetric or Chromogenic and Gel-Clot	F1, F2, F3, F4	F



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Accreditation is granted to the facility to perform the following conformity assessment activities:

1. Location of activity:

Location

F

Location

Conformity assessment activity is performed at the CABs fixed facility

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

3. This is the primary site for all quality management system activities.

