

**Changing Clinical Microbiology** 

## The MALDI Biotyper® System

Microbial identification with unequaled speed and accuracy

Innovation with Integrity

# In microbiology, speed and accuracy matter



### Game-changing technology for optimal 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 (MBT). This revolutionary technology has allowed clinical laboratories worldwide to achieve reliable, fast and efficient identification of a wide range of gram-negative and gram-positive bacteria, yeasts and molds, by an easy to operate, yet powerful benchtop system.

- NEW: Faster than ever, enabling analysis of up to 600 samples/hour
- NEW: Zero-button IDealTune feature securing optimal performance without extra cost or effort
- NEW: A mighty mold solution for identification of hundreds of filamentous fungi species/species groups
- Accuracy comparable to Nucleic Acid Sequencing
- Much faster than traditional methods
- Covering thousands of microorganisms
- Cost-effective
- Robust and easy to use
- A true benchtop system
- Easy to implement
- Optional workflow improvement tools
- Hosting interfaces for LIMS integration

## 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 the unique proteomic fingerprint of an organism. Specifically, the MALDI Biotyper System measures highly abundant proteins that are found in all microorganisms, and takes advantage of their specific differences.

The characteristic patterns of these proteins give the unique fingerprint of an organism and are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive IVD-CE certified reference library.

The outstanding capabilities of the system go well beyond microbial identification. Bruker is continuously working on further innovations to provide additional applications and workflows.

## A simple procedure for a sophisticated and fast platform

### Bacteria, yeast or mold: one workflow for all

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 plate is required. The hands-on time per isolate is only 20 seconds for nearly all microorganisms.

Our dedicated microbiology software fully automates the process of acquiring the mass spectrum and performing the match against the extensive IVD-CE certified reference library.

The identification results, presented using a 'traffic light' color scheme, are effortless to interpret.

The MALDI Biotyper simplifies microbial identification, and facilitates and harmonizes the workflow with only one system.

#### **Faster than ever**

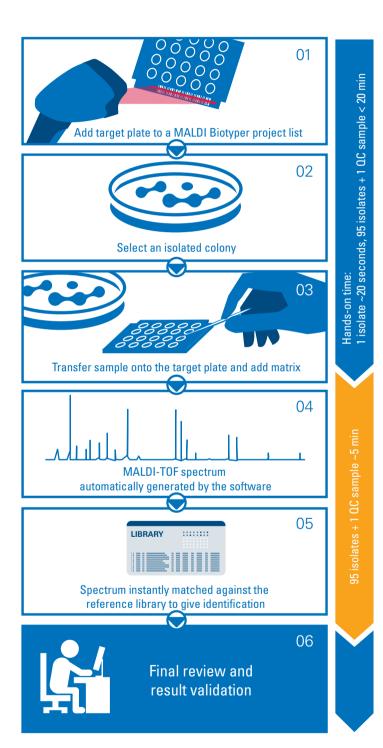
The new MBT Compass HT IVD software dramatically shortens the time-to-result; analysis of 95 isolates and 1 QC sample results in a complete identification report within ~5 minutes.

Sample preparation hands-on time:

- 1 isolate ~20 seconds
- 95 isolates < 20 min

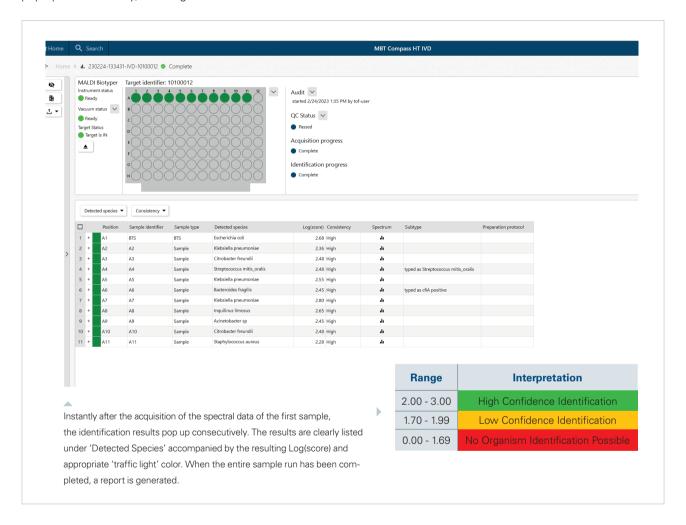
System analysis time to ID result:

■ 95 isolates + 1 QC sample ~ 5 min



## Easy-to-use software dedicated to clinical 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 and tuned using IVD Bacterial Test Standard (BTS) before each use. When the quality control procedure is successful, the system automatically begins the measurement process of the samples. Nearly simultaneously with the acquisition of the spectral data of the samples, the identification results pop up consecutively, enabling fast communication when time matters.



#### Easy reviewing and result validation

The informative MALDI Biotyper report facilitates easy validation by the microbiologist. Subsequently, a simple click in the software enables the export of the MALDI Biotyper results in a LIS or AST system compatible form.

### Open microbiology concept - easy implementation in your laboratory

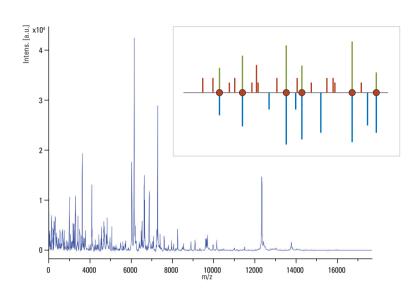
The MALDI Biotyper allows for smooth integration with existing AST systems, laboratory automation systems and laboratory informatics

## The heart of the system: an extensive library - annually updated

## The main spectra concept capturing true biological variability

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. Single-strain MSPs of the same species are maintained as separate entries in the reference library. This approach facilitates the validation of library updates and ensures that the true biological variability of an organism is reflected in the library.

Unknowns are then compared to the IVD-CE certified MSP reference library using a superior pattern-matching approach. This includes peak positions and intensities, ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.



## A continuously updated reference library covering thousands of species

The integrated reference spectra (MSP) library of the MBT Compass HT IVD software comprises spectra of close to twelve thousand strains (library version 2022). As each of these strains results in an MSP, the biological inter strain variability is carefully preserved within the reference library. At Bruker, an active program of reference spectra generation culminates in regular library updates for MALDI Biotyper users. These updates are focused on recommendations and strains from our clinical collaboration partners, and also include round robin strains and strains from certified strain collections. Our ultimate goal is to provide reliable microbial identification that stays current for every clinical microbiology lab. To achieve this, we make it a top priority to provide regular library updates. This ensures that our customers always have access to the latest information and technology, empowering them to make informed decisions and improve patient care.

#### **Taxonomy becomes easy**

The metadata of the MALDI Biotyper Reference Library facilitate the access to taxonomical information, such as synonyms and taxonomical modifications.

#### **NEW: A mighty mold solution**

The MALDI Biotyper is perceived as the most promising alternative for the identification of molds. A dedicated MBT HT Filamentous Fungi IVD Module, including a software module and a specific reference spectrum library, is available to facilitate the identification of hundreds of filamentous fungi species/species groups. Its easy yet powerful Mycelium Transfer (MyT) sample preparation procedure contributes to high identification success rates.

### High confidence mycobacteria identification

The optional MBT HT Mycobacteria IVD Module for the MALDI Biotyper is the comprehensive solution for highly reliable and fast mycobacteria identification. It is composed of a software module and a specific reference spectrum library covering the majority of the currently known mycobacteria species. A convenient and dedicated MBT Mycobacteria IVD Kit offers a safe and standardized sample preparation workflow for *Mycobacterium* spp. cultivated in liquid as well as on solid media.

### More than just routine identification

#### Sepsis - Make the difference when every minute counts

With the optional Rapid Sepsityper® workflow, Bruker is addressing the need for fast and accurate solutions to achieve prompt identification from Positive Blood Cultures (PBC). Obtaining an identification result within 15-20 minutes after the PBC alert allows quick reporting to the treating physicians. Sample preparation with the MBT Sepsityper IVD Kit needs only some minutes of hands-on time and can conveniently be done in batches of PBC bottles. Using the MBT Sepsityper IVD Kit eliminates the time-consuming step of subculturing the microorganisms before identification. The MBT HT Sepsityper IVD Module allows the definition of appropriate samples as blood culture samples in the MBT Compass HT IVD software, whereafter the sample data are processed using optimized methods and results are reported with adapted score thresholds.

#### An early resistance warning system - aiding antimicrobial stewardship

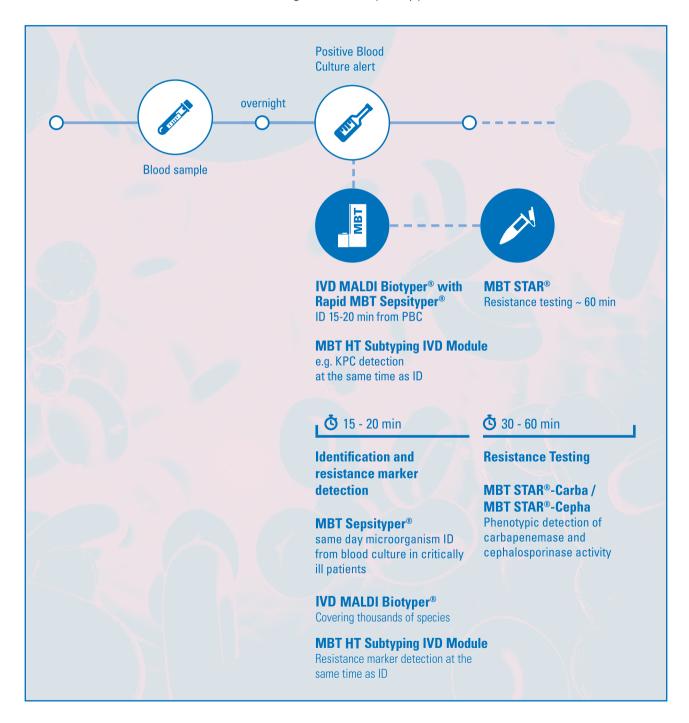
Whenever the MALDI Biotyper routine identification workflow results in successful identification of *Klebsiella pneumoniae, Escherichia coli or Bacteroides fragilis*, the optional MBT HT Subtyping IVD Module automatically looks for specific resistance marker peaks in the identified mass spectrum. As a result, the MBT HT Subtyping IVD Module quickly detects *bla*<sub>KPC</sub> expressing *K. pneumoniae* and *E. coli*, and distinguishes *cfiA* positive/negative *B. fragilis* strains, giving an early resistance warning to the clinical microbiologist without any additional work.

#### Fast phenotypic detection of carbapenemase and cephalorinase activity

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 the PBC 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 HT STAR®-BL IVD Module.

## Rapid blood culture workflow

Fast identification after PBC alert can conveniently be combined with automated resistance marker detection and fast phenotypic detection of carbapenemase and cephalosporinase activity, giving resistance information long before a dedicated AST method has revelead the microorganism's susceptibility profile.



## **Enjoy stress-free operation**

#### A platform suited to your needs

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

- The MALDI Biotyper sirius one IVD System with Bruker's proprietary lifetime\* smartbeam™ solid state laser technology at 200 Hz repetition rate, and positive ion mode.
- The **MALDI Biotyper sirius IVD System**, with the same innovative improvements, smartbeam<sup>TM</sup> 200 Hz laser and positive as well as negative ion detection. The additional capability of analysis in negative ion mode broadens the research applications, such as the analysis of lipids for e.g. resistance detection.

#### Analysis of up to 600 samples/hr - Even shorter Time-to-Result

With Smart Spectra Acquisition™, data generation is accelerated by minimizing the number of laser shots per sample needed to acquire a meaningful spectrum. An additional benefit of this function is the optimal exploitation of the laser lifetime. System improvements, including the newest low-power electronics and a high performance vacuum system, generate fast target exchange times for accelerated time-to-result - even faster than before.

The Time-to-Result is further shortened dramatically by the power of the new MBT Compass HT IVD software, resulting in identification results popping up simultaneously with spectra acquisition, one by one, without delay.

An entirely filled MBT Biotarget 96 IVD, holding 95 isolates and 1 QC sample, results in a complete identification report in  $\sim$ 5 minutes. This analysis speed, combined with a superior fast target exchange, allows analysis of up to 600 samples/hour.

#### Resolution optimized for reliable profile matching

Overall, the resolution is an important performance parameter in MALDI-TOF mass spectrometry. A high resolution is desired for more precise analysis of samples, as it refers to the ability to distinguish between two closely spaced peaks in a mass spectrum. Thanks to Bruker's patented PANTM resolution, the compact MALDI Biotyper achieves an optimal resolution over the relevant mass range of the mass spectral profile acquired from the unknown microorganisms. This accuracy is crucial when it comes to profile matching with thousands of reference spectra, for reliable identification of microorganisms.

### Optimal performance secured by zero-button IDealTune™

Experience peak performance without the hassle - thanks to automated tuning!

- No extra tuning samples
- No extra time
- No extra costs
- Focus on results!

The new zero-button IDealTune feature on our MALDI Biotyper sirius systems automatically finetunes the key parameters of the MALDI-TOF system, ensuring stable data quality. Without any user intervention, IDealTune is performed systematically in the background while analyzing the IVD Bacterial Test Standard, which is anyway part of a sample run. The quick and simple IVD Bacterial Test Standard quality check, performed before each run, ensures the highest standard of run-to-run reproducibility.

Forget about tedious preparation of dedicated tuning samples, forget about time-consuming manual tuning, forget about extra costs.

Relax knowing that machine-driven tuning is in place, and focus on results!

#### **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 by a few clicks in the software, without breaking vacuum.

## The best technology from the experts in mass spectrometry

Bruker, a renowned leader in MALDI-TOF technology, recognizes the significance of designing robust, high-performance platforms that cater to extensive and routine usage in microbiology laboratories. Through continuous hardware development, we proudly present the fourth-generation of Bruker's benchtop MALDI Biotyper systems that set new benchmarks in this field.

Our latest systems incorporate state-of-the-art low-power electronics and a high-performance vacuum system, resulting in rapid target exchange times for even faster time-to-result than ever before. These system improvements guarantee swift and precise identification of microorganisms, ensuring greater efficiency in your laboratory processes. At Bruker, we are committed to providing you with cutting-edge MALDI-TOF technology that empowers you to excel in your microbiology laboratory.

	MALDI Biotyper sirius one IVD System	MALDI Biotyper sirius IVD System
Speed of analysis	<ul> <li>95 isolates + 1 QC sample ~5 min to identification</li> <li>Identification of 600 samples/hr</li> <li>Identification results popping up simultaneously with spectra acquisition, one by one, without delay</li> </ul>	
Laser	Bruker's proprietary lifetime* smartbeam laser  200 Hz repetition rate  At least 500 million laser shots are guaranteed	
Polarity	Positive ion mode only	Positive and negative** ion mode
Mass range	Full functionality of a linear MALDI-TOF, with MALDI Biotyper applications focused to:  0-1.000 Da (resistance detection)  2.000-20.000 Da (microorganism identification)	
Vacuum system	Oil-free membrane pre-vacuum pump and high capacity turbomolecular pump  high pumping capacity, which in combination with a clever source design results in very fast target exchange  minimal downtime after maintenance	
Other features	LED strip to remotely observe system status  Perpetual Ion Source™ with IR-laser self-cleaning functionality  Whispermode™ <60 dB under normal operating conditions  Patented PAN™ technology for high mass resolution over a wide mass range  Latest low-power electronics protecting natural resources  Voltage: 220 V	
Dimensions & Operating Parameters	L x W x H: 500 x 710 x 1070 n  Net weight: 75 kg / 165.4 lb  Noise: < 60 dB  Temp Range: 16 - 30°C / 61 - 86  Operating Humidity: 20 - 75%, non-col	

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

<sup>\*\*</sup> Negative ion mode is for Research Use Only

## **MALDI Biotyper IVD System overview**

#### **Benchtop MALDI-TOF system**

- MALDI Biotyper sirius one IVD System, for routine microbial identification and resistance detection applications, supported by the positive ion mode or
- MALDI Biotyper sirius IVD System,
   for routine microbial identification and resistance detection applications, supported by the positive ion mode,
   and expanded research capabilities using the negative ion mode

## Routine identification of gram +/- bacteria, yeasts

#### Software

- MBT Compass HT IVD software, including the MBT IVD Library
- MBT IVD Library Extension

#### Consumables

- IVD Matrix HCCA-portioned
- IVD Bacterial Test Standard
- MBT Biotarget 96 IVD

## Mycobacteria identification (optional)

#### Integrated software module

- MBT HT Mycobacteria IVD Module Consumables
- MBT Mycobacteria IVD Kit

## Filamentous fungi identification (optional)

#### Integrated software module

 MBT HT Filamentous Fungi IVD Module

#### Identification directly from positive blood cultures

#### Integrated software module

- MBT HT Sepsityper IVD Module Consumables
- MBT Sepsityper® IVD Kit

## Resistance detection (optional)

#### Integrated software modules

- MBT HT Subtyping IVD Module
- MBT HT STAR®-BL IVD Module Consumables
- MBT STAR®-Carba IVD Kit
- MBT STAR®-Cepha IVD Kit

## Accessories for workflow optimization & automation (optional)

- MBT Shuttle ergonomic target holder
- MBT FAST<sup>TM</sup> Shuttle IVD for standardized and accelerated drying of matrix and other liquids
- MBT Pilot® for guided sample transfer
- Coming soon: MBT Pathfinder® IVD with Feeder IVD option for standardized, documented and fully transparent MALDI target preparation



## 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. Mandatory for maintaining optimal performance of the MALDI Biotyper with IDealTune.

Content: One box consisting of 5 tubes providing 50  $\mu$ L per tube / Part No. 8290190



#### **IVD HCCA Matrix, 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.

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



#### **Disposable MBT Biotargets**

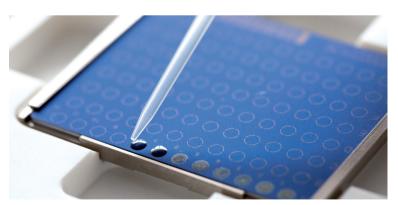
The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows.

#### **MBT Biotarget 96 IVD**

Set of 20 individually barcoded MALDI Biotyper target plates, 96 positions each / Part No. 1839298

#### MSP adapter for MBT Biotarget 96

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



## MBT IVD consumables for PBC workflow and resistance detection

#### MBT Sepsityper® IVD Kit

The MBT Sepsityper IVD Kit contains all reagents and consumables required for microorganism isolation from 50 positive blood culture samples.

Part No. 1834338



#### MBT STAR-Cepha® IVD Kit

The MBT STAR-Cepha IVD Kit provides all necessary reagents and components to conduct the cephalosporinase assay.

Part No. 1858555



#### MBT STAR-Carba® IVD Kit

The MBT STAR-Carba IVD Kit provides all necessary reagents and components to conduct the carbapenemase assay.

Part No. 1848467



## MBT IVD workflow accessories and automation

#### **MBT Shuttle Target Holder**

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

One target holder / Part No. 1847032



#### MBT FAST™ Shuttle IVD

Standardized and accelerated drying of MALDI Biotyper matrix and other liquid reagents.

Part No. 1878263



#### **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 Pathfinder® IVD and Feeder IVD

Coming soon: The MBT Pathfinder IVD is a semi-automated system for MALDI target preparation, assisting in selection, transfer and preparation of samples taken from microbiological colonies on culture plates. The Feeder IVD places culture plates by a robotic hand from the carousel into the specified position in the MBT Pathfinder IVD.

MBT Pathfinder IVD / Part No. 1885100 Feeder IVD / Part No. 1885300





## THE ORIGINAL Often imitated, never duplicated

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





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