

The way
forward in
microbial
identification.

Pharma analytics

MicroSEQ Rapid Microbial Identification System



applied biosystems

Achieve right-the-first-time microbial identification

Rapid microbial characterization and identification to support environmental monitoring for biopharmaceutical manufacturing

The answer is in the DNA

Microbial detection within biopharmaceutical manufacturing is a critical quality control (QC) activity to ensure drug products are free of viable microorganisms. Per regulatory guidelines, the implementation of an environmental monitoring program must comply with good manufacturing practices, and identification of microorganisms to the species level is a minimal requirement.

The Applied Biosystems™ MicroSEQ™ Rapid Microbial Identification (ID) System combines the benefits of both PCR and DNA sequencing technologies to help deliver highly accurate and reproducible results. It employs a preferred phylogenetic approach for microbial identification based on comparative rDNA sequencing of the 16S region (for bacteria) or the LSU D2 region (for fungi), and the comparison of the sequences to those in its robust, validated libraries.

Used in top pharmaceutical companies worldwide, the MicroSEQ system is ideal for:

- Environmental monitoring
- Contamination investigation
- Root cause analysis
- Raw materials testing
- Microbial identification in small-molecule and biopharmaceutical manufacturing and service labs

“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)

MicroSEQ Rapid Microbial Identification System

Streamlining every step in microbial identification, the MicroSEQ system (Figure 1) combines the advantages of Applied Biosystems™ MicroSEQ™ Microbial Identification Software with MicroSEQ™ bacterial and fungal application kits, and industry-leading thermal cyclers and sequencing systems. To help ensure optimal performance and system-wide integration, we develop and test all components of the system together.

Applied Biosystems™
SeqStudio™ QST and
SeqStudio™ Flex PA
Genetic Analyzers

Applied Biosystems™ MicroSEQ™
PCR and sequencing assay kits



MicroSEQ Microbial
Identification Software 4.0
featuring curated and validated
bacterial and fungal libraries

Applied Biosystems™
VeritiPro™
Thermal Cycler

Figure 1. Components of the MicroSEQ Rapid Microbial Identification System.

Go from culture to answer in less than 5 hours

Identify a wide range of microorganisms using a universal protocol that streamlines the workflow

With the MicroSEQ Rapid Microbial ID System, results can be obtained rapidly using a logical workflow that requires minimal hands-on time. A single, standardized procedure is used for identifying both bacterial and fungal isolates, giving you results from colony to identification in less than 5 hours (Figure 2).

MicroSEQ PCR and sequencing kits, along with complementary reagents for efficient sample preparation and purification, have been tested together to deliver optimal results.



Figure 2. Leverage the universal workflow with easy process steps to go from colony to results.

Designed to support regulatory guidelines

FDA guidance is intended to help manufacturers meet the requirements in the agency's current good manufacturing practice (cGMP) regulations (21 CFR Parts 210 and 211) when manufacturing sterile drug and biological products using aseptic processing. In the guidance document, "Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice," the FDA clearly identifies genotypic methods of microbial identification as more accurate and precise than traditional biochemical and phenotypical techniques.

The MicroSEQ Rapid Microbial ID System is designed to support the recommended qualification guidelines from:

- International Conference on Harmonisation (ICH)
- United States Pharmacopeia (USP)
- European Pharmacopoeia (EUP)
- Japanese Pharmacopoeia (JP)

"Genotypic methods have been shown to be more accurate and precise than traditional biochemical and phenotypic techniques. These methods are especially valuable for investigations into failures (e.g., sterility test, media fill contamination)."

(FDA, 2004, Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice, p. 35)

Identify your culture with confidence

Accurate identification of isolates at the species level

Identify and classify your bacterial or fungal sequence using the latest feature-rich release of our tried-and-true analysis software, specifically designed for the SeqStudio series of genetic analyzers. MicroSEQ Identification (ID) Software v4.0 allows users to leverage the advanced features of the SeqStudio systems while also meeting regulatory requirements to enable 21 CFR Part 11 compliance (Figure 2).

Features of MicroSEQ ID Software 4.0 include:

- Multiple concurrent user support
- Simple, intuitive browser-based interface
- Enhanced security, audit, and e-signature (SAE) compliance supporting both instrument and software
- Archive, backup, and restore data management functions
- Advanced sample- and project-level reporting with customizable output

The engine driving MicroSEQ ID software is its powerful database. Comprised of four meticulously curated libraries, it offers the largest validated *in silico* database, containing over 12,000 strain types (Table 1) and delivering accurate identification of and detailed information about your isolate (Figure 3).

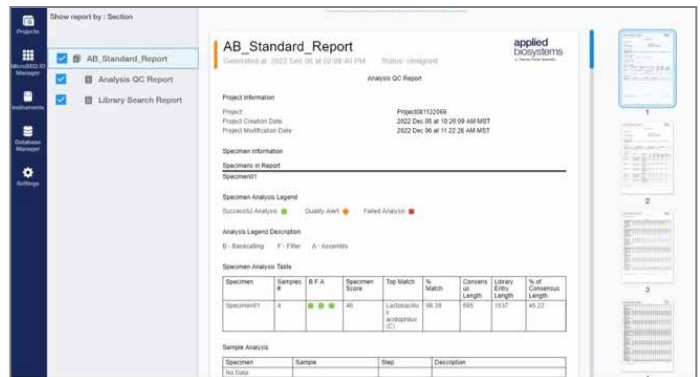
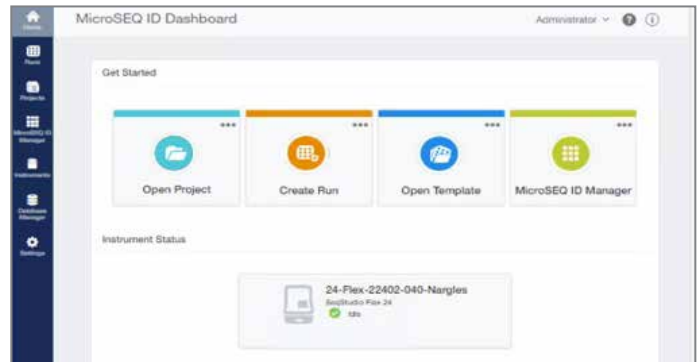


Figure 2. Input and data analysis. User-friendly screens to input run details and analyze data.

Table 1. Comprehensive bacterial and fungi database with confirmed strain information to compare against your samples.

Library	Entries
MicroSEQ ID 16S rDNA 500 Microbial Library, v2022	2,100
MicroSEQ ID 16S rDNA 500 Supplemental Library, v2022	7,645
MicroSEQ ID Fungal Gene Library, v2022	1,737
MicroSEQ ID 16S rDNA Full Gene Library, v2.1	1,262

Specimen: Specimen01
 _____ = 0.0378 %

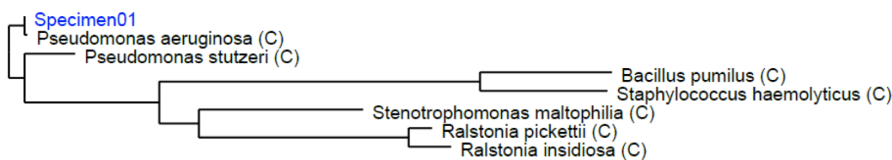


Figure 3. Know your microorganism. The MicroSEQ ID system provides detailed information on your isolate, including a phylogenetic tree. Matches made against custom libraries are flagged in the tree diagram with "(C)."

Simplicity, scalability, and speed—choose your system

Rapid and accurate microbial identification using the latest in genetic analyzer technology

Versatile and innovative, the Applied Biosystems™ SeqStudio™ family of instruments is the latest generation of genetic analyzers in our portfolio. As an integral part of the complete MicroSEQ Rapid Microbial Identification workflow, these genetic analyzers deliver the high level of data quality and reliable performance required by your QC and environmental monitoring applications.

The SeqStudio Genetic Analyzer provides a low-throughput platform featuring fast turnaround, ease of use, and a convenient all-in-one workflow based on a cartridge system.

The award-winning SeqStudio Flex Genetic Analyzer is the preferred system for medium- and high-throughput requirements. Available in both 8- and 24-capillary configurations, it offers ease of use and high sample loading flexibility.



	SeqStudio QST Genetic Analyzer	SeqStudio Flex PA Genetic Analyzer
Number of capillaries	4	8 or 24
IDs/8 hours*	10	6 or 22
IDs/24 hours*	46	34 or 94
Sample format	1 plate; 96-well plate; 8-strip tube (compatible)	4 plates; 96- or 384-well plates; 8-strip tube (compatible)
Supports 21 CFR Part 11	Yes	Yes
Library database	Bacterial/fungal	Bacterial/fungal
Remote monitoring and data sharing	Yes	Yes
Integrated remote troubleshooting tools	No	Yes
Connectivity	USB, ethernet ports, and Wi-Fi dongle	USB, ethernet ports, and Wi-Fi dongle

* All workflows include sample preparation time of 3 hours.

Qualify with ease, use with success

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

Support services include:

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

Benefit from worldwide implementation and support

Our 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



Ordering information

Description	Cat. No.
Sample prep kit	
PrepMan Ultra Sample Preparation Reagent	4318930
MicroSEQ PCR kits	
Fast MicroSEQ 500 16S rDNA PCR Kit, with protocol and quick reference card	4370489
MicroSEQ Full Gene 16S rDNA PCR Kit, with protocol and quick reference card	4349155
Fast MicroSEQ D2 LSU rDNA Fungal PCR Kit, with protocol and quick reference card	4382397
MicroSEQ sequencing kits	
MicroSEQ 500 16S rDNA Sequencing Kit, with protocol and quick reference card	4346480
MicroSEQ Full Gene 16S rDNA Sequencing Kit, with protocol and quick reference card	4347484
MicroSEQ D2 rDNA Fungal Sequencing Kit, with protocol and quick reference card	4347481
Purification/clean-up kits	
MicroSEQ ID Purification Combo Kit v2.0, with clean-up plates	A35852
MicroSEQ ID Purification Combo Kit v2.0, with 8-strips kit	A35854
Libraries and software	
MicroSEQ ID Microbial Identification Software v4.0 with all the libraries	A57311
MicroSEQ ID Microbial Identification Software v4.0	A56679
MicroSEQ ID 16S rDNA Full Gene Library v2.1	A57315
MicroSEQ ID 16s rDNA 500 Library, v2022	A57312
MicroSEQ ID Fungal Gene Library, v2022	A57314
MicroSEQ ID 16S rDNA 500 Supplemental Library, v2022	A57313
Instrumentation	
SeqStudio Genetic Analyzer QST with SAE	A49988
SeqStudio 8 Flex PA Desktop	A57829
SeqStudio 24 Flex PA Desktop	A57830
VeritiPro Thermal Cycler, 96 well	A48141
VeritiPro Thermal Cycler, 384 well	A48140

 Learn more at thermofisher.com/microseq

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