Changing Pharmaceutical Microbiology

The MALDI Biotyper® System

Microbial identification with unequaled speed and accuracy

Innovation with Integrity

GP

Accuracy, ease of use, and speed

At your fingertips

Fingerprint matching for accurate microbial identification

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 starting from colony material.
The unique pattern of this fingerprint is then matched to reference spectra of thousands of microorganisms, stored in the heart of the system, the reference library.

Unequaled speed and accuracy for fast and actionable results

- Analyze 95 isolates + 1 QC sample in ~5 minutes
- Identify more than 4,700 gram-positive and gram-negative bacteria, yeasts and molds
- Analyze filamentous fungi directly from agar with the easy MyT method and a dedicated library

The right and cost-effective fit for your lab

- Minimize maintenance with the integrated source cleaning, activated with a few mouse clicks
- Benefit from low training efforts, with a user-friendly software-guided workflow
- Supporting 21 CFR part 11 compliance
- Reduce the cost per identification by implementing the MALDI Biotyper as an in-house rapid microbiological method

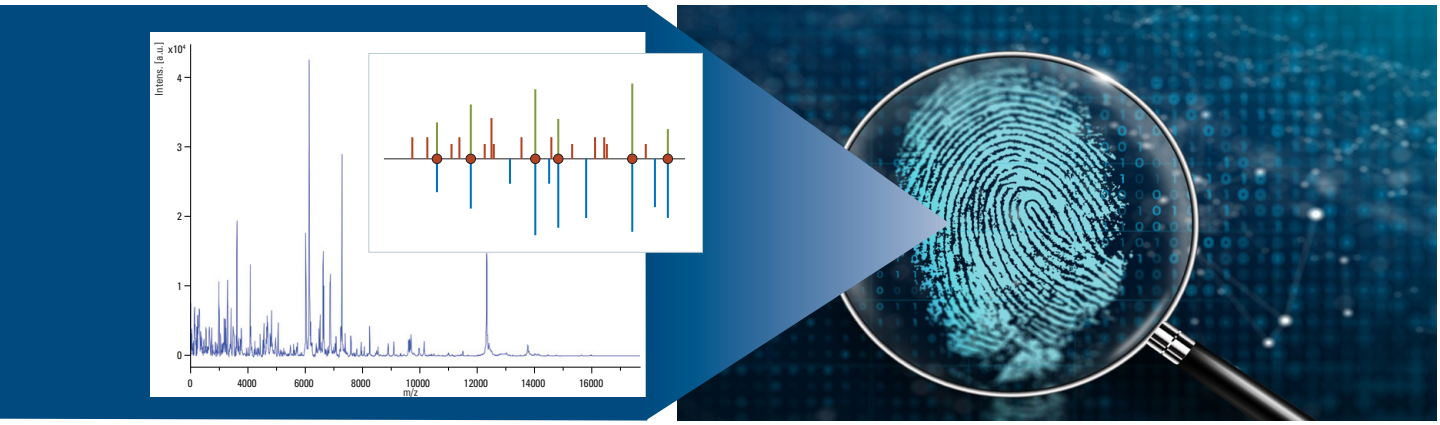
The beating heart of the system

Accurate fingerprint matching of the unknown

- Identification is based on matching the unique proteomic fingerprint spectrum of the unknown microorganism to a huge collection of reference spectra
- The expansive and up-to-date library gives you confidence in the results, ensuring fast and accurate decision-making

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



Create your own libraries and run your data comparison

Laboratories that need to create their own libraries can easily compile customized microorganism entries by software tools and share or export libraries.
These might be libraries with site-specific isolates and/or entries for important starters used for production.

Easy workflow: simplicity meets speed

Bacteria, yeast or mold: one 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

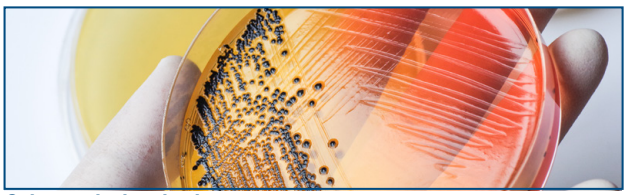
- Software-guided workflows provided by the MBT Compass HT Industry software deliver clear and fast results
- Rapid analysis of 95 isolates and 1 QC sample yields a complete identification report in ~5 minutes
- Identification results presented in an easy-to-interpret 'traffic light' color scheme
- Instant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

Faster than ever

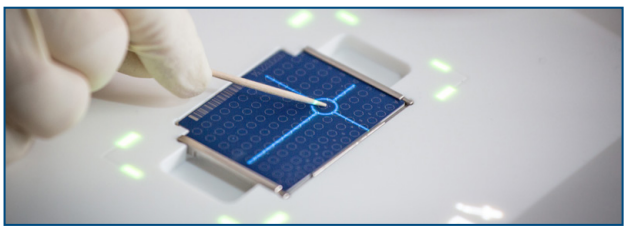
Sample preparation hands-on time:
- 1 isolate ~20 seconds
- 95 isolates < 20 min

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

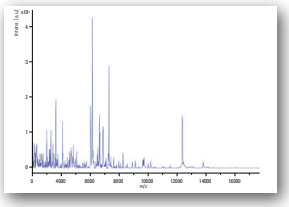
Add target plate to a MALDI Biotyper project list



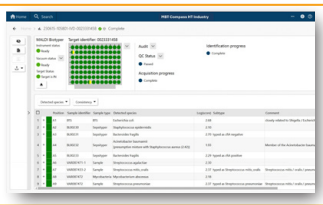
Select an isolated colony



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

Improve your filamentous fungi workflow

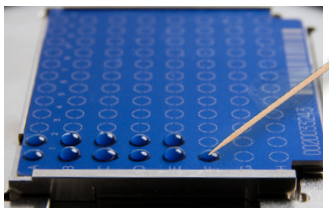
A mighty solution for molds

The easy yet powerful Mycelium Transfer (MyT) sample preparation procedure can be applied in most of the cases, when front mycelium is clearly visible and can be harvested easily, like in the example shown below. Hence, sample preparation is most often very straightforward while enabling a high identification success rate.

The workflow cleverly uses the surface structure of the MBT Biotarget 96. The slightly rough surface of the MBT Biotarget 96 ensures an intense homogenization and effective cell disruption of the fungal material on the MALDI target.
The MBT FAST™ Shuttle can conveniently be used to save time while drying the spots.

The dedicated MBT HT Filamentous Fungi Module includes a dedicated reference spectrum library, facilitating the identification of hundreds of filamentous fungi species/ species groups

A wooden inoculation pick is dipped into a droplet of formic acid, applied onto an MBT Biotarget 96. **1**



Sampling of the mold's front mycelium is improved by the wet wooden inoculation pick, while also already instantly enabling reaction of the acid with the mold. **2**

The mold is subsequently smeared in the formic acid droplet on the MBT Biotarget 96, liberating proteins which are - after drying and addition of a droplet of HCCA matrix - extracted into the solvent components of the matrix. **3**

MBT FAST™ Shuttle

Drying of the spots under controlled conditions at elevated temperature, using the MBT FAST™ Shuttle, ensures standardized crystallization of the matrix while speeding up the drying process. **4**

Boost your productivity: Automation & Standardization

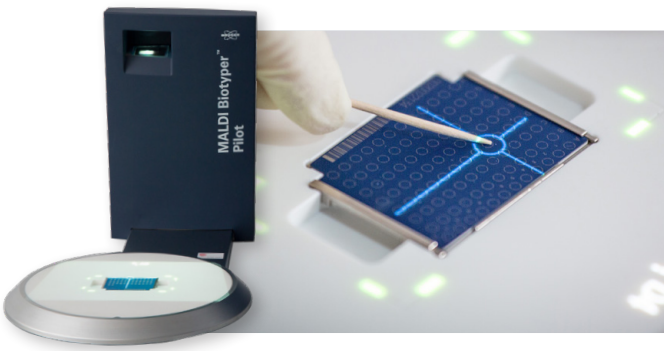
Your modular pathway to a standardized and fully transparent workflow

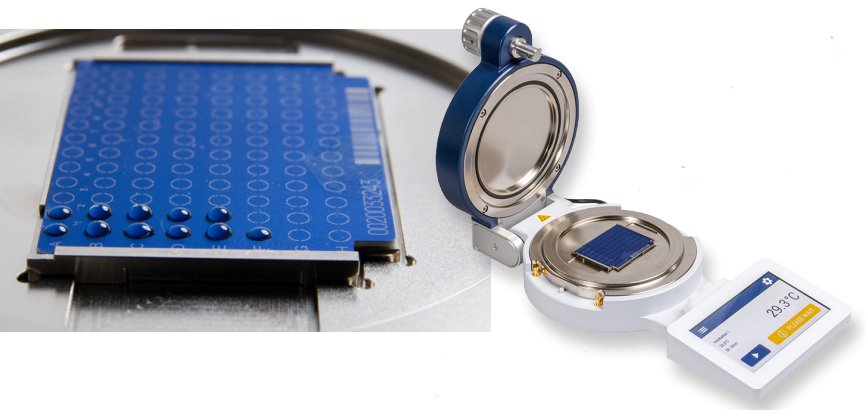
In recent years automation and standardization also have become an increasingly important topic in microbiology labs. Bruker addresses this demand with several optional and modular solutions, acknowledging that every lab has different needs and operating procedures. Choose and pick the right solutions for your workflow.

Guided manual preparation of MALDI target plates

The MBT Pilot® System offers guided sample positioning reducing the risk of errors during sample transfer. This simplifies your workflow and offers a paperless, fully documented and traceable procedure.

MBT Pilot® System / Part No. 1822041

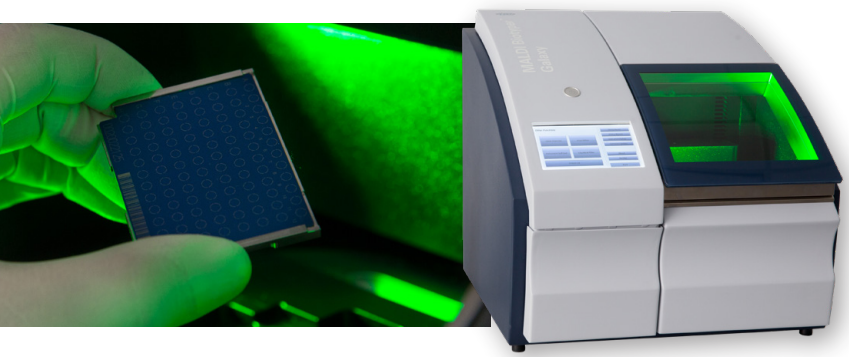




Accelerated & Standardized liquid drying

The MBT FAST™ Shuttle enables 2-3 times faster sample and matrix crystallization, speeding up your sample preparation. The resulting more homogeneous matrix crystallization improves the sample quality and subsequently the identification rate.

MBT FAST™ Shuttle / Part No. 1872847



The MBT Galaxy System frees up time for the things that matter. Automated and contact-free liquid dispensing eliminates the need for repetitive pipetting. Benefit from a well-documented and traceable workflow, while saving staff time and reducing plastic waste.

MBT Galaxy® System / Part No. 1821269

Elevate your MALDI Biotyper workflow to the next level

Seeking a slight workflow upgrade for microbial identification, or ready for complete automation?

The MBT Pathfinder® GP, along with the optional Feeder GP, is our flexible answer.

The MBT Pathfinder GP basic functionality, the reagent deposition module, removes the cumbersome repetitive motion from the MALDI target plate preparation workflow by automated and contactless deposition of precise droplets of formic acid and HCCA matrix onto the sample positions.

Equipped with the capability for colony selection, the MBT Pathfinder GP also assists in the selection and transfer of microbial colonies from agar to the MALDI target plate. The automated liquid reagent deposition delivers a MALDI target plate ready for analysis by the MALDI Biotyper.

The Feeder GP facilitates the placement of culture plates, seamlessly transferring them with a robotic precision from the carousel to the designated position within the MBT Pathfinder system. Subsequently the abovementioned features start their work to deliver a MALDI target plate with samples readily prepared for analysis by the MALDI Biotyper. This complete solution includes automated selection of microbial colonies for being transferred to the MALDI target plate.

MBT Pathfinder GP / Part No. 1890100
Feeder GP / Part No. 1890355

Key features and benefits

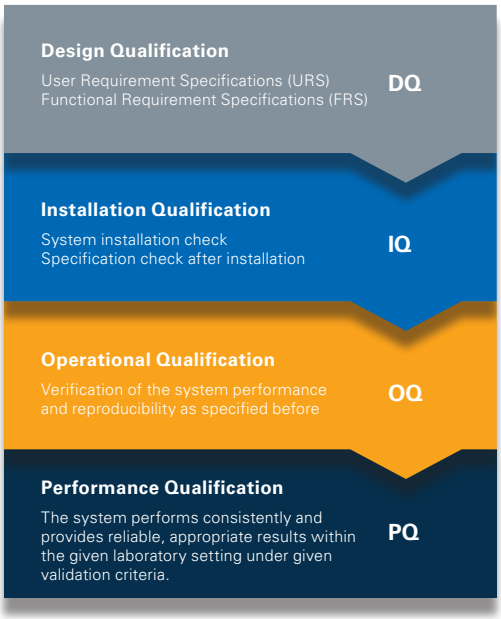
- Robotic system for colony transfer and reagent deposition for complete MALDI target preparation, increasing standardization and reproducibility
- Modular system for a flexible and stepwise implementation of automation, in line with the needs of the lab
- Significantly reducing hands-on time
- Preselection of colonies powered by AI software
- Fully documented system with data archive providing full workflow traceability and transparency
- No need for manual picking tools and disposable tips, keeping running costs low and minimizing waste

Enjoy smart and stress-free operation

Qualification of the MALDI Biotyper

Experience peace of mind knowing that Bruker supports the qualification process of the MALDI Biotyper system in your pharmaceutical laboratory.

With Bruker's MALDI Biotyper system, you gain more than just a reliable and accurate microbial identification solution. Our commitment to providing the required documentation for IQ, OQ, and PV, coupled with support for 21 CFR Part 11 compliance, ensures a streamlined qualification process for your pharmaceutical laboratory.



Supporting 21 CFR part 11 compliance

Bruker understands the significance of regulatory compliance, particularly when it comes to electronic records and signatures.
Our documentation supports your lab's adherence to 21 CFR Part 11 requirements, giving you the necessary tools to maintain data integrity and secure electronic records throughout the qualification process.
The MBT Compass HT Industry software has been designed to support compliance with the rules of regulated environments, addressing the following aspects:

- Authentication and user management
- User rights management
- Data integrity and archiving
- Audit trail including reason entry and timestamps
- Digital signatures

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.

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 Bacterial Test Standard, which is anyway part of a sample run.
The quick and simple 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!

MALDI Biotyper GP System overview

Benchtop MALDI-TOF system

- **MALDI Biotyper® sirius GP System**

System implementation and qualification

- IQ and OQ/PV
- MBT HT Compliance Assistant Module to support 21 CFR part 11 compliance

Identification of gram +/- bacteria, yeasts

Software
- MBT Compass HT Industry software, including the MBT Library
- MBT DB BTyp2.0-Sec.Library, covering highly pathogenic species

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

Filamentous fungi identification (optional)

Integrated software module
- MBT HT Filamentous Fungi Module
- MBT Filamentous Fungi Library Extension (RUO)

Workflow optimization & automation (optional)

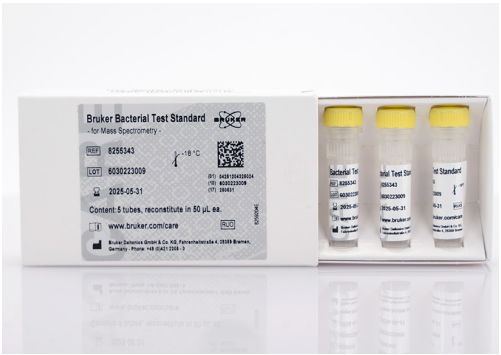
- MBT Shuttle ergonomic target holder
- MBT FAST™ Shuttle for standardized and accelerated drying of matrix and other liquids
- MBT Pilot® System for guided sample transfer
- MBT Galaxy® System for fully automated liquid deposition on the MALDI target plate
- MBT Pathfinder® GP with Feeder GP option for standardized, documented and fully transparent MALDI target preparation

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

The original
Often imitated, never duplicated

Consumables

Bacterial Test Standard (BTS)



BTS is an essential component of the MALDI Biotyper workflow enabling constant high accuracy and optimal operation. This mass calibration standard covers the complete mass range necessary for precise microbial identifications. It furthermore serves as integrated quality control for each run and enables the automated IDealTune™ function ensuring optimal performance of the MALDI Biotyper.

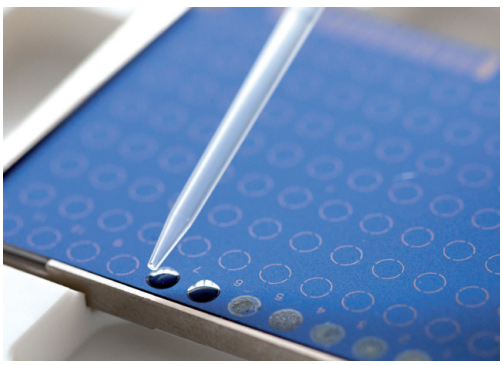
Content: One box consisting of 5 tubes providing
50 µL per tube / Part No. 8255343

HCCA Matrix, portioned

The HCCA matrix is tailored for microbial identification on the MALDI Biotyper. It is provided in stable dried portions to ensure it is always fresh when needed. The HCCA is subjected to a rigorous purification process and quality control to deliver highly sensitive measurements. Its outstanding purity minimizes the deposition of debris in the system's ion source and thus helps avoiding unnecessary downtime.

Content: One box consisting of 10 tubes providing
250 µL per tube / Part No. 8255344

Disposable MBT Biotargets



The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows. The AnchorChip™ effect makes it easy for users to achieve consistent preparation of the target and obtain reproducible results.

MBT Biotarget 96

Pack of 20 individually barcoded MALDI Biotyper target plates, 96 positions each / Part No. 1840375

MSP adapter for MBT Biotarget 96

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

Also looking for QC and source tracking with same-day results?

Here's the answer: The IR Biotyper®

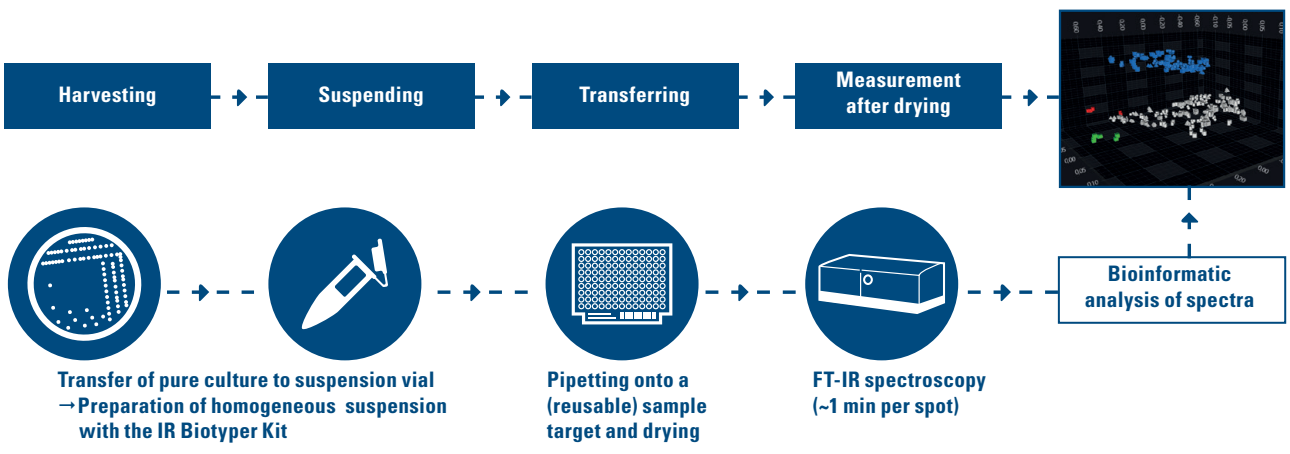
Until now, the identification of bacterial outbreaks or analysis of transmission routes has required subculturing the suspect followed by monoclonal antibody techniques, pulsed-field gel electrophoresis (PFGE), multi-locus sequence typing (MLST) or whole genome sequencing (WGS). All these approaches are associated with lengthy delays in obtaining results. Complementary to the MALDI Biotyper, the IR Biotyper addresses this challenge by using infrared spectroscopy to classify microorganisms based on their 'molecular fingerprint', also starting with colony material. This approach is fast, easy to use and economical, making it ideal for sample prescreening, strain discrimination, and cluster analysis, with minimal hands-on time.

- An individual spot is measured in about a minute
- Using 3 replicates per isolate (plus standards), up to 30 isolates can be harvested, prepared, measured and analyzed in 3 hours
- Standards are part of Bruker's IR Biotyper Kit

Benefits of using the IR Biotyper

Implementing the IR Biotyper in your laboratory:

- Allows cluster analysis and strain discrimination on subspecies level, of bacteria and yeast found on surfaces or staff as well as in water, ingredients or products
- Speeds up classification by bringing the initial screening step in-house, with same-day results starting from colony material
- Enables development of in-house screening classifiers and methods
- In conjunction with the MALDI Biotyper, allows development of workflows that identify microorganisms at the genus, species and serogroup levels.



Using the IR Biotyper workflow, an entire batch of about 30 isolates (each with three replicates), plus standards, can be harvested, prepared and analyzed in about 3 hours.

Not for use in clinical diagnostic procedures.
Please contact your local representative for availability in your country.

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