

IVD



# Clinical Microbiology

## MALDI Biotyper<sup>®</sup>

- Changing Microbiology



# In Microbiology, Speed and Accuracy Matter

## The MALDI Biotyper<sup>®</sup> System

### A powerful technology for better results

To help answer key challenges in Clinical Microbiology, Bruker has utilized its many years of experience to create the truly groundbreaking MALDI Biotyper System. This revolutionary technology has allowed both large reference laboratories and small hospital laboratories to achieve reliable and efficient identification of clinically significant gram-negative bacteria, gram-positive bacteria, and yeast within an easy to operate, yet powerful benchtop analyzer.

- Accuracy comparable to Nucleic Acid Sequencing
- Much faster than traditional methods
- Cost-effective
- Robust and easy to use
- A true benchtop system
- Easy to implement
- Optional workflow improvement tools

### Identifying microorganisms by their molecular fingerprint

The MALDI Biotyper System identifies microorganisms using MALDI-TOF (Matrix-Assisted Laser Desorption/Ionization Time of Flight) mass spectrometry to determine a unique proteomic fingerprint of an organism. Specifically, the MALDI Biotyper System measures highly abundant proteins that are found in all microorganisms.

The characteristic patterns of these highly abundant proteins are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive IVD-CE certified reference library to determine the identity of the microorganism.

But there's more. The outstanding capabilities of the system go well beyond microbial identification and Bruker is continuously working on further innovations.

# A Simple Procedure for a Sophisticated Platform

## Innovative design leads to enhanced performance and productivity

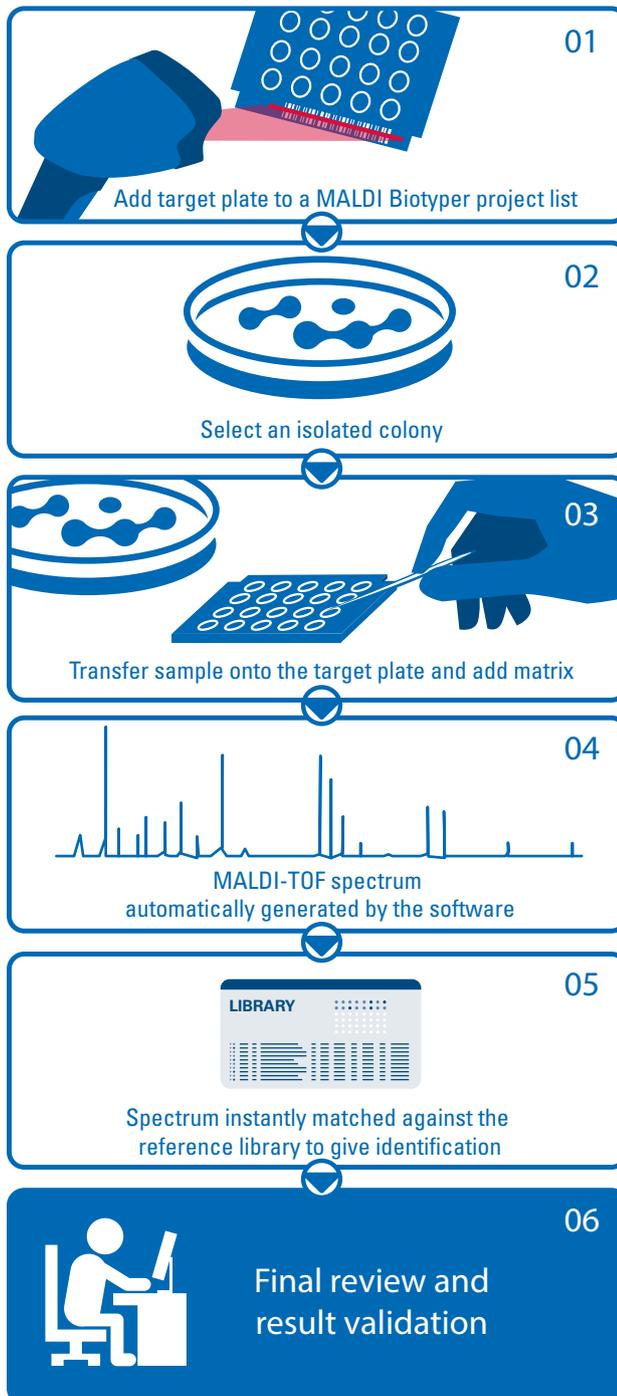
The MALDI Biotyper System workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

Typically, no more than an isolated single colony from a culture is required. The entire process needs only a few minutes to complete.

Our dedicated microbiology software automates the process of acquiring the mass spectrum and performing the match against the extensive IVD-CE certified reference library. The results, presented using a 'traffic light' color scheme, are effortless to interpret.

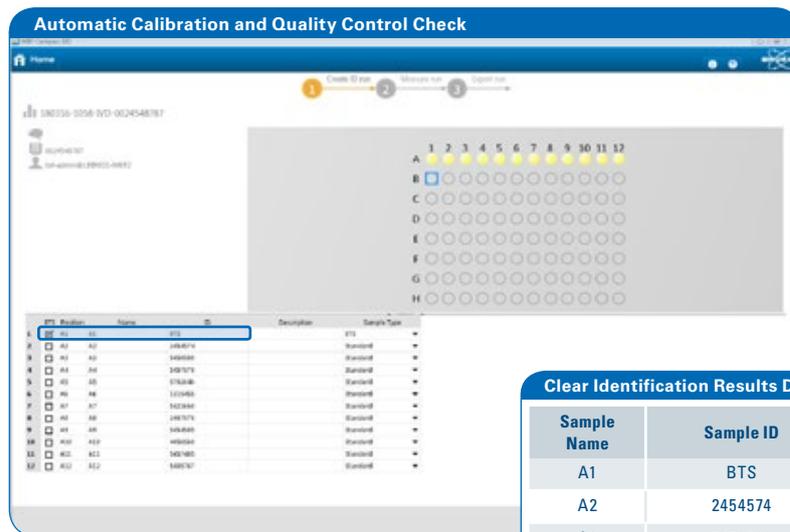
## Open microbiology concept

The MALDI Biotyper allows for smooth integration with existing laboratory informatics. MALDI Biotyper results are converted into a format that a LIS or an AST system can easily understand.



# Easy-to-Use Software that is Dedicated to Microbiology

In just a few steps, the simple-to-use software guides users through the set-up of samples for analysis.



◀ The MALDI Biotyper System is automatically checked using IVD Bacterial Test Standard (BTS) before each use. When the check is successful, the system automatically begins the measurement process.

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample is clearly listed under 'Organism (best match)' accompanied by the resulting score and appropriate 'traffic light' color scheme.

**Clear Identification Results Display at Species Level**

Sample Name	Sample ID	Organism (best match)	Score Value
A1	BTS	Escherichia coli	2.68
A2	2454574	Klebsiella pneumoniae	2.25
A3	5458588	Proteus mirabilis	2.62
A4	5457878	Candida albicans	2.19
A5	8782646	Pseudomonas aeruginosa	2.23
A6	1215455	Escherichia coli	2.53
A7	5423668	Escherichia coli	2.59
A8	2487878	Klebsiella pneumoniae	2.23
A9	5454585	Enterococcus faecium	2.32
A10	4456568	Staphylococcus aureus	2.37
A11	5457485	Trueperella bernardiae	2.47
A12	5485787	Candida glabrata	2.20

Range	Interpretation
2.00 - 3.00	High Confidence Identification
1.70 - 1.99	Low Confidence Identification
0.00 - 1.69	No Organism Identification Possible

## Make the difference when time matters

With the optional Rapid Sepsityper workflow, Bruker is addressing the need for fast and accurate solutions to achieve fast identification from Positive Blood Cultures within 15-20 minutes after the PBC alert. Sample preparation needs only some minutes of hands-on time and can be done in batches of PBC bottles.

The bacterial pellet resulting from the Sepsityper workflow can subsequently be used for phenotypic detection of carbapenemase and cephalosporinase activity, within 60-90 minutes of Positive Blood Cultures alert, by using the MBT STAR®-Carba IVD Kit, respectively MBT STAR®-Cepha IVD Kit. The use of both kits is supported by the dedicated MBT STAR-BL IVD Module.

# An Extensive Library - Annually Updated

## Up-to-date and traceable

The integrated reference spectra library of the MBT Compass IVD software comprises spectra of thousands of strains. The library is continuously maintained and updated according to strict quality controlled procedures.

Spectra are determined from clinical isolates from collaborating partners, round robin strains and strains from strain collections.

## The Main Spectra Concept

Reference library entries in the MALDI Biotyper System are stored as Main Spectra (MSP). These MSPs are based on multiple measurements of a single defined strain to ensure that the true biological variability of an organism has been captured.

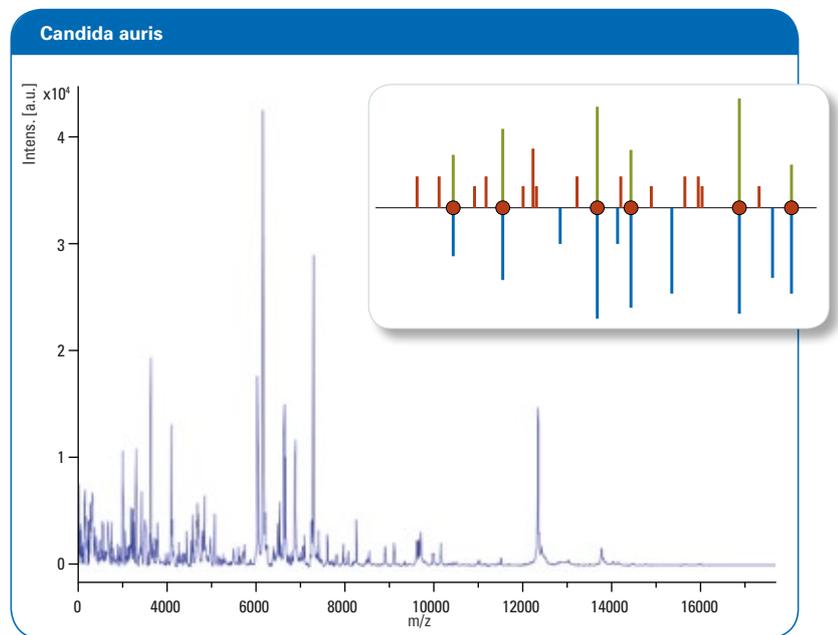
Unknowns are then compared to the MSP library using a superior pattern-matching approach that is based on statistical multi-variant analysis. This includes peak positions, intensities and frequencies ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

## Identification of highly pathogenic microorganisms

The MBT IVD Library Extension allows for early detection of highly pathogenic microorganisms in your IVD workflow, hence improving patient care, laboratory safety, and protection of public health.

## High confidence mycobacteria identification

The optional MBT Mycobacteria IVD Module for the MALDI Biotyper is the comprehensive solution for highly reliable and fast mycobacteria identification. It is composed of a specific reference spectrum library and a software module. The MBT Mycobacteria IVD Library contains spectra for 178 of the currently known 201 mycobacteria species. The natural variability of *Mycobacterium* species is covered by 807 strains – of which more than 480 are clinical isolates. The MBT Mycobacteria IVD Module with adapted data acquisition and analysis secures highly sensitive and specific mycobacteria identifications.





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# The Best Technology from the Experts in Mass Spectrometry

## A platform suited to your needs

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

Bruker offers laboratories the opportunity to choose the MALDI-TOF mass spectrometer that best fits their needs:

- The **MALDI Biotyper** based on the microflex™ LT/SH system with N<sub>2</sub> laser at 60 Hz repetition rate
- The **MALDI Biotyper smart** based on the microflex™ LT/SH smart system with Bruker's proprietary smartbeam™ solid state laser technology at 200 Hz repetition rate, the first MALDI-TOF system for microbial identification using a lifetime\* laser. Measurement cycle time is reduced to a minimum due to the fast target exchange time.

## Resolution meets sensitivity

Resolution and sensitivity are tailored to the needs of microbiologists. Due to Bruker's patented PAN™ resolution the MALDI Biotyper achieves optimal results from a compact benchtop instrument.

## Highly reproducible results

The quick and simple IVD Bacterial Test Standard quality check performed before each run ensures the highest standard of run-to-run reproducibility.

## Accelerated data acquisition

With Smart Spectra Acquisition™, data generation is accelerated by minimizing the number of laser shots per sample needed to acquire a spectrum. An additional benefit of this function is the optimal exploitation of the laser lifetime.

## Continuous operation

The integrated ion source cleaning permits continuous high performance with minimized maintenance requirements. Cleaning the source using the separate IR-laser is performed easily under push-button operator control, without breaking vacuum.

# Compact Benchtop Systems - No Performance Compromise

## True benchtop solutions

Low-noise operating systems with low weight and requiring less than 1 m of counter space offer flexibility in meeting laboratory needs for compact system solutions. Both systems need only a 220 V electrical supply which results in very minimal heat output.

	IVD MALDI Biotyper System (microflex LT/SH)	IVD MALDI Biotyper smart System (microflex LT/SH smart)
Laser	Nitrogen Laser <ul style="list-style-type: none"> <li>• 60 Hz repetition rate</li> <li>• ~200 samples/hr</li> <li>• 60 million laser shots</li> </ul>	Bruker's proprietary lifetime* smartbeam laser <ul style="list-style-type: none"> <li>• 200 Hz repetition rate</li> <li>• ~400 samples/hr</li> <li>• 500 million laser shots</li> </ul>
Vacuum system	Original vacuum system <ul style="list-style-type: none"> <li>• fast target exchange</li> </ul>	New high-performance vacuum system <ul style="list-style-type: none"> <li>• three times greater pumping capacity</li> <li>• even faster target exchange</li> <li>• less down-time after maintenance</li> </ul>
L x W x H	510 x 680 x 1093 mm	530 x 680 x 1093 mm
Weight	84 kg	99 kg
Common features	Ion Source with IR-laser self-cleaning functionality Whispermode™ Oil-free membrane pre-vacuum pump and turbo pump <60 dB under normal operating conditions Patented PAN™ technology for high mass resolution over a wide mass range Voltage: 220V	

\* Lifetime means: 500 million laser shots or seven years (whichever occurs first)

# MALDI Biotyper System Overview

## Basic microbial identification

- Gram +/- Bacteria, Yeasts

## System components

- microflex LT/SH smart mass spectrometer with 200 Hz smartbeam™ solid-state laser or microflex LT/SH mass spectrometer with 60 Hz laser
- MALDI Biotyper data system running under Windows® 7 or later operating system
- MBT Compass IVD software plus MBT IVD Library (and MBT IVD Library Extension for identification of highly pathogenic microorganisms)

## Optional mycobacteria identification

- MBT Mycobacteria IVD Module

## Optional identification directly from positive blood cultures

- MBT Sepsityper IVD Kit
- MBT Compass IVD Sepsityper Module

## Optional resistance detection components

- MBT STAR-Carba IVD Kit
- MBT STAR-Cepha IVD Kit
- MBT STAR-BL IVD Module

## Consumables

- IVD Matrix HCCA-portioned
- IVD Bacterial Test Standard
- Disposable MBT Biotarget 96 with individual barcode and 96 positions
- Reusable polished stainless steel MALDI target plates: 48 & 96 positions with barcode

## Accessories for workflow optimization

- MBT Shuttle ergonomic target holder
- MBT Pilot for guided sample transfer
- MBT Galaxy for automated application of matrix and formic acid

## Dimensions & Operating Parameters

### IVD MALDI Biotyper smart System (microflex LT/SH smart)

LxWxH:	530 x 680 x 1093 mm
Weight:	99 kg net weight
Noise:	<60 dB
Temp Range:	16- 33°C
Operating Humidity:	20-75% non-condensing @ 33°C

### IVD MALDI Biotyper System (microflex LT/SH)

LxWxH:	510 x 680 x 1093 mm
Weight:	84 kg net weight
Noise:	<50 dB
Temp Range:	16- 33°C
Operating Humidity:	20-75% non-condensing @ 33°C



# MBT IVD Consumables for Basic Identification

## IVD Bacterial Test Standard (BTS)

The BTS is an *E. coli* extract spiked with two high molecular weight proteins and has been developed for the quality control process of the MALDI Biotyper IVD System. Its specific composition covers the entire mass range of proteins used for precise identification of microorganisms.

Contents: One box consisting of 5 tubes providing 50 µL per tube / Part No 8290190



## IVD Matrix HCCA - portioned

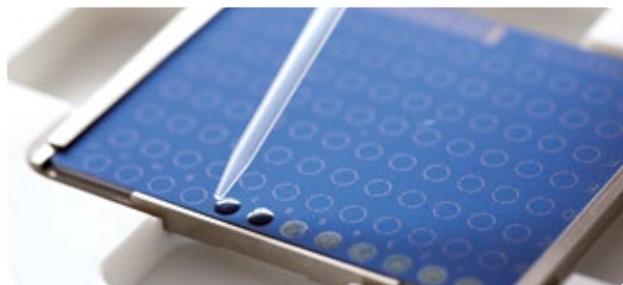
The instant HCCA matrix enables easy and convenient preparation of HCCA matrix solutions. The matrix is soluble in standard organic solvent, easy to handle, and enables highly sensitive measurements.

Contents: One box consisting of 10 tubes providing 250 µL per tube / Part No 8290200



## Disposable MBT Biotargets

The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows. Disposable MBT Biotargets render the same level of performance as reusable MALDI target plates without the need for time-consuming cleaning.



### MBT Biotarget 96

Set of 20 individually barcoded disposable 96 position MALDI target plates / Part No 1839298

### MSP adapter for MBT Biotarget 96

Adapter required to use MBT Biotargets with microflex instruments / Part No. 8267615

# MBT IVD Workflow Accessories

## Reusable Polished Steel Targets

Reusable barcoded polished steel MALDI target plates with 48 or 96 sample positions provide full traceability in paperless workflows.

MSP 48 target polished steel BC  
One target / Part No 8281817

MSP 96 target polished steel BC  
One target / Part No 8280800



## MBT Shuttle Target Holder

The MBT Shuttle target holder is used to securely hold MSP steel MALDI target plates and MBT Biotargets during the sample preparation process. The secure grip, non-slip rubber feet and ergonomic form make sample preparation easier.

One target holder / Part No 1847032



## MBT Pilot

The MBT Pilot facilitates correct sample positioning through patented microprojection technology by indicating the next free MALDI target plate position.

Part No 1836006



## MBT Galaxy

The MBT Galaxy frees laboratory personnel from cumbersome pipetting while ensuring the highest preparation quality under controlled conditions and complete traceability in a paperless workflow.

Part No 1836007



Please contact your local representative for availability in your country.  
Not for sale in the USA.

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