



PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

PSN Labs 5368 Kuhl Road, Erie, PA 16510

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, Chemical, and Mechanical 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:

March 20, 2019

July 05, 2025

August 31, 2027

Accreditation No.:

Certificate No.:

100921

L25-499

Tracy Szerszen President

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.pjlabs.com





Certificate of Accreditation: Supplement

PSN Labs

5368 Kuhl Road, Erie, PA 16510 Contact Name: Bobbie Heisler Phone: 814.969.1179

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
Mechanical	Plastics, Rubbers, Composites	Glass transition temperature, Dynamic Mechanical Properties	ASTM D4065 ASTM D7025 ASTM E1640	DMA	F1, F2	F
Mechanical	Organic and Inorganic Solids, Liquids, Plastics, Rubbers, and Composites	Transition Temperature & Enthalpies of Fusion; Glass Transition Temperature; Oxidative Induction Time: Specific Heat capacity; Purity; Melting Temperature	ASTM D3418 ASTM E793 ASTM D7426 ASTM E1356 ASTM D3895 ASTM E1858 ASTM E1269 ASTM E928 ASTM D1519	DSC	F1, F2	F
Mechanical	Organic and Inorganic Solids, Liquids, Plastics, Rubbers, and Composites	Material Composition; Thermal Degradation of Materials	ASTM D3850 ASTM E1131 ASTM D6370	TGA	F1, F2	F
Mechanical	Organic and Inorganic Solids, Liquids, Plastics, Rubbers, and Composites	Coefficient of Linear Thermal Expansion	ASTM E831 ASTM E1545	TMA	F1, F2	F
Mechanical	Plastics, Rubbers, and Composites	Mass Change and Volume Swell; Specific Gravity	ASTM D471 ASTM D792	Analytical Balance	F1, F2	F
Mechanical	Plastics, Rubbers, and Composites	Tensile Properties	ASTM D638 ASTM D412	Mechanical Load Frame	F1, F2	F
Mechanical	Plastics, Rubbers, and Composites	Flexural Properties	ASTM D790	Mechanical Load Frame	F1, F2	F
Mechanical	Finished Medical Devices, Food Contact Surfaces, Medical Device Components and Packaging, Plastics, Rubbers, and Composites	Accelerated Aging	ASTM F1980	Environmental Chambers Data loggers Humidity Sensors	F1, F2	F
Chemical	Water, Residue, Plastics, Composites, Elastomers	Trace Metals	ASTM D5673-16 ASTM C1345-08	ICP-MS	F1, F2	F





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Chemical	Medical Devices	Volatile Organic Compounds	ISO 18562-3	Sorbent Tubes, Mass Flow Controllers, Sampling Pumps, GCMS, HPLC, Environmental Chamber Markes Microchamber	F1, F2	F
Chemical	Medical Devices	Biocompatibility Analysis	ISO 18562-1	Toxicological Risk Assessment	F1, F2	F
Chemical	Medical Devices	Particulate Matter	ISO 18562-2	Particulate Meter	F1, F2	F
Chemical	Plastics, Rubbers, and Composites	Spectral Analysis	ASTM E168	FTIR-ATR	F1, F2	F
Chemical	Medical Devices	Biocompatibility Analysis	ISO 10993-17	Toxicological Risk Assessment	F1, F2	F
Chemical	Finished Medical Devices, Food Contact Surfaces, Medical Device Components and Packaging	Chemical Characterization; Extractables and Leachable Analysis	ISO 18562-4	QQQ LCMSMS ICPMS GCMS QToF Gravimetric Analysis	F1, F2	F
Chemical	Finished Medical Devices, Food Contact Surfaces, Medical Device Components and Packaging	Chemical Characterization; Extractables and Leachable Analysis	ISO 10993-18	QQQ LCMSMS ICPMS GCMS QToF Gravimetric Analysis	F1, F2	F
Chemical	Finished Medical Devices, Food Contact Surfaces, Medical Device Components and Packaging	Chemical Testing	ISO 8536-4, Section 8	Titration Burettes UV-Vis ICPMS Balance	F1, F2	F
Chemical	Finished Medical Devices, Food Contact Surfaces, Medical Device Components and Packaging, Pharmaceuticals	Spectral Analysis	USP 787 USP 665	UV-Vis	F1, F2	F





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OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	USED		OF
	TESTED	PARAMETER TESTED				ACTIVITY
Chemical	Finished Medical Devices, Food	Elemental Impurities	USP 232	ICPMS	F1, F2	F
	Contact Surfaces, Medical		USP 233			
	Device Components and					
	Packaging, Pharmaceuticals					
Chemical	Finished Medical Devices, Food	Residual Solvents	USP 467	GCMS	F1, F2	F
	Contact Surfaces, Medical					
	Device Components and	/				
	Packaging, Pharmaceuticals					
Chemical	Finished Medical Devices, Food	Nitrosamines	USP 1469	QQQ LCMSMS	F1, F2	F
	Contact Surfaces, Medical					
	Device Components and					
	Packaging, Pharmaceuticals					
Biological	Medical Devices	Cleaning Validation	AAMI TIR 30	Microplate Assay Testing	F1, F2	F
		-	AMMI ST98			

1. Location of activity:

Location

Location

F

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