

# PERRY JOHNSON LABORATORY ACCREDITATION, INC.

### Certificate of Accreditation

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

### **Infinity Laboratories**

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 (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:

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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 May 09, 2022 July 31, 2024

Revision Date:Accreditation No.:Certificate No.:April 3, 2024108803L22-360-R2

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="www.pjlabs.com">www.pjlabs.com</a>





### Certificate of Accreditation: Supplement

#### **Infinity Laboratories**

30 Silverline Drive - First Floor, North Brunswick, NJ 08902 Contact Name: Mr. Nick Mangroo Phone: 732-253-7373

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
Chemical <sup>F</sup>	Cleaning Validation, Water (WFI, PW, DIW)	Total Organic Carbon	<643> CHM-0003
	Water (WFI, PW, DIW)	Conductivity	<645> CHM-0001
	Water Raw Materials, FP	рН	<791> CHM-0002
	Raw Materials, FP	FTIR UV Spectrophotometer	<197K>, <197F>, <197U> CHM-0004
		Refractive Index	<831> CHM-0016
		Specific Gravity	<841> CHM-0005
		Water Determination (KF)	<921> CHM-0020
		HPLC	<621> CHM-0029, CHM-0032
		GC	<621> CHM-0028, CHM-0032
Biological (Microbiological) F	/	Method Suitability - Microbial Enumeration Testing	<61> MIC-0006
		Microbial Enumeration	<61> MIC-0007
		Method Suitability - Microbial Tests for Specified Microorganisms	<62> MIC-0015
		Microbiological Tests for Specified Microorganisms	<62> MIC-0015
		Method Suitability - Antimicrobial Effectiveness Testing	<51> MIC-0017
		Antimicrobial Effectiveness Testing	<51> MIC-0018
		Antibiotic Assay	<81> MIC-0016
	Cleaning Validation	Microbiological Enumeration of Swabs	<1116>, <61>, <62> MIC-0006, MIC-0015
	Facilities Validation	Environmental Monitoring: Plates/Strip/Swabs	<61>, <1116> MIC-0021
	Raw Material, Finished Product,	Sterility	USP <71>
	Medical Devices, Water		MIC-0028

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.