Pharmaceutical Microbiology

MALDI Biotyper®

Changing Microbiology

Innovation with Integrity
Fast, Accurate and Traceable Identification of Microorganisms

The MALDI Biotyper System:
- Robust and Easy to Use
- Compact Bench Top System
- Comprehensive Species Library
- Easy to integrate
- Intuitive software
- 21CFR part 11 support
  - Audit Trail
  - User Management
  - Data Security
  - Electronic Signature
- IQ/OQ/PV documentation

Ensure Safety and Quality of Pharmaceutical Products

Pharmaceutical microbiologists are responsible for ensuring that the supply of life-saving drugs and vaccines are free from contamination of microorganisms.

MALDI Biotyper provides specific identification of microorganisms within minutes.

Its performance reaches far beyond traditional methods and its outcome is comparable to molecular sequencing techniques.

Implementing MALDI Biotyper in the microbial QC workflow can directly translate to significant cost savings by accelerated control of raw materials as well as quicker in-process production and end-product testing.
Straightforward to Result

There is nothing faster - and easier

The MALDI Biotyper identifies microorganisms using MALDI-TOF (Matrix Assisted Laser Desorption Ionization-Time of Flight) Mass Spectrometry to determine the unique molecular fingerprint of an organism. The characteristic spectrum pattern of this molecular fingerprint is used to reliably and accurately identify a particular microorganism by matching thousands of reference spectra of microorganism strains.

The MALDI Biotyper workflow has been designed to be as robust and easy to perform as possible. Only a few simple steps are required to generate high quality and reliable microorganism identification. The process of mass spectra acquisition and spectra-matching is standardized, resulting in highly accurate microorganism identifications in every run.

Typically, no more than an isolated colony from a culture plate or small aliquot from a broth is required. The entire procedure takes only a few minutes to complete. Fully traceable paperless workflows are possible through the use of barcoded MALDI target plates.

**MALDI Biotyper Identification Workflow**

1. **Select an isolated colony**
2. **Transfer sample and add matrix**
3. **Add to MALDI-TOF project list**
4. **Software automatically generates MALDI-TOF spectrum**
5. **Spectrum instantly matched against reference library to give identification**
6. **Final review and validation**
Rigorous and Sophisticated Data Analysis Assures Accuracy

Meaning of score values

The acquired spectrum of the sample is transformed into a peak pattern, utilizing dedicated spectral analysis tools. This pattern is compared to reference peak lists of organisms in the reference database and a log(score) value between 0.00 and 3.00 is calculated.

The higher the log(score) value, the higher the degree of similarity to a given organism in the reference database. Values ≥ 2 (green) indicate high confidence identifications. Log (score) values between 1.70 and 1.99 (yellow) need to be confirmed by additional methods. Values below 1.70 (red) indicate that no organism identification was possible.

<table>
<thead>
<tr>
<th>Range</th>
<th>Interpretation</th>
<th>Symbols</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.000 - 3.000</td>
<td>High Confidence Identification</td>
<td>(+++)</td>
<td>green</td>
</tr>
<tr>
<td>1.700 - 1.999</td>
<td>Low Confidence Identification</td>
<td>(-)</td>
<td>yellow</td>
</tr>
<tr>
<td>0.000 - 1.699</td>
<td>No Organism Identification Possible</td>
<td>(-)</td>
<td>red</td>
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More Than a Comprehensive Library

Up-to-date and traceable

The integrated library of the MBT Software comprises spectra of thousands of strains including bacteria and fungi (yeast and mold). The library is continuously maintained and updated according to strict quality controlled procedures.

Spectra are determined from
- isolates from collaborating partners
- round robin strains
- ISO 9001: 2008 Certified Strain Collection isolates

Flexible

Laboratories that need to create their own spectra entries can make use of an optional SW module to compile customized microorganism libraries. Users can create, export and share libraries.
In just a few easy steps, the simple-to-use software guides users through the set-up of an isolate or batch of isolates for analysis.

**Convenient user interface for easy set-up of working lists**

Before each identification run, the MALDI Biotyper system executes a performance check using a QC standard. This guarantees consistent system performance for every spectra acquisition.

**Clear identification results display at species level**

Identification results are displayed in a standardized report after acquisition of spectral data and spectra-matching. The report lists the best match for each sample along with the associated log(score) value.
The Best Technology from the Experts in Mass Spectrometry

As leader in MALDI-TOF technology it is of great importance to us to design robust, compact, high performance platforms intended for extensive and routine usage in the microbiology laboratory.

The core of the MALDI Biotyper system is the cutting-edge microflex LT/SH MALDI-TOF mass spectrometer.

A space saving system
A true bench-top solution taking up less than 1 meter/ 40” of counter space to provide flexibility in meeting laboratory needs. Requires only a 110/220 V electrical supply and generates minimal thermal output.

Resolution meets sensitivity
Resolution and sensitivity of the spectrometer are tailored to the needs of microbiologists. Optimal results are achieved without the need for long and bulky instrument flight tubes.

Accelerated data acquisition
Data generation is accelerated using Smart Spectra Acquisition by minimizing the required number of laser shots per sample to generate a signal.

At approximately 200 identifications per hour, the system offers the highest throughput for MALDI-TOF microbiology testing.

Highly reproducible results
The quick and simple performance check executed before each run provides the highest standard of reproducibility.

Continuous operation
Routine maintenance such as cleaning is reduced to a minimum and can be easily performed by the user.

High Quality Consumables Ensure Optimum Identification Performance

Over 20 years of experience in the manufacture of high quality consumables used in mass spectrometry, such as calibration standards and HCCA matrix, guarantees optimal system performance.
Continuous Process Control

Installation qualification (IQ) and operation qualification (OQ) for new technologies in the Quality Control laboratory must be efficiently performed and documented. Dedicated documents for the MALDI Biotyper IQ and OQ-PV are provided which fully supports 21 CFR part 11 compliance.
MALDI Biotyper System Overview

Microbial Identification Applications
- Gram +/- Bacteria, Yeast, Filamentous Fungi, Mycobacteria

System Components
- Instrument: microflex LT/SH Mass Spectrometer (manufactured under QSR regulations)
- MALDI Biotyper datasystem running under Windows 7
- MALDI Biotyper System Software

Accessories
- MALDI Biotyper Pilot workstation
- MALDI Biotyper Galaxy automated MALDI target preparation system

Consumables and Ancillaries
- HCCA Matrix
- Bacterial Test Standard (BTS)
- Reusable polished stainless steel targets: 48 & 96 position with barcode
- Disposable 48 position biotarget with individual barcode

System Implementation and Qualification
- IQ and OQ-PV documentation
- 21CFR part 11 support (option)

Dimensions & Operating Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LxWxH:</td>
<td>510 x 680 x 1093mm [20.1” x 26.8” x 43”]</td>
</tr>
<tr>
<td>Weight:</td>
<td>84kg (185 lb) net weight</td>
</tr>
<tr>
<td>Noise:</td>
<td>&lt;30 dB under normal operating conditions</td>
</tr>
<tr>
<td>Temp Range:</td>
<td>10-30°C (50-86°F)</td>
</tr>
<tr>
<td>Operating Humidity:</td>
<td>15-85% non-condensing @ 30°C</td>
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Not for use in diagnostic procedures.

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