



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017¹

PACKAGING COMPLIANCE LABS, LLC
4334 Brockton Dr. SE Suite E
Kentwood MI 49512

Ryan Ott Phone: 616-227-4546
Matthew Lapham Phone: 616-227-4540

MECHANICAL

Valid To: April 30, 2025

Certificate Number: 3774.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory as well as the one satellite location listed below to perform the following tests on healthcare packaging, including flexible and rigid trays, pouches, and bags:

Tests:

Test Method(s):

Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM F1980

International Safe Transit Association

ISTA 1A, 1B, 1C, 1D, 1G, 1H,
2A, 2B, 2C, 3A, 3B, 3F,
6-AMAZON.com-B,
6-FEDEX-A, 6-SAMSClub

Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4169

Conditioning Containers, Packages, or Packaging Components for Testing

ASTM D4332

Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery

ASTM F2825

Standard Test Method for Random Vibration Testing of Shipping Containers

ASTM D4728

Standard Test Method for Vibration Testing of Shipping Containers

ASTM D999

Standard Test Method for Drop Test of Loaded Containers by Free Fall

ASTM D5276

Standard Test Method for Concentrated Impacts to Transport Packages

ASTM D6344

Tests:**Test Method(s):**

Standard Test Method for Determining Compressive Resistance of Shipping Containers

ASTM D642

Determining the Effects of High Altitude on Packaging Systems by Vacuum Method

ASTM D6653

Determining Integrity of Seals for Flexible Packaging by Visual Inspections

ASTM F1886/1886M

Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

ASTM F1929

Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration.

ASTM F3039

Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Leak)

ASTM F2096

Seal Strength of Flexible Barrier Materials

ASTM F88/F88M

Internal Pressurization Failure Resistance of Unrestrained Packages (Burst Testing)

ASTM F1140

Linear Measurement Using Precision Steel Rule

ASTM F2203

Standard Method for Thickness Measurement of Flexible Packaging Material

ASTM F2251

Abrasion Resistance of Printed Materials by the Sutherland Rub Tester

ASTM D5264

Barcode Grading

GS1 General Specifications
ISO 15415/15416

Air Permeance (Gurley Method)

TAPPI T460, ISO 5636

Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

ASTM D3078

Additional Scope Parameters:

Equipment:

Environmental Conditioning Chamber

Drop Tester

Compression Machine

Vertical Motion Vibration Table 60" x 60"

Parameters:

Temperature Range: -70°C –
180°C (-94°F – 356°F) Humidity
Range: Up to 95%RH
Capabilities: Programmable,
Cycling

Release Type: Swing Arm,
Pneumatic Payload Capacity:
177lbs Drop Height: 12" – 72"

Top-to-Bottom, Fixed Platen
Platen Size: 30" x 44" Maximum
Force Rating: 5,000 lbf
Maximum Opening Height: 47.5"
Travel Speed: 0.1 ipm – 0.51 ipm

Payload Capacity: 2000 lbs
22,000 lbf Dynamic Force Rating
Maximum Velocity 200in/s
Frequency Range: 1 hz – 300 hz
Capabilities: Sine Sweep, Sine
Dwell, Random Vibration, Shock

*Using the test methods and equipment listed above, as well as customer-supplied and laboratory developed methods, within the parameters listed above.

PACKAGING COMPLIANCE LABS, LLC
3498 Kraft Ave SE
Grand Rapids, MI 49512

Tests:

Test Method(s):

Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM F1980
International Safe Transit Association	ISTA 1A, 1B, 1C, 1D, 1G, 1H, 2A, 2B, 2C, 3A, 3B, 3F, 6-AMAZON.com-B, 6-FEDEX-A, 6-SAMSClub
Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D4169
Conditioning Containers, Packages, or Packaging Components for Testing	ASTM D4332
Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	ASTM F2825
Standard Test Method for Random Vibration Testing of Shipping Containers	ASTM D4728
Standard Test Method for Vibration Testing of Shipping Containers	ASTM D999
Standard Test Method for Drop Test of Loaded Containers by Free Fall	ASTM D5276
Standard Test Method for Concentrated Impacts to Transport Packages	ASTM D6344
Standard Test Method for Determining Compressive Resistance of Shipping Containers	ASTM D642
Determining the Effects of High Altitude on Packaging Systems by Vacuum Method	ASTM D6653
Determining Integrity of Seals for Flexible Packaging by Visual Inspections	ASTM F1886/1886M
Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	ASTM F1929
Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	ASTM F3039

Tests:**Test Method(s):**

Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Leak)	ASTM F2096
Seal Strength of Flexible Barrier Materials	ASTM F88/F88M
Internal Pressurization Failure Resistance of Unrestrained Packages (Burst Testing)	ASTM F1140
Linear Measurement Using Precision Steel Rule	ASTM F2203
Standard Method for Thickness Measurement of Flexible Packaging Material	ASTM F2251
Abrasion Resistance of Printed Materials by the Sutherland Rub Tester	ASTM D5264
Barcode Grading	GS1 General Specifications ISO 15415/15416
Air Permeance (Gurley Method)	TAPPI T460, ISO 5636
Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	ASTM D3078

Additional Scope Parameters:**Equipment:**

Environmental Conditioning Chamber

Parameters:

Temperature Range: -70°C – 180°C (-94°F – 356°F)

Humidity Range: Up to 95%RH

Capabilities: Programmable, Cycling

Drop Tester

Release Type: Swing Arm, Pneumatic Payload

Capacity: 177lbs Drop Height: 12" – 72"

Compression Machine

Top-to-Bottom, Fixed Platen Platen Size: 30" x 44"

Maximum Force Rating: 5,000 lbf Maximum Opening

Height: 47.5" Travel Speed: 0.1 ipm – 0.51 ipm

Vertical Motion Vibration Table 60" x 60"

Payload Capacity: 2000 lbs 22,000 lbf Dynamic Force

Rating Maximum Velocity 200in/s Frequency Range:

1 hz – 300 hz Capabilities: Sine Sweep, Sine Dwell,

Random Vibration, Shock

¹This accreditation covers the specified testing/calibrations performed at the laboratory locations listed in this scope of accreditation.



Accredited Laboratory

A2LA has accredited

PACKAGING COMPLIANCE LABS, LLC

Kentwood, MI

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 8th day of March 2023.

A blue ink signature of Mr. Trace McInturff, Vice President of Accreditation Services.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3774.01
Valid to April 30, 2025

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.