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## **MicroSEQ® Microbial Identification System MicroSEQ® ID 16S rDNA 500 Library v2.2 Validation Statement**

MicroSEQ® Microbial Identification System is a genotypic system for the identification of bacteria and fungi. MicroSEQ® ID system methods are based on the 16S ribosomal RNA gene for bacterial identification and the D2 region of the Large SubUnit of the fungal ribosomal rRNA gene. The complete MicroSEQ® ID system includes the following:

MicroSEQ® Bacterial and Fungal Identification Kits  
MicroSEQ® ID v2.X Analysis Software

- MicroSEQ® ID 16S rDNA 500 v2.2 Library
- MicroSEQ® ID 16S rDNA Full Gene v2.0 Library
- MicroSEQ® ID Fungal Gene v2.0 Library

PrepMan™ Ultra Sample Preparation Reagent  
Applied Biosystems Genetic Analyzers and Thermal Cyclers

The MicroSEQ® ID 16S rDNA 500 Library v2.2, MicroSEQ® ID 16S rDNA Full Gene Library v2.0, and MicroSEQ® ID Fungal Gene Library v2.0 (collectively "MicroSEQ® ID Libraries") are a key part of the MicroSEQ® ID system. A rigorous validation process of the MicroSEQ® ID Libraries facilitates accurate species identification for new entries and revalidation of existing entries facilitates continued taxonomic accuracy.

This document summarizes the procedures conducted by Applied Biosystems to validate the correct genus and species of new bacteria and revalidate existing entries in the MicroSEQ® ID 16S rDNA 500 v2.2 Library ("Validation") only. Please refer to the MicroSEQ ID v2.0 Library Validation Statement for all v2.0 MicroSEQ ID Libraries.

- Obtained type strains or genomic DNA from type strains from preeminent culture collections, such as ATCC or DSMZ.
- Generated 16S rDNA sequences using the Fast MicroSEQ® ID 500 16s PCR and Sequencing rDNA kit, verified visually, and measured the quality of the sequence generated.
- Searched public databases for a semi-qualitative match. Additional steps to determine match are taken based on results of the search.
- Determined the new species of rDNA sequences are the correct phylogenetic topology.
- Updated nomenclature according to rules of International Journal of Systematic and Evolutionary Microbiology

The Validation process is followed for every new entry and updates to existing libraries follow a similar Validation procedure. Validation of each entry is completed by trained personnel. MicroSEQ® ID Libraries are tested in accordance with ISO 9001:2000 quality systems requirements to ensure integrity with MicroSEQ® ID v2.X series analysis software.

Please contact Applied Biosystems Technical Support at 1-800-831-6844 for complete details of the Validation and for any further questions. We appreciate your continued support and interest in the MicroSEQ® Microbial Identification System

Signed and reviewed by:

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