Changing Clinical Microbiology

The MALDI Biotyper® System

Microbial identification with unequaled speed and accuracy

Innovation with Integrity

CE-IVD

Accuracy, ease of use, and speed

At your fingertips

The MALDI Biotyper story: a journey of innovation leading to a paradigm shift

Over two decades ago, it all started with a visionary dream - one with the audacious goal of revolutionizing the microbiology landscape. This dream ignited a journey of relentless innovation, pushing boundaries and reimagining the possibilities within reach. At the core of this transformative quest lies the MALDI Biotyper.

Bruker leveraged its extensive experience to bring forth the groundbreaking MALDI Biotyper System. This revolutionary technology stands as a testament to our commitment to pushing the limits of what's achievable. The MALDI Biotyper empowers clinical laboratories globally, offering a seamless, reliable, and expeditious microbial identification solution for a diverse array of gram-negative and gram-positive bacteria, yeasts, and molds. Operating as a user-friendly yet powerful benchtop system, it has changed microbiology.

Accurate fingerprint matching to find the culprit

The MALDI Biotyper operates based on Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) mass spectrometry. The principle involves creating a proteomic fingerprint spectrum of the unknown microorganism. The unique pattern of this fingerprint is then matched to reference spectra of thousands of microorganisms, stored in the heart of the system, the IVD-CE certified software including a reference library.

The original
Often imitated, never duplicated

Unequaled speed for fast and actionable results

- Analyze 95 isolates + 1 QC sample in ~5 minutes
- Get instant results at a glance, no need to wait for the end of the run
- Enhance your throughput to up to 600 samples/hour
- Prioritize urgent samples swiftly and get the critical result in minutes

Unmatched efficiency with a large reference library coverage

- Identify more than 4,600 gram-positive and gram-negative bacteria, yeast and filamentous fungi species/species groups
- Analyze filamentous fungi directly from agar with the easy MyT method and a dedicated library
- Enable high-confidence mycobacteria identification with a dedicated library and workflow including safe sample handling
- Increase the identification power with our regular updates of reference libraries to meet expanding clinical needs

Rapid workflow for direct identification from positive blood culture bottles

- Improve patient outcome by identification results within 15-20 minutes post PBC alert
- Quickly report actionable results to the physician
- Explore the sample further for early resistance detection

The right fit for your lab

- Benefit from low training efforts, with a user-friendly software-guided workflow
- Avoid implementation challenges with an easy-to-deploy benchtop system
- Focus on results while relying on the hands-free IDealTune™ autotuning feature - no extra cost, effort or user intervention required
- Minimize maintenance with the integrated source cleaning, activated with a few mouse clicks

Broader interface and workflow solutions

- Enjoy seamless integration with AST systems, laboratory automation systems, and LIMS
- Streamline your workflow with the MBT FAST™ Shuttle IVD, MBT Pilot® System, MBT PrepMatic™ IVD and Feeder IVD

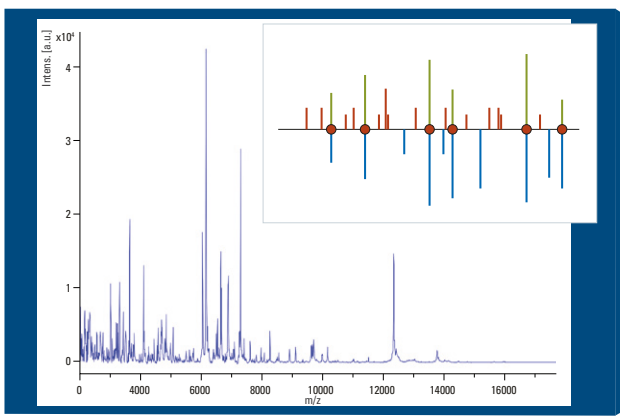
The beating heart of the system

Accurate fingerprint matching providing identification results you need to "stay ahead of the game"

- Identification is based on matching the unique proteomic fingerprint spectrum of the unknown microorganism to a huge collection of reference spectra
- Our continuously evolving library that keeps pace with emerging microorganisms helps you to stay ahead
- We listen to and empower our customers with regular updates of clinically relevant organisms into our powerful "fingerprint" library
- The expansive and up-to-date library gives you confidence in the results, ensuring fast and accurate decisions to enhance patient care

A reference library covering thousands of bacteria and yeast

- Access a library covering thousands of gram-positive/negative bacteria and yeast
- Each reference library entry is based on multiple measurements of a single defined strain, safeguarding true biological variability
- This library structure and powerful algorithms simplify expansion and validation of the library



A mighty solution for molds

- The MBT HT Filamentous Fungi IVD Module includes a dedicated reference spectrum library, facilitating the identification of hundreds of filamentous fungi species/species groups
- The easy yet powerful Mycelium Transfer (MyT) sample preparation procedure enables a high identification success rate
- The workflow cleverly uses the surface structure of the MBT Biotarget 96 IVD to break the rigid cells walls, contributing to accurate identification

High confidence mycobacteria identification

- A dedicated MBT Mycobacteria IVD Kit enables a safe and standardized sample preparation workflow for *Mycobacterium* spp. cultivated in liquid as well as on solid media
- Combined with the kit, the MBT HT Mycobacteria IVD Module provides a comprehensive solution covering the majority of the currently known mycobacteria species

Find hidden secrets in the fingerprint spectra

The MBT HT Subtyping IVD Module empowers the automated differentiation of some species that are typically hard to distinguish, by identifying decisive peaks in the high-quality spectra or employing an advanced algorithm:

- Differentiation of *Mycobacterium chimaera* from *Mycobacterium intracellulare*
- Differentiation of *Streptococcus pneumoniae*, *S. mitis_oralis* and *S. pseudopneumoniae*

Easy workflow: simplicity meets speed

Bacteria, yeast or mold: an easy workflow for all

- Efficient and user-friendly
- Fully traceable streamlined workflow with a few simple steps
- Typically starting from an isolated single colony from a culture plate
- Minimal hands-on time per isolate (only 20 seconds for most microorganisms)

Dedicated microbiology software

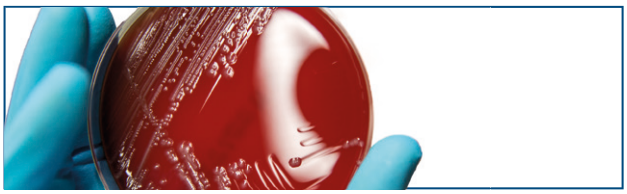
- Software-guided workflows provided by the MBT Compass HT IVD software deliver clear and fast results
- Rapid analysis of 95 isolates and 1 QC sample yields a complete identification report in ~5 minutes
- Identification results presented in an easy-to-interpret 'traffic light' color scheme
- Instant result display on the screen, no need even to wait for the final report

Faster than ever

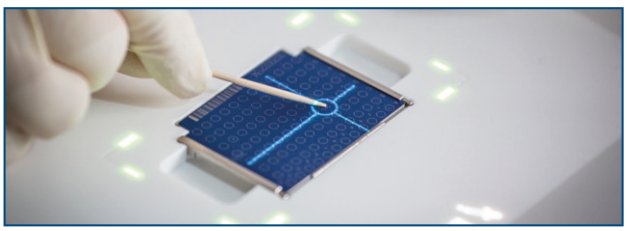
Sample preparation hands-on time:
- 1 isolate ~20 seconds
- 95 isolates < 20 min

System analysis time to ID result:
- 95 isolates + 1 QC sample ~ 5 min

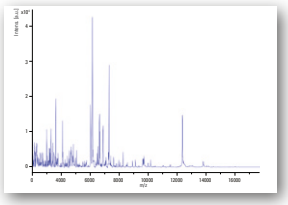
Add target plate to a MALDI Biotyper project list



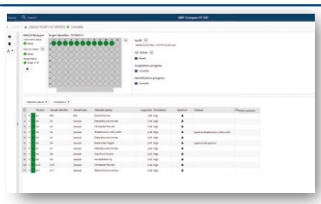
Select an isolated colony



Transfer sample onto the target plate and add matrix



MALDI-TOF spectrum automatically generated by the software



Spectrum instantly matched against the reference library to give identification

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

Easy result reporting with "traffic light" color scheme

Hands-on time:
1 isolate ~20 seconds, 95 isolates + 1 QC sample < 20 min

95 isolates + 1 QC sample ~5 min

When every minute counts: rapid blood culture workflow

Make the difference for your sepsis patient

With the Rapid Sepsityper® Workflow, Bruker is addressing the need for fast and accurate solutions to achieve prompt identification from Positive Blood Cultures (PBC).

Subsequent automated analysis of the spectral data can efficiently uncover resistance markers, providing early warnings about resistance to the clinical microbiologist without the need for additional efforts.

If beta-lactamase activity is suspected, additional rapid assays can be employed to phenotypically detect carbapenemase and cephalosporinase activity.

MBT Compass HT IVD Software Products

Part No.	Module
1877017	MBT Compass HT IVD
1877012	MBT HT Mycobacteria IVD Module
1877013	MBT HT Filamentous Fungi IVD Module
1894123	MBT HT STAR®-BL IVD Module
1877010	MBT HT Subtyping IVD Module
1877011	MBT HT Sepsityper® IVD Module

Rapid Sepsityper® Workflow

- Improve patient outcome by rapid identification results within 15-20 minutes post PBC alert
- Quickly report actionable results to the physician, enabling early adjustment of antibiotic therapy
- Eliminate the time-consuming subculturing step before identification
- Prepare the PBC samples quick and batch-friendly with the MBT Sepsityper IVD Kit
- Let the dedicated MBT HT Sepsityper IVD Module assist you, with optimized methods and adapted score thresholds for efficient sample data processing and result reporting
- Explore the sample further for early resistance detection

An early resistance warning system supporting 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_{KPC} 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 rapid phenotypic detection of carbapenemase and cephalosporinase activity, by using the MBT STAR®-Carba IVD Kit or MBT STAR®-Cepha IVD Kit, respectively. The use of both kits is supported by the optional MBT HT STAR®-BL IVD Module.

For all above listed MBT Compass HT IVD Software Modules, as well as the MBT STAR®-Carba IVD Kit and MBT STAR®-Cepha IVD Kit the following marking is applicable: CE 0123 IVD

MALDI Biotyper IVD System overview

Benchtop MALDI-TOF system

- **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, such as the analysis of lipids for e.g., resistance detection.

or

- **MALDI Biotyper® sirius one IVD System**,
  for routine microbial identification and resistance detection applications, supported by the positive ion mode

* Negative ion mode is for Research Use Only

Routine identification of gram +/- bacteria, yeasts

Software
- MBT Compass HT IVD software, including the MBT IVD Library
- MBT HT Library Extension IVD, covering highly pathogenic species

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

Identification directly from positive blood cultures

Integrated software module
- MBT HT Sepsityper® IVD Module

Consumables
- MBT Sepsityper® IVD Kit

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
- MBT HT Filamentous Fungi IVD Library Extension

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

Workflow optimization & automation (optional)

- MBT Shuttle ergonomic target holder
- MBT FAST™ Shuttle IVD for standardized and accelerated drying of matrix and other liquids
- MBT Pilot® System for guided sample transfer
- MBT PrepMatic™ IVD with Feeder IVD option for standardized, documented and fully transparent MALDI target preparation

Please contact your local Bruker sales representative for availability of the optional MBT IVD system components in your country.

IVD consumables

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 µL per tube / Part No. 8290190

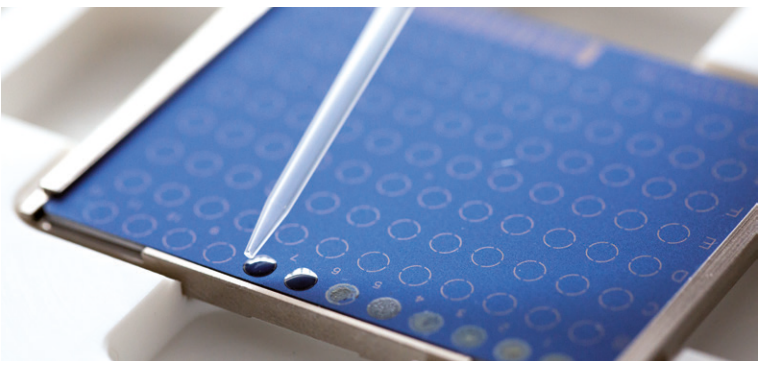
IVD HCCA Matrix, portioned

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 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 Mycobacteria IVD Kit

The MBT Mycobacteria IVD Kit provides all necessary reagents and components to conduct safe inactivation and sample preparation of mycobacteria species, from liquid or from solid media.

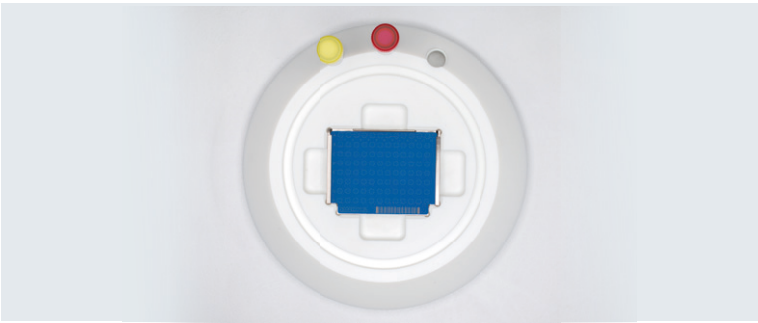
Part No. 1889166

Workflow optimization & automation (optional)

MBT Shuttle Target Holder

The MBT Shuttle target holder is a non-slip device securely holding MBT Biotargets, matrix and BTS tubes during the sample preparation process.

One target holder / Part No. 1847032



MBT FAST™ Shuttle IVD

Standardized and accelerated drying of MALDI Biotyper matrix and other liquid reagents, increasing the matrix crystallization quality, improving the microorganism identification success rate.

Part No. 1878263

MBT Pilot® System

The MBT Pilot System facilitates correct sample positioning through patented micro-projection technology by clearly highlighting the next free MALDI target plate position.

Part No. 1836006

Coming soon

MBT PrepMatic™ IVD and Feeder IVD

The MBT PrepMatic 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 PrepMatic IVD.

The magic behind hassle-free operation

Years of experience condensed in a benchtop system

The high performance and tailored design of the MALDI Biotyper are rooted in over 30 years of Bruker's in-house MALDI-TOF experience, applied to filling a gap in microbial analysis.
Crafting a state-of-the-art and groundbreaking system demands extensive expertise and a commitment to innovation. Unlike merely copying existing systems, the development of the MALDI Biotyper reflects a dedication to pioneering advancements in technology, ensuring that it stands as a must-have in the field of microbiology.
Explore the magic behind the system's speed, resolution and performance.

Unequaled 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. Besides saving time, this also allows an optimal exploitation of the laser lifetime.
Fast target exchange contributes to an accelerated Time-to-Result, enabling swift prioritization of time-critical samples.
The analysis speed is further dramatically boosted by the power of the MBT Compass HT IVD software, resulting in identification results popping up simultaneously with spectra acquisition, one by one, without delay.
The complete identification report of an entirely filled MBT Biotarget 96 IVD, holding 95 isolates and 1 QC sample, is generated in ~5min. This speed, combined with a superior fast target exchange, allows analysis of up to 600 samples/hour.

Optimal performance secured by zero-effort 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 zero-effort 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!

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 PAN™ 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.

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.

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

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