**Listeria spp. Identification Library License Installation and User Guide**

### Intended Use

The *Listeria* Organism Library License is an add-on Identification Library for the MIT 1000 Rapid Microbial Identification (RMID) System (SYSTEM). This Organism Library, once installed into the MIT 1000 RMID Program enables it to identify the *Listeria* Genus.

### Principle

The MIT 1000 RMID System is a rapid microbial identification device that uses the principles of light scattering coupled with proprietary algorithms to identify bacteria after being cultured and placed in a vial of filtered water. The *Listeria* species Organism Library License (LICENSE) is a series of data files that are installed into the MIT 1000 RMID Program (PROGRAM) that enables the SYSTEM to identify *Listeria* species. The LICENSE is installed in exactly the same manner that programs are installed on a personal computer (PC). Once installed, The LICENSE will appear in the License Display of the PROGRAM and can be selected for use in an Identification Test as described in chapter 4 of the MIT 1000 User Guide (USER GUIDE.)

### Contents

- 1 *Listeria* spp Organism Library License CD
- 1 package insert (this document.)

### Instructions for Installation

To install the LICENSE, do the following:

1. Make certain the System PC is turned on.
2. Place the Listeria spp LICENSE CD into the CD tray.
3. If the LICENSE Installation does not automatically startup, navigate to the CD using Windows Explorer and double-click on the file “setup.msi.”
4. Click Next in the first dialog.
5. Click Next in the second dialog. Do not change the installation folder.
6. Click Next in the third dialog to confirm the installation.
7. Enter your Product Key (found on the CD and the CD jewel case) and press OK.
8. After the installation is complete, exit the installation process.
9. Remove the Installation CD.

After installing the LICENSE, Click on the License button in the PROGRAM and the LICENSE will appear in the Registered Identification Libraries list of the License selection dialog box.

The installation of this LICENSE does not change, in any way, the methods and procedures outlined in the USER GUIDE.

### Quick Reference for Use

Refer to Chapter 3 and 4 of the User Guide:

1. Turn on the SYSTEM and start the PROGRAM.
2. Click the License button.
3. Add the *Listeria* spp Organism Library License to the list of Organism Libraries that will be used for Identification Tests by:
   a. Clicking on “Listeria spp” in the Registered Identification Libraries list and then click the Down Arrow; or
   b. Double-Click on “Listeria spp” in the Registered Identification Library list.
4. Click OK.
5. Clean and rinse a MIT RMID Vial with 0.1 micron filtered water.
6. Add about 15 mL of 0.1 micron filtered water to the RMID Vial.
7. Cover with Parafilm and secure with a rubber band.
8. Clean and rinse a 0.6 mL microcentrifuge tube with 0.1 micron filtered water.
9. Fill the microcentrifuge tube to about 0.2 mL with 0.1 micron filtered water.
10. Sample a small amount of a single colony from a culture plate with a 1 μL sterile inoculating loop.
11. Dislodge the colony material on the loop into the water in the microcentrifuge tube.
12. Close the microcentrifuge tube and vortex.
13. Remove the rubber band and gently lift the Parafilm covering the RMID Vial and pipette 1 μL from the microcentrifuge tube into the RMID Vial.
14. Re-cover the RMID Vial with Parafilm and replace the rubber band.
15. Lift up the tails of the Parafilm and press into place to get the Parafilm off the neck.
16. Wipe the round bottom of the RMID Vial with a Kimwipe dampened with 70% IPA.
17. Place the RMID Vial in the MIT 1000 System.
18. Start the MIT 1000 RMID software system.
19. Click on License and select the appropriate Organism Library(s).
20. Click Identify.

### Specimens (Collection and Preparation)

The LIBRARY is not for use directly with clinical or other specimens. The microorganisms to be identified must first be isolated on TSA with 5% sheep blood (or other approved) solid agar medium as described in the USER GUIDE.
Warnings and Precautions

- For professional use only.
- Listeria monocytogenes is a significant human pathogen. Immuno-compromised individuals, such as pregnant women should not be in the vicinity of samples being enriched or tested for Listeria as they represent particularly susceptible populations. Extreme care should be used in handling samples which could potentially contain this pathogen, enriched media, and used RMID Vials. Ensure all biohazardous waste is disposed of appropriately.
- All specimens, microbial cultures, and inoculated sample vials (RMID Vials) should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacteria should be observed throughout the identification procedure. Refer to “NCCLS M29-A. Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue. Approved Guideline – December 1997” For additional handling precautions, refer to “Biosafety in Microbiological and Biomedical Laboratories, HHS Publication No. (CDC 93-8395, 3rd Edition (May 1993)”. Or to the regulations currently in use in each country.

Confirmation

Presumptive positive sample results must be confirmed by Bacteriological Analytical Manual (BAM) or the USDA/FSIS methods for the detection of Listeria. It is recommended that roast beef, deli turkey, hot dogs, pepperoni, and all environmental samples be confirmed using the FSIS/USDA protocol. It is recommended that ricotta cheese, smoked fish, cooked shrimp, whole milk, ice cream, and potato salad be confirmed using the FDA protocol.

Simultaneous Use with Other Organism Libraries

This LIBRARY may be selected and used simultaneously with any combination of Organism Libraries offered by Micro Imaging Technology.

Quality Control

For those users, who wish to perform their own quality control tests, please use TSA with 5% sheep blood and any of the strains below:
- Listeria monocytogenes ATCC 19115
- Listeria monocytogenes ATCC 19118
- Listeria ivanovii ATCC 19119

Limitations of the Method

- The Listeria spp Identification Library is intended expressly for the identification of bacteria belonging to the genus Listeria. It cannot be used to identify any other microorganisms or to exclude their presence.
- Only pure cultures of a single organism should be used.

Performance

One hundred five ID tests were performed on 55 strains of Listeria and other bacteria.
- 99.0% of the strains were identified without supplementary tests.
- 1.0% of the strains were not identified.

Disposal

Decontaminate RMID Vials, pipettes and media by autoclave, bleach, etc., in accordance with local, state, and federal regulations.