

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

INFINITY LABORATORIES

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MECHANICAL

Valid To: January 31, 2025 Certificate Number: 3545.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on <u>mechanical</u>, <u>vibration</u> and <u>temperature on customer products and packaging</u>, <u>medical devices for packaging integrity and effects of environment by conditioning and aging:</u>

Test: Test Method(s):

Medical Devices Packaging Testing

Distribution Testing (Distribution Cycle 1-17) ASTM D4169, D7386

Drop Testing (Schedule A – Handling)

Concentration Impact Testing (Schedule J)

Bridge Impact Testing

ASTM D6344

ASTM D5265

Incline Impact

ASTM D880, D5277

Mechanical Handling ASTM D6055

Drop Test for Corrugated Container TAPPI T802

Non-simulation Integrity Performance Testing ISTA 1A, 1B, 1C, 1D, 1E, 1F, 1G, 1H

Partial simulation Integrity Performance Testing
General-simulation Integrity Performance Testing
ISTA 2A, 2B, 2C, 2D, 2E, 2F
ISTA 3A, 3B, 3E, 3F, 3H, 3K

Packaged Products for Amazon, Sam's Club, Walmart, ISTA-6 Series

and FedEx
Cold chain Temperature Testing
ISTA 7D

Environmental Conditioning

Practice for Conditioning Containers ASTM D4332 Schedule I - Altitude Test ASTM D6653

Low Pressure (Altitude) MIL-STD-810 500.5

Accelerated Aging of Sterile Barrier System for Medical ASTM F1980

Devices

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Test:	<u>Test Method(s):</u>
<u>Vibration Testing</u>	
Schedule E - Vehicle Vibration	ASTM D4728
Schedule F - Loose Load Vibration	ASTM D999
Sine Vibration	ASTM D3580
Random Vibration	ASTM D4728
High Frequency Vibration	MIL-STD-810G
Compression Testing	
Schedule C - Vehicle Stacking	ASTM D642
Compression Resistance of Package under Static Load	ASTM D4577
Compression Test of Container	TAPPI T804
Seal integrity Testing for Medical device Packaging	
Internal Pressurization Failure Resistance of	ASTM F1140
Unrestricted Packages	
Seal Strength of Flexible Materials	ASTM F88
Performance Testing of Shipping Containers and	ASTM F2096
Systems Detecting Gross Leaks in Packaging by Internal	
Pressurization (Bubble Test)	
Detecting Seal Leaks in Porous Medical Packaging by	ASTM F1929
Dye Penetration	
Standard Test Method for Determining Integrity of Seals	ASTM F1886/F1886M
by Visual Inspection	
Labeling	
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ASTM D5264

Abrasion Resistance of Printed Materials



Accredited Laboratory

A2LA has accredited

INFINITY LABORATORIES

San Jose, California

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system

(refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 31st day of January 2023.

Mr. Trace McInturff, Vice President, Accreditation Services For the Accreditation Council

Certificate Number 3545.01

Valid to January 31, 2025

Revised on December 17, 2024