



Laboratory Testing & Sterilization Services Without Limits.



Infinity Laboratories is a single-source contract testing laboratory partner for medical and combination devices. Powered by our coast-to-coast network of testing facilities, we offer services including small scale EO sterilizations and validations, package testing, extractables/leachables and microbiology services. At Infinity, we want to learn about the unique considerations of your project and assure quality, efficiency, and safety as we accelerate your path to patients.

ETHYLENE OXIDE (EO) SERVICES

We can help.

Infinity Laboratories has 30+ years experience helping our customers deliver safe and effective products to market.

Ethylene Oxide (EO) sterilization can efficiently penetrate the surfaces of most medical devices and its lower temperature make it an ideal process for a wide variety of material including single-use medical devices and pharmaceutical containers.

Per ISO 11135 and CFR 820 requirements, we can validate your product in our 3MSteri™-Vac™ sterilizers in preparation for routine sterilization at our facility.

SERVICES INCLUDE:

- EO Cycle Development and Validation per ISO 11135 and CFR 820
- Comparative Resistance Studies
- Sterilization Process Validation
- Full Validation Qualification
- Batch Release Qualification
- Aeration Qualification
- PCD Qualification
- Turn Key Validations
- Product Validation Support
- Routine Production Sterilization (24-48 hour TATs)
- Validation for changes to "Sterile" Products
- Consulting Services





The Contract Testing Partner That Puts Customer Success First.

Infinity Laboratories delivers precision results, rapid turnaround time, and regulatory support through our team of experienced scientists, chemists, and site leaders. With Infinity, you will have access to a project manager and laboratory operations team, committed to transparency and excellence throughout the execution of your program.

PACKAGE VALIDATION TESTING

We can help.

Infinity Laboratories has 30+ years experience helping our customers deliver safe and effective products to market. Our San Jose Laboratory provides robust package and environment testing of packaging of medical devices, pharmaceutical drug products, and combination drug products. Services include package integrity, distribution testing, conditioning, accelerated aging, shelf life and cross-leak testing.



We are here to help confirm package performance and integrity and can help you design and troubleshoot any package related issues and conduct in-depth failure analysis. Infinity Laboratories completes rigorous validations to ensure every package meets the requirements to protect medical devices by complying with ISO and ASTM standards.



SERVICES WE INCLUDE:

- Packaging Validation (ISO 11607)
- Distribution Testing (ASTM D4169)
- Atmospheric Conditioning (ASTM D4332)
- Accelerated Aging (ASTM F1980)
- Tensile Strength (ASTM F88)
- Gross Leak (ASTM F2096)
- Burst Testing (ASTM F1140)
- Dye Penetration (ASTM F1929)
- Visual Inspection (ASTM 1886)
- Abrasion Resistance (ASTM D5264)
- ISTA 1A-6A Testing Services
- 6-AMAZON.COM-SIOC Testing
- MIL-STD Testing

Infinity Laboratories has over three decades of experience helping the Medical Device industry assure the safety and efficacy of their devices and products. We offer a full suite of testing services from our national network of facilities, ensuring regulatory compliance while also accelerating the path to market.



Leverage a Single-Source Solution

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