

identify microbial and fungal contaminants
with **high accuracy**
and **speed**

MicroSEQ® Rapid Microbial Identification System

Featuring the 3500 Genetic Analyzer

Top pharmaceutical companies worldwide use the MicroSEQ[®] Microbial Identification System

Ideal for:

- Environmental monitoring
- Contamination investigation
- Root cause analysis
- Raw material testing

Drain-line_3

Pseudomonas aeruginosa ATCC = 10145

Pseudomonas aeruginosa ATCC = 25619

Pseudomonas citronellolis

Pseudomonas stutzeri

Pseudomonas nitroreducens

Pseudomonas monteilii

Pseudomonas oleovorans

Pseudomonas pseudoalcaligenes



Achieve right-first-time microbial identification

Next-generation, high-throughput comparative DNA sequencing system for identification of bacteria and fungi

The answer is in the DNA

Harmful bacteria and fungi can contaminate raw materials, production facilities, and even worse, branded products.

The Life Technologies MicroSEQ® Rapid Microbial Identification System (Figure 1) uses a highly accurate phylogenetic approach for microbial identification based on the sequencing of the 16S rRNA gene for bacteria or the D2 region of the large subunit for fungi and comparison of the sequences to those in its validated libraries.

After sequencing the rRNA gene, the MicroSEQ® system automatically compares the results to validated sequences in the MicroSEQ® microbial libraries. The results are ranked according to genetic distance of the reference sequences to the sample and displayed on the system monitor along with a phylogenetic tree (Figure 2).

The system includes the largest fully validated bacterial and fungal libraries. The bacterial library includes over 2000 species, including *Staphylococcus* spp., *Bacillus* spp., coryneforms, mycobacteria, and Gram-negative non-fermenters. The library for fungal species includes over 1100 entries. Both are frequently updated and expanded with new entries.



Figure 1. MicroSEQ® Rapid Microbial Identification System. (A) 3500 and 3500xL DNA sequencing instruments; (B) MicroSEQ® ID Analysis Software with 3 libraries; (C) FAST MicroSEQ® Bacterial 500 16S ID Kit, FAST MicroSEQ® Fungal D2 ID Kit, MicroSEQ® Full Gene 16S ID Kit; (D) Veriti® Thermal Cycler.

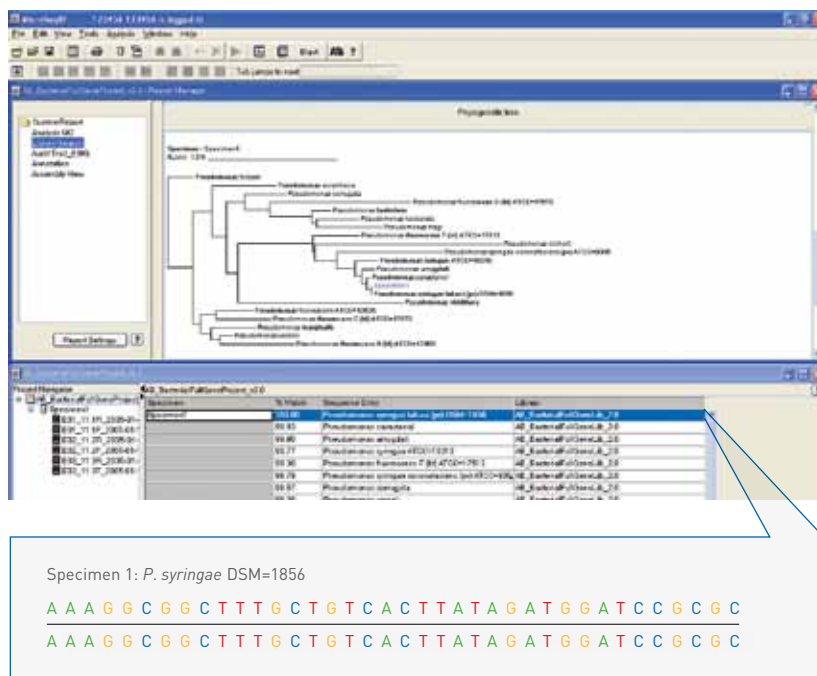


Figure 2. MicroSEQ Rapid report. Genetic distance from reference sample and phylogenetic tree.

Regulatory Guidance

“Sterility test isolates should be identified to the species level. Microbiological monitoring data should be reviewed to determine if the organism is also found in laboratory and production environments, personnel, or product bioburden. Advanced identification methods (e.g., nucleic-acid based) are valuable for investigational purposes. When comparing results from environmental monitoring and sterility positives, both identifications should be performed using the same methodology.”

Source: FDA Guidance, Sterile Drug Products Produced by Aseptic Processing-cGMP, September 2004

Generate actionable results in less than 5 hours

With the MicroSEQ® Rapid Microbial ID System, bacteria and fungi can be identified in under 5 hours, using a logical workflow that requires minimum hands-on time (Figure 3). A single, standardized procedure is used for identifying both bacterial and fungal isolates.

With the data collection analysis software (Figure 4), the system delivers a guided setup process and performs the analysis with limited interaction from the user.

No Gram staining or ancillary tests are required to achieve the highest level of accuracy in the minimum amount of time.

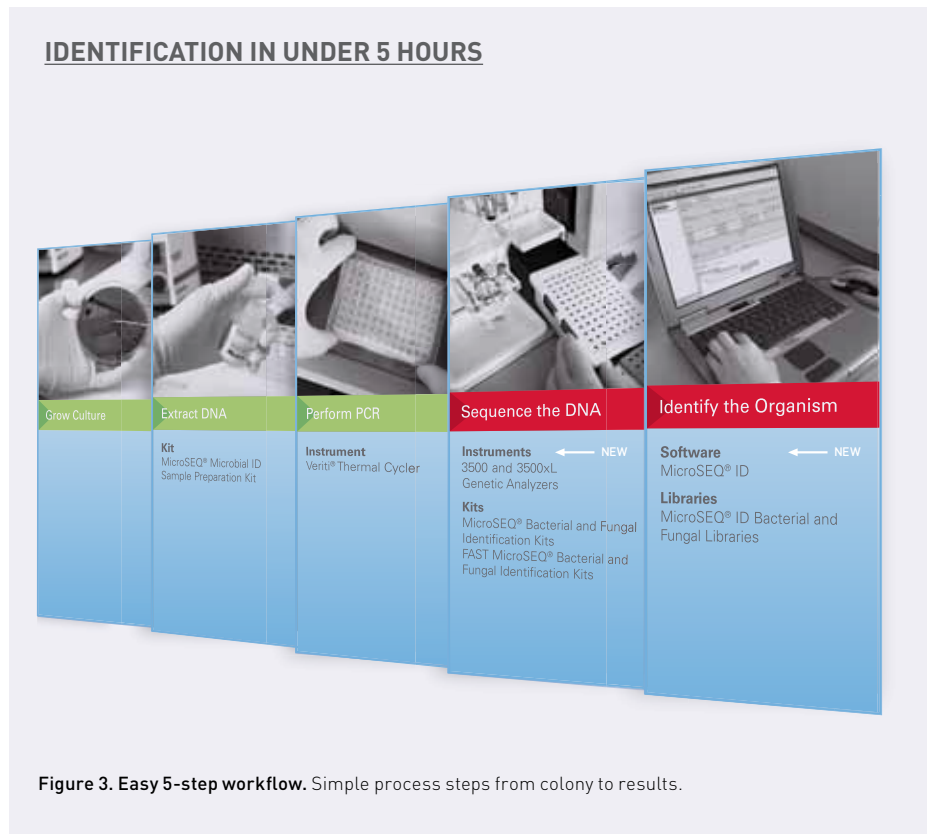


Figure 3. Easy 5-step workflow. Simple process steps from colony to results.

“DNA-based amplification and sequencing results are faster, more sensitive, more accurate and more reproducible than current microbiological methods.”

—Dr. Robert Johnson
Director, Dialogue (Switzerland)

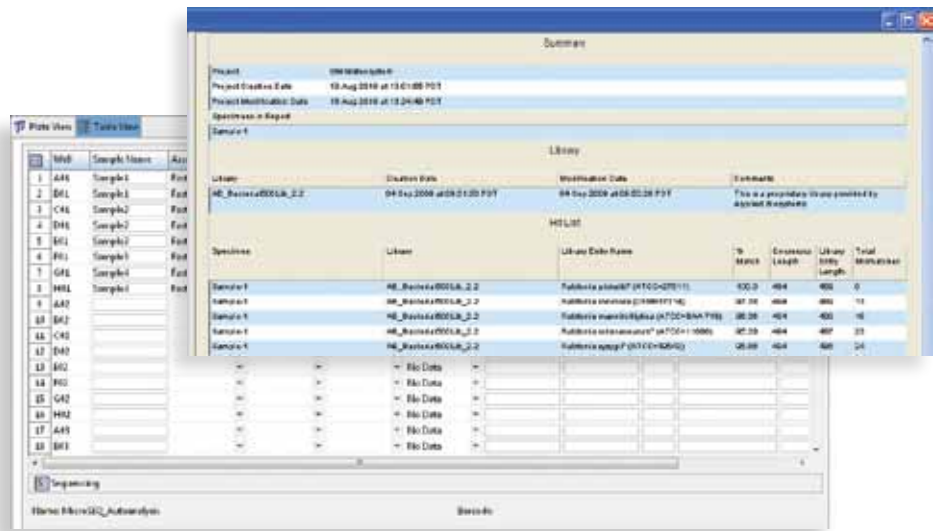


Figure 4. Data analysis. Easy-to-use sample input screens with automated data analysis.

Increased throughput with greater ease-of-use

The MicroSEQ® Rapid Microbial ID System powered by the 3500 Series Genetic Analyzer simplifies the user experience and enables faster identifications for the QC laboratory.

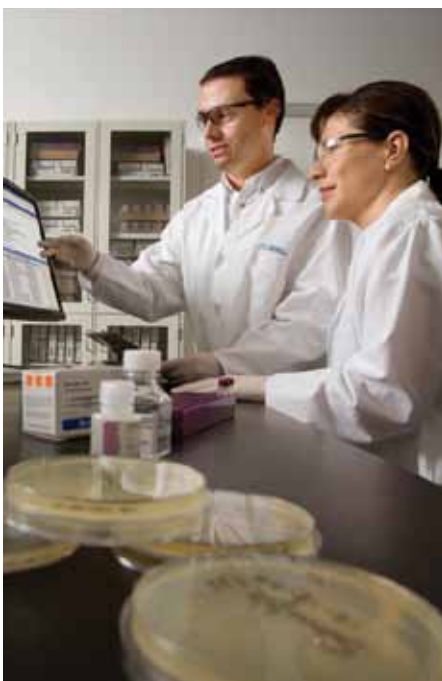
- Plug-and-play capillary array and consumables (Figure 5)
- Consumables dashboard monitor (Figure 6)
- Automated consumable usage tracking
- Simple on-screen navigation with automated maintenance tracking



Figure 5. 3500 Series Analyzer. (A) Prepacked consumables. (B) Expanded capillary array.



Figure 6. Consumables dashboard. Easy-to-understand real-time information on consumable status.



Qualify with ease, use with success

To help ensure seamless integration into your laboratory from installation to routine operation, Life Technologies offers comprehensive installation and operational qualification (IQ/OQ) and validation support services.

The program includes:

- Consultation with client to determine needs for training, system installation and validation timelines and plans
- System software installation, operation, and security verification
- Installation Qualification (IQ) Protocol and Service
- Operational (OQ) Qualification Protocol and Service
- Detailed data analysis and review
- Consultation on laboratory workflow
- Performance qualification (PQ)–recommended guidelines

Benefit from worldwide implementation and support

The Life Technologies distribution and service network, composed of highly trained support and application personnel, reaches 150 countries on six continents. In addition to basic service and support, the following additional services are offered for the MicroSEQ® Rapid Microbial ID system:

- On-site workflow and data analysis training
- Validation guidance

Description	Part Number
System	
MicroSEQ® Rapid Microbial ID System with 3500 Genetic Analyzer	4462991
MicroSEQ® Rapid Microbial ID System with 3500xL Genetic Analyzer	4462990
Software	
MicroSEQ® ID Analysis Software Bundle	4448336
MicroSEQ® ID v2.2	4371431
Installation and IQ/OQ	
IQ/OQ, 3500 MSID Service	4457843
IQ/OQ, 3500xL MSID Service	4457844
Kits	
FAST MicroSEQ® 500 16S rDNA Bacterial PCR Kit with Protocol and Quick Reference Card	4370653
MicroSEQ® 500 16S rDNA Bacterial Sequencing Kit with Protocol and Quick Reference Card	4346479
MicroSEQ® Full Gene 16S rDNA Bacterial PCR Kit with Protocol and Quick Reference Card	4349161
MicroSEQ® Full Gene 16S rDNA Bacterial Sequencing Kit with Protocol and Quick Reference Card	4347483
FAST MicroSEQ® D2 rDNA Fungal Identification Kit with Protocol and Quick Reference Card	4382395
MicroSEQ® D2 rDNA Fungal Sequencing Kit with Protocol and Quick Reference Card	4347482

Life Technologies offers a breadth of products DNA | RNA | protein | cell culture | instruments

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