DDL Testing Services

TOTAL TESTING INTEGRATION
DDL is an ISO 9001:2000 registered resource for product, packaging and material testing services. We serve the medical device, chemical electronics, aerospace, packaging and automotive industries. Founded in 1990, our two strategically located testing facilities offer a wide range of test services, including accelerated aging, material evaluation, shipping/distribution simulation and package integrity testing. Our single source, totally integrated approach enables globally recognized corporations to maximize product performance, reliability and safety while seamlessly achieving regulatory compliance.

UNPARALLELED EXPERTISE
By applying decades of collective experience in test development and analysis, DDL’s professional team of packaging and product testing engineers has creatively resolved a broad spectrum of project challenges. For products seeking initial validation, we provide critical insight to identify and resolve potential design flaws before the final testing process is initiated. Our approach to testing projects requiring a strategic third-party analysis involves a detailed investigation and review process. With this technique, we uncover potentially damaging and costly inconsistencies or oversights in testing and reporting methodologies that may have occurred at the point of origin. A protocol is then developed to ensure compliance measures are never compromised.

COMPREHENSIVE DOCUMENTATION
DDL’s clear, precise and detailed approach to protocol development and implementation allows us to generate a comprehensive, fully documented test methodology and results report, ready for direct submission to the FDA. You then have the option of receiving a copy of this extensive analysis, or a succinct one-page overview, based on your desired level of involvement.
A COMMITMENT TO PROJECT DEADLINES
The critical package testing process is often the final step in the lengthy journey to bring products to market. Winning the battle over stressfully tight time constraints poses a difficult challenge for companies attempting to meet looming project and first to market deadlines. At DDL, we alleviate time concerns by initially providing a clear, comprehensive project quotation within four hours of your request. And, we offer an unmatched commitment to timelines and budgetary parameters. While the majority of testing protocols are completed within one week from receipt of samples, we also offer Priority One emergency expedition of your project to meet market critical product debut demands.

FEDERAL REGULATION COMPLIANCE
At DDL we invite you to eliminate the uncertainty of meeting challenging FDA, OE and ISO 11607 compliance mandates by transferring this responsibility to DDL's proven and trusted industry experts. Serving active roles on all major technical committees for medical device packaging, DDL project engineers are made instantly aware of all forthcoming industry regulations. This enables us to immediately and correctly apply new standards to your particular project scenario, providing your company with ultimate security that your products will perform safely, efficiently and effectively.
PACKAGE TESTING CONSULTING SERVICES
Gain the Most Value for Your Testing Dollar
Today, more than ever, it is extremely important for packages containing medical devices or substances to maintain sterility or a reliable cold chain through appropriate package design.

For this reason, it is important to work with a packaging testing provider that not only tests and reports on packaging integrity, but also commits to consult with you in terms of how you can improve your packaging integrity and strength.

As tested and proven package testing professionals, DDL engineers believe that consulting services should be a value added service that comes with all package testing projects.

PACK ADVICE
The Right Packaging Advice
Core DDL services include package testing and detailed reports of package pass/fail integrity status. To augment this service, DDL also offers Pack-Advice counsel to package engineers actively engaged in a package testing initiative.

Advice can range from recommending methods that can improve your package sterility and strength, detailing alternative packing processes or materials and even addressing package manufacturing vendor selection.

BENEFIT FROM COMPLIMENTARY PACKAGE CONSULTING
Exceed Quality Standards
Contact DDL today for a preliminary analysis of your package testing requirements to ensure that your packaging meets and exceeds quality standards such as:
• ISO 11607 (CE Mark), and
• the FDA Modernization Act, which calls for the safety and effectiveness of medical devices.
ASSURING PRODUCT INTEGRITY AND STRENGTH

Testing the Life of a Package

Medical, pharmaceutical, food & beverage, heavy chemical, appliance, electronics, and even military organizations, all manufacture and distribute products that are eventually transported within a package. In order to deliver a product that remains sterile, and has not been damaged during shipment or aging, it is extremely important for a manufacturer to seek out and engage a package testing professional with the following ASTM testing expertise:

Package Integrity Testing
- Bubble Leak F2096
- Vacuum D3078
- Dye Leak F1929

Package Strength Testing
- Pull Strength F88/F1140

Package Distribution Testing
- ASTM D4169 Distribution Simulation
- ISTA Distribution Testing

CHOOSING A TESTING PROVIDER

Assure Depth of Service

Tested and proven, DDL offers one of the broadest range of testing services within the package testing industry. Industry-leading package testing engineers at DDL are proud to offer the highest quality package testing and consulting services, including:
- Distribution Simulation
- Accelerated Aging
- Compression
- Environmental
- Shock
- Package, Strength & Integrity
- Vibration, and
- Many other types of analysis

The Quick Test

When choosing a testing provider, call for a detailed quote. Take note of the response time and the way the quote is delivered. These are often indicators of future project performance, willingness to consult and even a clear understanding of your testing needs. Another way to determine validation expertise is by posing detailed questions regarding how a vendor would develop a statistically relevant sample.
PACKAGE INTEGRITY
Identifying Shelf Life
ISO 11607 Packaging for Terminally Sterilized Medical Devices states that manufacturers “shall demonstrate that, under the rigors of distribution, storage, handling, and aging, the integrity of the final package is maintained at least for the claimed shelf life of the medical device under storage conditions specified by the manufacturer, as long as the package is undamaged or unopened.”

Confidence in Expiration Dates
The best way for manufacturers to confidently affix valid expiration dates to their products is to first submit their package to accelerated aging testing.

DETERMINE PACKAGE DETERIORATION RATES
Tested and Proven Package Testing
Tested and Proven package Testing professional, DDL, follows the American Society for Testing and Materials (ASTM) F1980-02, “Standard Guide for Accelerated Aging of Sterile Medical Device Packages.” This testing standard calls for determination of the rate of the chemical reactions which cause package deterioration. Once this is identified by DDL package testing engineers, package shelf can be clearly identified.

ACCELERATED AGING TESTING
Package Testing Tips
When identifying package expiration dates, DDL accelerates exposure to:
• Climate: High and low temperature and humidity
• Shipping and handling: Vibration, manual handling and stacking

DDL Helps Medical Manufacturers
Accelerated Aging Testing, from DDL, has helped thousands of Medical Manufacturers to clearly identify package expiration dates. Call today for an Accelerated Aging quote.
Materials behave differently in compression than they do in tension, so it can be important to perform tests which simulate the conditions the materials will see in actual use. We often test materials and products in compression for those situations, and we have fixtures and transducers to do the job.

Compression testing is typically performed on the following types of material: plastics, foam, rock, concrete, asphalt. It is rarely used to test metals.

Compression testing is also used in specialized ways to evaluate the behavior of finished products. For example, a hypodermic needle may be pushed into a material to see how easily it penetrates and assess its sharpness.

**Application Note:**
DDL provides specialization in container testing for all types of industries. One application of DDL Material Tests System uses small compression platens and a low force compression load cell to provide lateral compression capacity of high-density polyethylene (HDPE) plastic bottles.
Vibration testing is the shaking of a product or package to determine its ability to survive in real world conditions. DDL performs vibration testing on a package or product to simulate one of three environments:

**Transportation environment**
Packages and products must be assessed to ensure that they can survive transportation via truck, air or rail.

**Operating environment**
Many products have to survive vibration in their daily working life, regardless of how they were originally transported. Examples include electronics in vehicles, construction equipment, and aircraft.

**Storage environment of sensitive products**
Some sensitive products experience vibrating when sitting on the floor of a building, since most buildings vibrate. External factors that causes this kind of vibration include air conditioning, other operating equipment, and passing vehicles.

The procedure for vibration testing involves placing the product or package on a vibration testing table, which is driven so that the surface of the table vibrates. The most common types of vibration testing equipment are:

- **Hydraulic Vibration**
  Used for larger loads and lower frequency testing (1-500 HZ)

- **Electro-dynamic Vibration**
  Used for high-frequency testing (20-10,000 HZ)

There are many types of vibration test techniques, but the two primary methods are:

- **Sinusoidal Testing**
  Here, the specimen is exposed to vibration at a constant or slowly changing frequency. Often used to reveal a product or package's resonant (sensitive) frequencies, it is the oldest type of vibration testing.

- **Random Testing**
  This test is typically used to simulate real world environments. Random testing can be used to duplicate transportation vibration, seismic vibration and operating vibration.

Many products and packages undergo vibration testing at either extremely hot or extremely cold temperatures. For example, aircraft parts might be tested at very cold temperatures, whereas under-the-hood automotive parts would be tested at a high temperature.
Flexural Testing

This mechanical testing method measures the behavior of materials subjected to simple bending loads. Like tensile modulus, flexural modulus (stiffness) is calculated from the slope of the bending load vs. deflection curve.

Flexural testing involves the bending of a material, rather than pushing or pulling, to determine how much the material can bend before it breaks, as well as the relationship between bending stress and deflection.

Flexural testing is commonly used on brittle materials such as ceramics, stone, masonry and glasses. It can also be used to examine the behavior of materials which are intended to bend during their useful life, such as wire insulation and other elastomeric products.

Some frequently used flexural testing standards are:

- ASTM C1161  Flexural Strength of Advanced Ceramics at Ambient Temperature
- ASTM C393  Flexural Properties of Sandwich Constructions
- ASTM D2990  Tensile, Compressive and Flexural Creep and Creep-Rupture of Plastics
- ASTM D623  Rubber Property- Heat Generation and Flexing Fatigue in Compression
- ASTM D648  Deflection temperature of plastics under flexural load
- ASTM D790  Flexural Properties of Un-reinforced and Reinforced Plastics and Electrical Insulating Materials
Material tests can be divided into “monotonic” (or constant rate) and fatigue (or cyclical loading). Fatigue tests are often used to determine how many load cycles a material can sustain or the failure load level for a given number of cycles.

The results of fatigue testing vary dramatically depending on the material. For example, most steels and aluminum alloys behave very differently under fatigue. Steel typically has a fatigue threshold, which means that if it is tested at loads lower than the threshold, it will never break. Most aluminum alloys do not have a fatigue limit, so it is more difficult to judge when they will break. Even at a small load, most aluminum alloys will fail after a sufficient number of cycles.

Plastics (Polymers) are very sensitive to strain rate, or the speed of testing. Testing plastics at a higher rate will lead to different results than testing them at a low speed. Similarly, plastics are temperature sensitive, meaning that they behave very differently at high temperatures than at low temperatures.

Fatigue testing is very common in the automotive and aerospace industries. This type of mechanical testing is performed using very simple sinusoidal load cycles, or may include very complex reproductions of actual service life load profiles.

Some ASTM Standards used to perform various types of fatigue testing are:

- ASTM D623  Rubber property-heat generation and flexing fatigue in compression
- ASTM F1612  Cyclic fatigue of metallic stemmed HIP arthropaty femoral components with torsion
- ASTM F1717  Static and fatigue for spinal implant constructs in a vertebrectomy model
- ASTM F1798  Evaluating static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis
Tensile Testing

DDL testing services is equipped with a number of tensile testing systems and offers a wide variety of tensile testing services.

**Test description**
Tensile testing involves pulling on a specimen material to determine the relationship between force and stretch, and the force at failure. This mechanical testing method is performed on virtually any kind of material: metals, plastics, paper, film, foil, wire, cordage etc.

There are many material properties that can be determined by tensile testing. Among the most common are:

**Modulus**
This is the measurement of the stiffness of a material—how much it deflects elastically for a given load.

**Elongation**
This is the total elastic and plastic (irreversible) stretch of the material before it breaks.

**Ultimate Load**
This is the maximum force that the specimen will accept before failure.

**Yield Strength**
This is the stress (load/area) at which a material begins to deform plastically.

Tensile testing can be performed on either finished products or specially cut or formed samples. Careful consideration must be given to such issues as speed of testing, grip design and application, load cell selection, and others, to yield accurate and credible results.

Among the many industry standards used for tensile testing, some common ones are:

- ASTM D638 Tensile Properties of Plastics by Use of Microtensile Specimens
- ASTM D882 Tensile Properties of Thin Plastic Sheeting
- ASTM D2256 Tensile Properties of Yarns by the Single Strand Method
- TAPPI T494 Tensile Properties of Paper & Paperboard