WESTPAK
TESTING. OWNERSHIP. INTEGRITY.

Medical Device Package Testing Services

State-of-the-Art Testing Services Since 1986

At the heart of medical device packaging validation is patient safety. Ensuring that your package system and product arrive intact and ready for use, with sterile integrity, label clarity, and full functionality preserved, is our priority.

Our Validation Process

To uphold package integrity per ISO 11607 Parts 1 and 2, WESTPAK offers a comprehensive validation process that includes:

- Package System Performance Testing
- Accelerated & Real-Time Aging
- Material Evaluation
- Sterile Barrier Testing

These tests are all mandated by both the Food & Drug Administration (FDA) and Conformité Européenne (CE). WESTPAK partners with you throughout the validation process with the aim of getting your product to market on time, while maintaining a focus on total patient safety.

Testing Standards

- ASTM D4169
- ASTM D4332
- ASTM D4728
- ASTM D5265
- ASTM D5276
- ASTM D642
- ASTM D6653
- ASTM D7386
- ASTM D999
- ASTM F1140
- ASTM F1929
- ASTM F1980
- ASTM F2054
- ASTM F2096
- ASTM F2825
- ASTM F88 / F88M
- ASTM F3039
- ASTM F1886 / F1886M
- ISTA 3A & 3B
- ISTA 4A & 4B
- ISTA 7D

WESTPAK is here to guide you through every step, committed to bringing your product to market efficiently, safely, and on schedule.

ISO 17025 ACCREDITED LABORATORY

ista CERTIFIED LABORATORY

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Key Testing Services

Environmental Conditioning

This process subjects test samples to varied temperature and humidity levels, assessing environmental impact prior to other tests such as package performance.

Seal Strength (Peel) Testing

Measures the force needed to peel seal layers, validating the heat-sealing process and ensuring seal integrity within acceptable limits.

Package Performance Testing

Simulates distribution hazards (vibration, impact, compression, temperature, humidity, altitude) in a controlled environment, ensuring reliability and repeatability.

Sterile Barrier System Integrity Testing

Detects any material fatigue or leaks within the sterile barrier using methods such as Gross Leak Detection and Dye Penetration.

Shelf Life Studies

Accelerated aging studies help establish product shelf life, verified by real-time storage tests to meet FDA requirements.

Gross Leak Detection (Bubble) Testing

This test submerges lightly pressurized packages to detect leaks through visible bubbles, ensuring defect-free packaging.

Customized Test Protocols

WESTPAK offers tailored protocols and test plans to meet your specific needs, backed by our experienced network and specialized equipment for tests like Tensile Strength, Compression, Bend, Shock, and Material Evaluation.

Trust **WESTPAK**'s specialized package testing to ensure that every product reaches its destination with the integrity, durability, and safety it needs for patient care.

WESTPAK, Inc., a third-party, independent test laboratory specializing in product and package testing solutions, supports speed to market with testing expertise, service, and quality. Its California-based facilities total more than 100,000 square feet of testing and administrative space. Testing is accredited to ISO/IEC 17025 by the American Association for Laboratory Accreditation (A2LA); laboratories are certified by the International Safe Transit Association (ISTA).