

## Life Science Testing Services



### What Is Package Testing For The Life Sciences Industry?

The Life Sciences industry, which includes Medical Device, Pharmaceuticals and Biopharmaceuticals, is tasked with getting product to the end user in a manner where product functionality, sterile barrier, label or the product is not compromised in any shape or form. It is essential that package systems used in these industries protect the products as lives depend on their successful delivery.

The package systems containing the sterile barrier or the primary package may be subjected to a variety of tests which include package performance, accelerated and real time aging, material evaluation and sterile barrier integrity testing. These tests are all mandated by the FDA and CE. Following the guidelines of ISO 11607 Part 1 and 2, as well as CFR Title 21, Westpak provides product and package testing services for both first articles and production devices.

#### Note from Greg Schwinghammer, Director of Engineering

“Our services here at Westpak go beyond simply providing certification. We pride ourselves with providing timely, high-quality and detailed test reports that offer the value added feature to which our customers are accustomed. We always go the extra mile to ensure that our customers receive the best service possible.”



#### Note from Andrew Thomas, Laboratory Manager

“Gross Leak Detection testing is qualitative - pass or fail! When the package passes, you move on. However, when there is a failure, you might ask ‘What’s next?’ Westpak is more than a testing laboratory. With over 32 years experience and knowledge, we are here to help you during that frustrating time and assist in finding a solution.”



### Medical Package Tests

- Conditioning
- Distribution
- Gross Leak (Bubble) Detection
- Dye Penetration
- Seal Strength (Peel)
- Burst
- Accelerated Aging
- Real Time Aging
- Pharmaceutical Package Validation

*Westpak's ISO 17025 accreditation assures you of the highest quality testing and data provided by any testing laboratory.*

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## Package Performance Testing

Package Performance testing simulates the shipping environmental hazards within a controlled laboratory setting. Testing inside a laboratory yields a high degree of repeatability and provides accurate results with a high level of confidence. Environmental hazards of shipping typically include temperature, humidity, impacts, compression, altitude, and vibration.

## Sterile Package Seal Integrity

Sterile Package Seal Integrity testing can be conducted using several methods such as Gross Leak Detection and Dye Penetration. Although these tests are qualitative, these methods have the ability to ascertain failures due to material fatigue or identify channel leaks within the seal area of the Sterile Barrier System.

## Seal Strength Tests

Peel and Burst tests conducted on the Sterile Barrier System measure seal strength. These tests are used to validate the heat sealing process and to determine if the seals of the Sterile Barrier System are within acceptable limits.

## Accelerated and Real Time Aging Studies

Accelerated Aging studies establish product shelf-life data per FDA requirements. Accelerated Aging studies are verified by conducting real-time storage testing for an equivalent period of time. With our newly expanded aging facility, Westpak can provide both Accelerated and Real-Time aging of the Sterile Barrier System.



## Altitude Testing

Many products and packages can be sensitive to the reduced atmospheric pressure experienced at high altitudes. Altitude tests can identify product/package sensitivity to this hazard prior to shipment.

## Pharmaceutical Package Validation

Includes leak detection, torque and closure testing, insulated shipper evaluation, label adhesion, label abrasion, needle insertion, Luer fitting, and plunger initiation force testing.

## Medical Device Product Evaluation Services

Additional tests may be necessary and Westpak can provide a variety of tests which may include the development and use of specialized test equipment. Tensile Strength, Compression, Bend, Shock, and Material Evaluation are additional test capabilities we conduct regularly and can provide additional value in determining the performance of the product or assistance with vendor evaluation.

## Testing Standards Include:

ASTM D4169  
ASTM D4332  
ASTM D4728  
ASTM D5112  
ASTM D5265  
ASTM D5276  
ASTM D642  
ASTM D6653  
ASTM D7386  
ASTM D999  
ASTM E515  
ASTM F1140  
ASTM F1929  
ASTM F1980  
ASTM F2054  
ASTM F2096  
ASTM F2825  
ASTM F88 / F88M  
IEC 60068  
IEC 60601  
ISO 11607  
ISO 2233  
ISO 2247  
ISO 2248  
ISTA 1A thru 7D

**For more information or a quote, please contact one of our offices below or go to: [www.westpak.com/contactus.aspx](http://www.westpak.com/contactus.aspx)**

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