MicroSEQ™ Microbial Identification System Libraries

Validation Process Statement: All library versions

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MicroSEQ™ system overview

The MicroSEQ™ Microbial Identification System combines all of the instruments, reagents, sequence libraries, and software required for automated microbial identification using DNA sequencing.

The MicroSEQ™ system is easy to use and suitable for the routine identification of all bacterial and fungal isolates, including organisms that are difficult to grow, non-viable, or unidentifiable using phenotypic methods. The MicroSEQ™ system identifies bacterial and fungal isolates from a small sample of pure culture without preliminary testing or growth on selective media.

System components

- MicroSEQ™ bacterial and fungal identification kits
- MicroSEQ™ ID Microbial Identification Software v2.x or v3.x
- MicroSEQ™ ID libraries:
    - MicroSEQ™ ID 16S rDNA 500 Library v2019
    - MicroSEQ™ ID 16S rDNA Full Gene Library v2.0
    - MicroSEQ™ ID Fungal Library v2018
    - MicroSEQ™ ID 16S rDNA 500 Supplemental Library 2019
- PrepMan™ Ultra Sample Preparation Reagent
- Applied Biosystems™ genetic analyzers and thermal cyclers

Validation process

MicroSEQ™ ID libraries are tested to ensure integrity with MicroSEQ™ ID Microbial Identification Software v2.x or v3.x and MicroSEQ™ ID Software For SeqStudio™ Genetic Analyzer v1.0.

All versions of MicroSEQ™ ID libraries are tested to validate the correct genus and species of new bacteria and fungi library entries and to revalidate existing library entries.

Libraries are validated using the following process by trained personnel in accordance with ISO 9001:2000 quality systems requirements.

1. Obtain type strains or genomic DNA from type strains from preeminent culture collections, such as ATCC or DSMZ.
2. Generate sequences using the appropriate MicroSEQ™ ID PCR and sequencing kits, verify accurate sequence identification, and measure the quality of the sequence generated.
3. Search public databases for a semi-qualitative match. Investigate further if needed to determine the match.
4. Ensure that any new species of rDNA sequences are the correct phylogenetic topology.
5. Update nomenclature in libraries according to rules of *International Journal of Systematic and Evolutionary Microbiology*.

For more information on the validation process, contact us at **bp@thermofisher.com** or contact your local Thermo Fisher Scientific representative.

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