



# Laboratory Testing 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.

## **Small Scale EO Services**

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

- Batch Release Qualification
- Comparative Resistance Studies
- Full Validation Qualification
- Routine Production Sterilization (24-48 hour TATs)
- Turn Key Validations

## **Extractables/Leachables and Chemical Characterization**

Infinity Laboratories leverages its unique knowledge of Medical Device development to help clients communicate and interact with various regulatory agencies.

E/L studies performed by Infinity:

- Elemental Impurities
- Material Compatibility
- Plastic Components
- Finished Devices

## **Packaging Validation Testing**

Our package testing services 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



# 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.

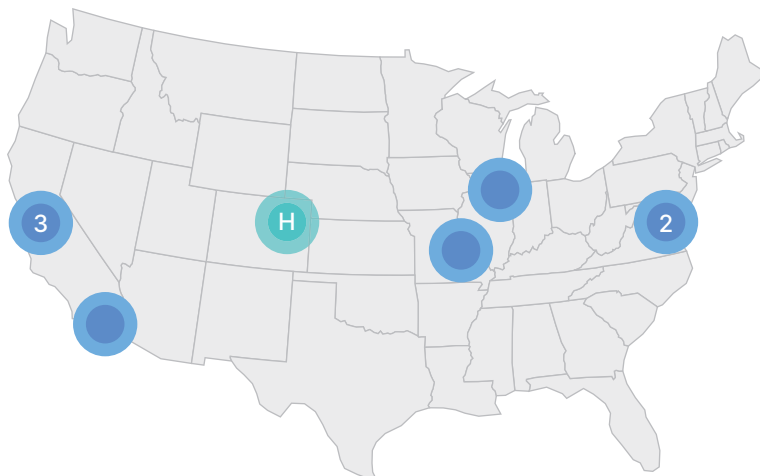
## Microbiology Testing

Infinity offers robust microbiological testing for every stage of your device's lifecycle to eliminate the risk of microbial contamination.

- Bioburden testing
- BET/LAL testing
- Cleanroom certification
- Environmental monitoring
- Sterility assurance testing
- Radiation validation support
- EO residuals
- BI sterility
- Microbial identification
- Water testing
- DES and cleaning studies



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.



## Your Local Testing Partner, Nationwide.

- 130+ staff
- 8 state-of-the-art laboratories
- FDA registered and operating to cGMP
- DEA licensed
- ISO accredited

## Leverage a Single-Source Testing Solution

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