



Medical Device Testing Services

Gamma/Ethylene Oxide (EO) Sterilization Validation

- Bioburden
- Bioburden recovery
- Bacteriostasis/fungistasis
- Sterility
- Dose calculation
- Spore strip population
- EO Residuals

Reusables

- High/low level disinfection
- Cleaning studies
- Steam/EO/chemical sterilization

Endotoxin

- FDA/USP gel clot
- Chromogenic
- Turbidimetric

Sterility

- USP
- ANSI/AAMI/ISO
- Product immersion
- Product flush
- Biological indicator
- Membrane filtration
- Steritest™/Sterisolutest™

Related Services

- Biocompatibility/toxicology
- Environmental monitoring
- Package stability and validation

Microtest's deep expertise and process flexibility have earned a leadership position in medical device testing services. With more than 20 years of support for the industry, our problem solving approach provides clients with reduced cost and risk, rapid regulatory approvals, and faster time to market.

We offer a broad range of services, including EO sterilization validation and testing, reusables, Endotoxin, and Sterility testing. Our transparent, seamless approach and custom method development give customers greater control over their testing programs. And our team's passion for quality minimizes lab excursions, out-of-spec tests, and schedule disruptions.

In addition, our growing pharmaceutical division provides attractive synergies to clients with medical devices that contain pharmaceuticals, such as drug-coated stents.

Only Microtest brings you the expertise and exceptional customer service that builds confidence — fostering a stress-free, frictionless relationship.

Investing in People and Technology

Microtest continuously invests in its professional skills and its testing technology. Our highly educated staff brings years of experience to their bench assignments. A \$7.5 million capital improvement program has expanded capabilities and capacity, including new edge-of-the-art sterility suites and a MicroSeq Microbial Identification System by Applied Biosystems, for faster,

more accurate identification of microbial hazards and contaminants. Our knowledgeable team and technologies help medical device manufacturers deliver safe, high-quality products with speed and cost-effectiveness.

Clients that demand minimal supply chain disruption and the fastest time to revenue make Microtest their supplier of choice for medical device testing services.



Our Technology

- Multiple Class 100 cleanrooms
- Multiple Class 100 laminar flow hoods
- Anaerobic chamber
- Steris™ ethylene oxide sterilizer
- Gravity prevacuum steam sterilizer
- Sensaphone™ Scada™ 3000

The Knowledge That Solves Your Problems The Flexibility That Gives You Control

Microtest offers a broad portfolio of medical device testing services built on a foundation of scientific knowledge, process flexibility, quality, and customer service. No other laboratory gives you this unique testing platform:

Expertise

A leader in medical device testing since 1984, Microtest has the experts that can solve your most difficult problems, such as very challenging bacteriophage or mycoplasma assays. Our team understands your product development process and supply chain. We're focused on minimizing cost and risk while accelerating time to market. Microtest employs a collaborative approach that yields greater customer input and involvement. With a management heritage in FDA regulation, our team achieves faster regulatory approvals for minimal schedule disruption.

Flexibility

Flexible — it's how we approach our work at Microtest. We test your products the way you do, for maximum confidence and greater control of the process. Only Microtest gives you the power of custom testing methods for smoother product development. In addition, our flexibility extends to meeting additional global regulatory requirements or responding rapidly to changes in your production schedule.

Quality

Quality is more than a given at Microtest, it's our passion. We raise quality assurance to a level more typically found in pharmaceutical manufacturing. Our ISO 9001-certified and FDA-regulated facilities are managed to the strictest standards, guidelines, and GLP/GMP practices. That means we minimize lab excursions, out-of-spec tests, and schedule disruptions. You get precise, accurate results on time and on budget. That's why Microtest enjoys the best on-time performance in the industry.

CUSTOMER SERVICE

Microtest believes clients deserve total transparency to the process. This customer service philosophy yields greater client control and security, while minimizing supply chain interruptions. You get clear, concise documentation, formatted for customer or regulatory submissions. We encourage clients to talk with the analysts conducting their testing programs. We forge a partnership to support you throughout the process. And we stay with you after the work is completed to interpret results for your customers or regulators.

www.microtestlabs.com

1-800-631-1680
1-413-786-1680
fax: 1-413-789-4334

Microtest Laboratories, Inc.
104 Gold St
P.O. Box 848
Agawam, MA 01001

