

# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

## Certificate of Accreditation

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

### Eurofins Infinity Laboratory Group Inc.

30 Silverline Drive - First Floor, North Brunswick, NJ 08902

(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:

July 31, 2020 June 28, 2024 August 31, 2026

Revision Date: Accreditation No.: Certificate No.:

November 1, 2024 108803 L24-488-R1

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: <a href="https://www.pjlabs.com">www.pjlabs.com</a>



Issue: 06/2024

### Certificate of Accreditation: Supplement

#### **Eurofins Infinity Laboratory Group Inc.**

30 Silverline Drive - First Floor, North Brunswick, NJ 08902 Contact Name: Amrika Ramrup Phone: 732-253-7373

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, F4	Chemical F	Cleaning Validation, Water (WFI, PW, DIW)	Total Organic Carbon	USP 643 CHM-0003	Total Organic Carbon Analyzer
F1, F2, F4	-	Water (WFI, PW, DIW)	Conductivity	USP 645 CHM-034	Conductivity Meter
F1, F2, F4		Water Raw Materials, FP	рН	USP 791 CHM-033	pH Meter
F1, F2, F4		Raw Materials, FP	Identification of raw materials	USP 197K, USP 197F, USP 197U CHM-0004	FTIR UV Spectrophotometer
F1, F2, F4	-		Refractive Index	USP 831 CHM-0016	Refractometer
F1, F2, F4			Specific Gravity	USP 841 QAG-15	Pycnometer and Thermometer
F1, F2, F4			Water Determination	USP 921 CHM-0020	KF Titrator
F1, F2, F4			Purity	USP 621 CHM-0029, CHM-0032	HPLC
F1, F2, F4			Purity	USP 621 CHM-0028, CHM-0032	GC
F1, F2, F3, F4	Biological F		Method Suitability - Microbial Enumeration Testing	USP 61 MIC-0006	Incubator Petri Dish
F1, F2, F3, F4			Microbial Enumeration plates	USP 61 MIC-0007	Incubator Petri Dish
F1, F2, F3, F4			Method Suitability - Microbial Tests for Specified Microorganisms	USP 62 MIC-0015	Incubator Petri Dish
F1, F2, F3, F4	2		Method Suitability - Antimicrobial Effectiveness Testing	USP 51 MIC-0017	-
F1, F2, F3, F4	-		Antimicrobial Effectiveness Testing	USP 51 MIC-0018	-
F1, F2, F3, F4			Antibiotic Assay	USP 81 MIC-0016	Incubator Petri Dish Penni Cylinder
F1, F2, F3, F4		Cleaning Validation	Microbiological Enumeration of Swabs	USP 1116, USP 61, USP 62 MIC-0006, MIC-0015	Incubator Petri Dish
F1, F2, F3, F4		Facilities Validation	Environmental Monitoring: Plates/Strip/Swabs	USP 61, 1116 MIC-0021	MET ONE Particle counter and SAS Air sampler





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FLEX	FIELD	ITEMS, MATERIALS,	COMPONENT,	SPECIFICATION OR	TECHNOLOGY OR				
CODE	OF TEST	OR PRODUCTS	CHARACTERISTIC,	STANDARD METHOD	TECHNIQUE USED				
		TESTED	PARAMETER TESTED						
F1, F2, F3,	Biological F	Raw Material,	Sterility	USP 71	Incubator, Petri Dish				
F4		Finished Product,		MIC-0028	and Sterility suite				
		Medical Devices,			•				
		Water							

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.

#### 2. Flex Code:

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- F1-Introduction of the testing of a new item, material, matrix, or product for an accredited test method
- F2-Introduction of a new version of an accredited standard method (with no modifications)
- F3-Introduction of a new parameter/component/analyte to an accredited test method
- F4- Introduction of a new version or modifications of an accredited non-standard method
- F5-Introduction of a new method that is equivalent to an accredited method (using same technology or technique)

