



TOTAL SOLUTIONS FOR CLEAN ROOM TESTING

From ISO certification to viable and nonviable sampling, disinfection validation to microbial identification, Microtest is the industry's best resource for testing of controlled environments. Medical device and pharmaceutical manufacturers as well as hospital pharmacies depend on Microtest to keep contamination under control.



MICROTEST'S COMPREHENSIVE CLEAN ROOM TESTING

Depend on Microtest to ensure your clean rooms are controlled — and that they remain that way.

Microtest's environmental sciences group is your best resource for continuous control of your controlled environment. It's a proven leader for contamination testing in medical device and pharmaceutical manufacturing, as well as sterile compounding hospitals.

Call on Microtest to provide:

- Ensured regulatory compliance
- Low or no process disruption
- Less downtime
- Greater productivity

Our work meets or exceeds applicable clean room testing standards including the International Organization for Standardization (ISO), the European Union (EU) Annex, and the U.S. Food and Drug Administration (FDA).

Microtest recently tripled its staff and doubled the size of its facilities with a \$7.5 million investment in laboratories, people, and technology. Our microbiologists bring long experience in applying modern testing technologies to all controlled environments.

Microbial identification

Contamination by an unknown organism often calls for total shutdown of a clean room's operation, with catastrophic effects on schedules and productivity.

For the industry's fastest, most reliable microbial ID solution, Microtest maintains two state-of-the-art MicroSEQ 3130 DNA sequencing analyzers to identify bacteria and fungi/mold. We can produce preliminary microbial IDs in 24 hours, with final reports in 1 week or less! Microtest offers remote and onsite sampling for clients anywhere within the U.S.



ISO certification

Government regulations require controlled environments to be tested and certified per ISO 14644. Microtest can certify, to any ISO Class required, all controlled environments:

- Clean rooms
- Laminar flow hoods
- Biological safety cabinets
- Compounding aseptic isolators
- Fume hoods

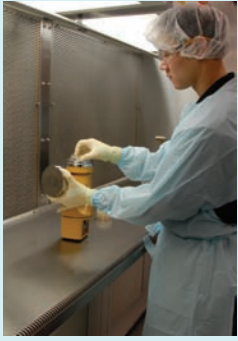
Our trained technicians have worked on virtually every type of clean room and HEPA filtration system now in use. They can quickly troubleshoot issues when they arise, and ensure worry-free ISO certification — for less downtime and more productivity.

HEPA filter replacement

Tears, rips, and cracks — which cause leaks and compromise filter performance — often result when HEPA filters are not properly installed. Microtest's certified technicians can find the leak, change out the filter or patch and seal, then recertify onsite.

Microtest's environmental sciences group repairs or replaces HEPA filters for all controlled environments, ensuring continuing functionality and process performance.





Viable sampling

ISO 14698 and USP Chapters <1116> and <797> require regular testing of controlled environments for the presence of microbial organisms.

Microtest's fully trained microbiologists can evaluate your environment for aerobic and anaerobic microorganisms, including both bacterial and fungal (yeasts & molds) sources. We can perform surface testing and analysis via RODAC or swab, carry out active air sampling using state-of-the-art PBI samplers, and collect passive air samples with settling plates. (If contamination is detected, we can also ID it quickly: see "Microbial identification" below.)

Finally, we can help isolate and eliminate the source, returning you to full production in record time.

Nonviable air particulate sampling

Microtest provides routine monitoring of your controlled environment under ISO 14644 guidelines, the EU Annex, or both. We employ advanced Met-One laser particle counters, as well as Biotest airborne particle counters with the capability to sample a full cubic meter of air in only 10 minutes. Our experienced technicians can collect appropriate samples at your facility without disturbing production.

If and when a nonviable air particulate spike is detected, we help track down the source with minimum downtime and maximum efficiency.



Disinfection validation

All disinfectants must be validated and documented as effective for intended use. In Microtest validation testing, data is reported in summary format acceptable to the U.S. FDA.

Our microbiologists test a given concentration of disinfectant using the following standard bacterial strains, fungi, and environmental isolates:

- Use dilution testing: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*
- Phenol coefficient testing: *Salmonella typhi*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*
- Sporicidal testing: *Bacillus atrophaeus* and *Clostridium sporogenes*
- Germicidal testing: *Trichophyton mentagrophytes*, *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*



Compressed air/gas testing

Compressed air lines or gas lines fed directly into a controlled environment must meet the same ISO classification as the clean rooms they serve, and must be similarly monitored.

Microtest tests your lines for nonviable air particulates; viable aerobic, anaerobic, and fungal (yeast & mold) organisms; and contaminants such as hydrocarbons and water vapors.



Gowning validation

Experts strongly recommend validation of gowning technique for each person who enters a controlled environment.

Microtest specialists can come to your facility to help develop a gowning procedure appropriate for your specific workforce and workspace; to demonstrate proper aseptic gowning techniques directly to your team; to explain the relevant microbiological science underlying particular gowning protocols; and to validate each individual's gowning process.



Ensure your clean room stays contamination-free. Call on the Microtest environmental sciences group today!

ABOUT MICROTEST

Microtest is a leader in testing services and contract manufacturing for medical devices, pharmaceuticals, and biotechnology. Founded in 1984, the company provides expertise and flexible processes that enhance product safety and security, accelerate time to market, and minimize supply chain disruption. Microtest's unique single-source capability to furnish testing and manufacturing solutions allows the company to support a full pharmaceutical or medical device product release. Our facilities in Agawam, Massachusetts, U.S.A., include state-of-the-art aseptic manufacturing areas; analytical chemistry, microbiological, and virological laboratories; Class 100 clean rooms; onsite steam and ethylene oxide sterilization, plus depyrogenation capabilities; purified water systems; and voice/data systems.



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