

ISO 9001
FDA REGISTERED
ISO 17025

PACKAGING VALIDATION TEST SERVICES

Nelson Laboratories, Inc. is an independent testing laboratory that supports many industries, including the medical device, pharmaceutical, and nutraceutical industries.

This segment sheet is designed to provide you with a better understanding of how Nelson Laboratories can assist you with your test service needs. To receive a full capabilities list or for a price quote, please contact the Nelson Sales Department at sales@nelsonlabs.com.



CAPABILITIES

Nelson Laboratories specializes in package validation testing and has developed test methods for this testing. The basis for these test methods is to help the manufacturer in the development and validation of their packaging operations.

It is crucial to assure package integrity for sterile medical devices. With the new revision of ISO 11607 “Packaging for terminally sterilized medical devices” being released an emphasis on providing a validated sterile barrier system has become more prevalent. Focusing on the attributes required of materials and preformed systems, while considering a wide range of sterilization methods, medical devices, and packaging system designs are included as part 1. Whereas development and validation guidance is addressed in Part 2. The methods developed at Nelson Laboratories are based on meeting the requirements outlined by this standard while providing fast and friendly service.



Accelerated Aging

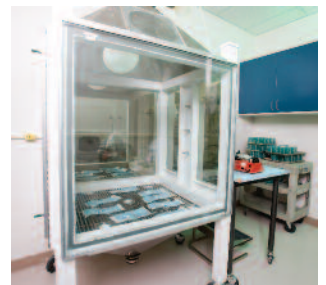
Guidance Document: ASTM F1980, ISO 11607

Simulated aging studies can be run with a designated time period ranging from one month to five years (or longer). The time of simulated aging depends on the temperature at which the products are held. Real-time aging is required when establishing an expiration date. Accelerated aging is an option allowing manufacturers the ability to get product to market faster.

Aerosol Challenge

Guidance Document: AAMI TIR 17, ISO 11607

This test is intended to challenge the whole package in order to determine package integrity of a finished product package. Chamber size is one meter cubed with a single layer of product, configured for appropriate challenge flow. The test includes the whole package microbial challenge, subsequent testing on the packaged product to determine penetration of the indicator organism used and test controls.



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Dye Migration

Guidance Documents: ASTM F1929, ISO 11607

The dye migration test involves injecting dye into the package and placing the weight of the solution against each portion of the seal for a specific length of time. The package is examined for evidence of seal failure demonstrated by dye slipping through the seal.

Bubble Emission

Guidance Documents: ASTM F2096, ISO 11607

A probe is inserted into the package and submerged in a surfactant fluid. A steady stream of bubbles through the package is considered evidence of a failure.

Burst/Creep

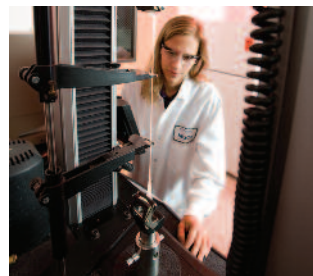
Guidance Document: ASTM F1140, ISO 11607

The burst test determines package strength by pressurizing a package until it bursts. The creep test determines package strength by pressurizing a package at 80% of the known burst pressure for a set amount of time.

Seal Peel Strength

Guidance Document: ASTM F88, ISO 11607

The package segments are prepared by measuring a one inch segment along one of the heat seals. The sample segment is inserted into the grips of the instrument with the heat seal centered between the two grips. The results are reported as maximum load.

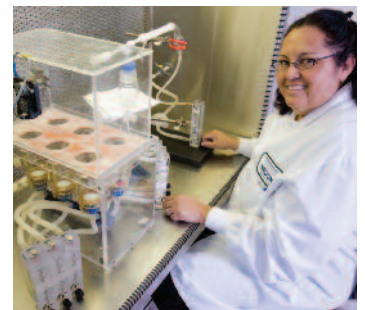


Microbial Ranking of Porous Packaging Materials

(Exposure Chamber Method)

Guidance Document: ASTM F1608, ISO 11607

This test procedure is used to evaluate porous materials intended for use in packaging sterile medical devices. This test employs a low flow rate, extended exposure time, and increased challenge level, which allows testing of materials with high differential pressure values.



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