PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Azzur Labs, LLC

4125 Independence Drive, Suite 5, Schnecksville, PA 18078

(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 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:*
June 5, 2019	September 22, 2021	October 31, 2023

Accreditation No.:	*Certificate No.:*
80916	L21-571

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

Azzur Labs, LLC
4125 Independence Drive, Suite 5, Schnecksville, PA 18078
Contact Name: Katie Neetz Phone: 484-550-7709

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[F]	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	pH	USP <791>; EUPh Water, purified	4 pH to 10 pH
		TOC	USP <643>	40 ppb to 90 ppm
		Conductivity	USP <645>: EUPh water, purified	0.01 µS/cm to 300 µS/cm
Biological[F]	Raw Materials, Excipients, intermediate and finished products for the pharmaceutical, pharmacy, dietary supplement, human cells, tissue products, water, and medical device industries.	Antimicrobial Effectiveness Testing	USP <51>: EUPh 5.1.3: CTFA M3; CTFA M4	10 CFU [3] to 250 CFU [3] With typical 1:10 dilution D.L. = Up to 10 CFU
		Enumeration Tests: Total Aerobic Microbial Count and Total Combined Yeast and Mold count	USP <61>; EUPh 2.6.12; ANSI/AAMI/ISO 11737[2]	10 CFU [3] to 250 CFU [3] With typical 1:10 dilutions D.L. = UP to 10 CFU
		Environmental Monitoring Analysis- Viable Air, Viable Surface (Plates/Swabs)	ISO 14698; USP <1116>; USP <797>; CAG-009	Settle Plates: 1 CFU to 250 CFU Bacterial plates on contact/air: D.L. = 1 CFU to 250 CFU Fungal plates on contact/air: D.L. = 1 CFU to 80 CFU
		Endotoxin-Chromogenic Technique	USP <85>	D.L. = 0.01 EU/ml [3] to 10 EU/ml [3] Based on product dilution
		Microbial Enumeration of Water-Heterotrophic Plate Count, Coliforms, Fluorescent Pseudomonas Group	USP <1231> EUPh water, purified [2]	D.L. = 1 CFU [3] to 250 CFU [3] Based on product dilution
		Identification Bacteria, Yeasts & molds-biochemical/ Microscopic Fungal Analysis	USP <1113>	Qualitative
		Media Fill Analysis (for Compliance with FDA-Aseptic Processing Guidelines)	USP <797> USP <71>	Qualitative
		Recovery of Biological Indicators	USP <55>	Qualitative
		Sterility Testing- Bacteriostasis & Fungistasis	USP <71>	Qualitative
		Tests for Specified Organisms	USP <62>; EUPh 2.6.13	Qualitative

Certificate of Accreditation: Supplement

Azzur Labs, LLC
4125 Independence Drive, Suite 5, Schnecksville, PA 18078
Contact Name: Katie Neetz Phone: 484-550-7709

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. Example: Outside Micrometer^{F} would mean that the laboratory performs this testing at its fixed location.

2. Additional methods other than listed above may fall under the accreditation of the laboratory. A complete listing of methods capabilities can be derived from the laboratory upon request.

3. Limit of Detection varies based on product dilution which is decided at the time of Method Suitability testing.