

MALDI Biotyper[®]

- AOAC-OMA & ISO 16140-part 6 validated for microbiology of the food chain

Not for use in clinical diagnostic procedures.

In Food Microbiology, Speed and Accuracy Matter

MALDI Biotyper[®]

Confirmation and identification of microorganisms by their molecular fingerprint

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

Integrating the MALDI Biotyper into routine testing workflows results in a significant consolidation of resources, as it replaces multiple traditional and biochemical identification methods, and eliminates the burden of multiple steps, workstations and metrology requirements of DNA sequencing.

Additionally, the MALDI Biotyper can be conveniently used as a fast and easy pre-screening method, prior to extensive strain characterization by the IR Biotyper, by sequencing or another DNA fingerprinting technique.



AOAC-OMA & ISO 16140-part 6 Validated for Food Microbiology

The Bruker MALDI Biotyper method is designed to rapidly:

- Confirm microorganisms:
confirm the preliminary presumptive result of an alternative or a reference method
- Identify microorganisms:
determine the identity of an analyte from a variety of agar plates.



The AOAC-OMA and ISO 16140-part 6 validation studies have clearly shown the reliability and reproducibility of the MALDI Biotyper.

The MALDI Biotyper is recognized as an **Official Method of Analysis by AOAC International** with the two following reference numbers and claims:

- Method AOAC-OMA #2017.09:
Confirmation and Identification of *Salmonella* spp., *Cronobacter* spp., *Campylobacter* spp., and other gram-negative organisms by the Bruker MALDI Biotyper method;
- Method AOAC-OMA #2017.010:
Confirmation and Identification of *Listeria monocytogenes* and *Listeria* spp., and other gram-positive organisms by the Bruker MALDI Biotyper method.

The AOAC-OMA #2017.09 and AOAC-OMA #2017.10 protocols are available on www.eoma.aoc.org.

The MALDI Biotyper is **ISO 16140-part 6 validated by MicroVal** with the four following certificate numbers and scopes:

- Certificate N° 2017LR72:
Confirmation of *Cronobacter* spp. from various agar plates;
- Certificate N° 2017LR73:
Confirmation of *Salmonella* spp. from various agar plates;
- Certificate N° 2017LR74:
Confirmation of *Campylobacter* spp. from various agar plates;
- Certificate N° 2017LR75:
Confirmation of *Listeria* spp. and *Listeria monocytogenes* from various agar plates.

The certificates and the reports of the ISO 16140-part 6 validation studies are available on www.microval.org.

MALDI Biotyper – Ensure Customers Trust Your Brand

Food Quality

Fast identification of microbial contaminants and technological strains during quality and hygiene controls

Accurate quality controls along the fermentation and ripening processes, or during storage, are fundamental to guarantee the stability of starters and the absence of unexpected microbial contaminants. This is crucial to ensure the organoleptic qualities or the probiotic benefits of your fermented products.

Reliable identifications of microbial spoilers reveals their heat resistance and growth parameters. This helps in optimizing food formulations, production processes and storage conditions to prevent microbial growth. In addition, a relevant screening plan of raw materials and other ingredients can easily be developed.

Surface sampling and related colony counts help in controlling potential biofilm development. However, identifying the involved bacteria is usually key to establishing appropriate corrective plans.

The MALDI Biotyper system can be employed in all of these different application fields with one single easy workflow for **bacteria, yeasts and molds**, providing rapid and reliable identification of positive microflora and microbial contaminants. The results can then automatically be transferred to the LIMS.

In addition to using the standard MALDI Biotyper Reference Library, the open concept of **the system offers the flexibility to build your own reference library** with your starter cultures or site-specific contaminants.

Easy and minimal handling

1 isolate
~20 sec

Short time-to-result

1 isolate
~15 min

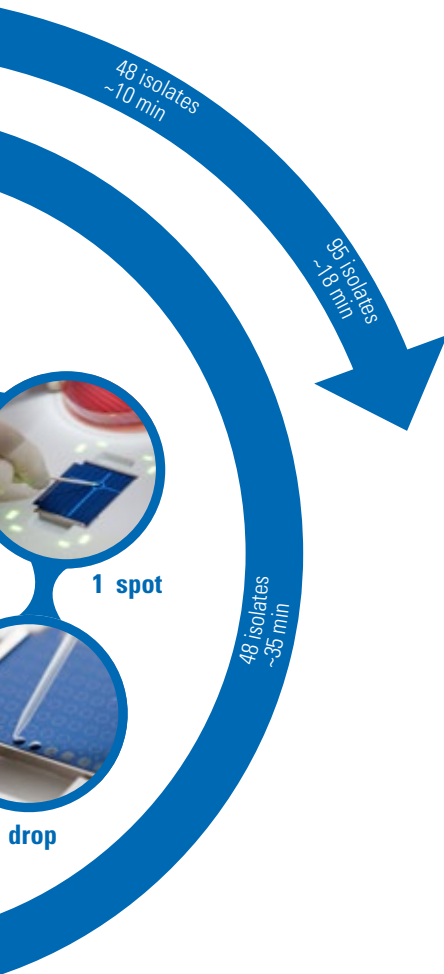


MALDI Biotyper: Official Method of Analysis by AOAC International a

Approved culture media

- Xylose Lysine Deoxycholate (XLD)
- Brilliant Green Sulfa Agar (BGA)
- RAPID' *Salmonella*
- Brilliance *Salmonella*
- ASAP
- *Enterobacter Sakazakii* Isolation Agar (ESIA)
- *Cronobacter* Chromogenic Isolation Agar (CCI)
- Ottaviani & Agosti (O&A)
- PALCAM
- Oxford Agar
- Modified Oxford Agar (MOX)

Decision – Making Driven by Real-Time Results



Food Safety

Fast confirmation of pathogens and quality indicators

Using the same workflow and the same consumables, confirmation of *Salmonella* spp., *Cronobacter* spp., *Campylobacter* spp., *Listeria* spp. and *Listeria monocytogenes* can reliably be performed in no time, from various agar plates. The flexible and low cost workflow encourages convenient testing of multiple colonies in one run, gaining crucial time for confirmation.

The AOAC-OMA and ISO 16140-part 6 validation allows confirmation of the above mentioned pathogens and quality indicators from validated culture media. Furthermore, the AOAC-OMA allows identification of bacterial isolates from any of the validated culture media mentioned for isolation of foodborne pathogens and quality indicators.

Confirmation and identification available within minutes

A fast confirmation result allows for timely actions, such as food batch withdrawal or release of safe food batches. Implementing the system in the laboratory workflow can directly translate to significant cost savings by accelerated testing along the entire process chain.

and ISO 16140-6 validated by MicroVal

- RAPID'*L.mono*
- modified Charcoal Cefoperazone Deoxycholate Agar (mCCDA)
- CampyFood Agar
- RAPID'*Campylobacter* Agar
- Campy Cefex Agar
- Non-selective agar, e.g. Tryptic Soy Agar (TSA), Tryptic Soy Yeast Extract Agar (TSYEA), Columbia Blood Agar (CBA)

Approved Reference Spectrum Libraries

- MBT Compass Library version 2016, covering 2461 species/ species groups, or any more expanded version

A Simple Procedure for a Sophisticated Platform

Bacteria, yeast or mold: one workflow for all

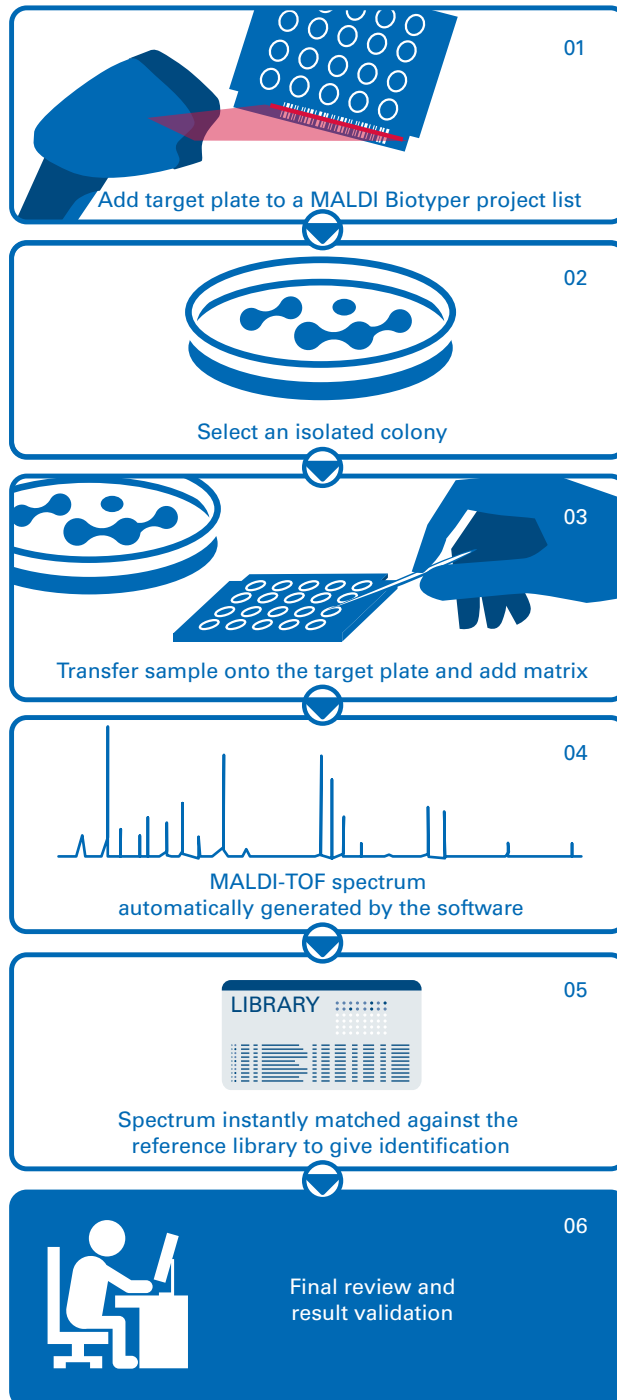
The MALDI Biotyper system workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

No need to know the type of microorganism prior to analysis; bacteria, yeast or mold samples are all analyzed together, following the same workflow.

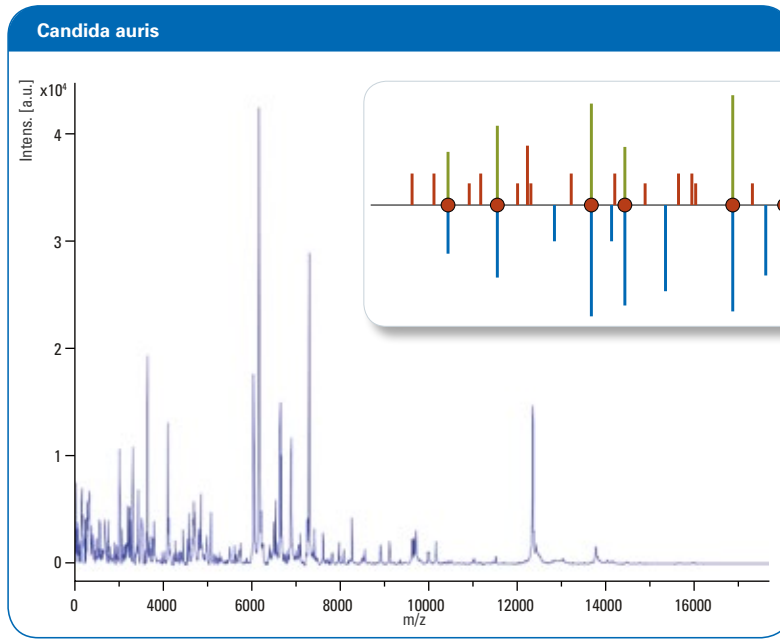
Typically, no more than an isolated single colony from a culture is required.

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

The hands-on time per isolate is only 20 seconds for 95% of the microorganisms. The short time-to-result allows investigation of a full 96-spot target plate in an hour. The MALDI Biotyper simplifies and shortens the confirmation and identification step, facilitating and harmonizing the workflow with only one system.



More Than a Comprehensive Library



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. This includes peak positions, intensities and frequencies ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

A continuously updated reference library

Bruker is fully committed to the continuous development of the reference library. An active program of reference spectra generation culminates in regular library updates for MALDI Biotyper users. These updates focus on strains from various origins being primary production, raw materials and food products, environmental samples, veterinary samples etc.

Taxonomy becomes easy

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

No need of expertise in mycology anymore

The MALDI Biotyper is perceived as the most promising alternative for molds identification. A dedicated

MBT Filamentous Fungi Library is available to facilitate the identification of this group of microorganisms. Conveniently again, prior to the analysis there is no need to know whether you are dealing with bacteria, yeast or mold samples.

Create your own libraries and run your data comparison

Laboratories that need to create their own libraries can make use of software tools to easily compile customized microorganism entries and to share and export libraries.

These might be libraries with site-specific isolates and / or entries for important starters used for production.

For further investigations, software tools – such as dendrogram analysis – are available.

MALDI Biotyper Subtyping Module

Applications dedicated to primary production and food testing

Fast microorganism identification combined with instant typing

The prerequisite for the automated typing process is high confidence identification of the bacterium in the MALDI Biotyper workflow. For species differentiation the MBT Subtyping Module then looks for decisive peaks in the mass spectrum. For detection of specific resistances, the software searches for peaks associated with proteins responsible for antibiotic resistance and, if present, reports the respective bacterium presumptive resistant.

Facilitating differentiation of closely related *Listeria* species

Differentiation of *Listeria* species is now as easy as can be! The MBT Subtyping Module supports the differentiation of *L. monocytogenes* from the other closely related *Listeria* species and starts automatically when a high identification score is achieved by the MALDI Biotyper.

This enables food microbiology laboratories to implement routine confirmation on *Listeria* spp. and *L. monocytogenes* in the daily workflow, directly from culture without any major effort. Additionally, the identification of the other *Listeria* species is provided: *L. grayi*, *L. innocua*, *L. ivanovii*, *L. seeligeri* and *L. welshimeri*.

Instant resistance marker detection in primary production

The rise of antimicrobial resistant strains of bacteria is observed in livestock. Surveillance and epidemiological studies are currently of major concern in food animal production.

The MBT Subtyping Module enables fast detection of specific resistances in an automated workflow.

Some of the available applications are of interest, such as MRSA subtyping. MRSA (Methicillin-Resistant *Staphylococcus aureus*) strains are resistant to beta-lactam antibiotics, and are more and more encountered in primary production. MRSA surveillance is currently increasing, e.g. in dairy cattle and raw milk, veal calves and pigs.

Seamless and fast workflow

To acquire a typing result, no additional sample preparation is required once the samples are directly transferred to MALDI target plates. When the bacterium has been identified, the software automatically performs the typing and result reporting.



Easy-to-Use Software

Dedicated to routine testing, easy export to the LIMS

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

Automatic Calibration and Quality Control Check

BTS	Position	Name	ID	Description	Sample Type
<input checked="" type="checkbox"/>	A1	A1	bts		BTS
<input type="checkbox"/>	A2	A2	180610		
<input type="checkbox"/>	A3	A3	180611		
<input type="checkbox"/>	A4	A4	180612		
<input type="checkbox"/>	A5	A5	180613		
<input type="checkbox"/>	A6	A6	180614		
<input type="checkbox"/>	A7	A7	180615		

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

Report on Confirmation/Identification Results

Result Interpretation Table		
Sample name	Sample ID	Sample Confirmation
A1	BTS (BTS)	Escherichia coli identification
A2	180610 (Standard)	Cronobacter spp. confirmation
A3	180611 (Standard)	L. monocytogenes confirmation
A4	180612 (Standard)	Listeria spp. confirmation L. welshimeri identification
A5	180613 (Standard)	Campylobacter spp. confirmation Campylobacter jejuni identification
A6	180614 (Standard)	Enterococcus faecalis identification
A7	180615 (Standard)	Listeria spp. confirmation L. innocua identification

The MALDI Biotyper report for food microbiology directly provides the final interpretation of the results: pathogen confirmations and other identifications are clearly listed.

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample is clearly listed under 'Sample Confirmation'.

Open microbiology concept

The MALDI Biotyper allows for smooth integration with existing laboratory informatics. MALDI Biotyper results are converted into a format that can easily be exported to the LIMS.





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 microflex™ LT/SH MALDI-TOF mass spectrometer with N₂ laser at 60 Hz repetition rate
- 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 fastest target exchange time of all microbial mass spectrometry systems.

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 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 utilization of the laser lifetime.

Continuous operation

The MALDI Perpetual Ion Source™ permits continuous high performance with minimized maintenance requirements. Cleaning the source using the separate IR-laser is performed easily under push-button operator control.

True benchtop solutions

Low-noise operating systems with low weight and requiring less than 1 m / 4 feet of counter space offer flexibility in meeting laboratory needs for compact system solutions. Both systems need only a 220 V / 110 V electrical supply which results in very minimal heat output.

Compact Benchtop Systems – No Performance Compromise

	microflex™ LT/SH	microflex™ LT/SH smart
Laser	Nitrogen Laser <ul style="list-style-type: none"> • 60 Hz repetition rate • ~200 samples/hr • 60 million laser shots 	Bruker's proprietary lifetime* smartbeam laser <ul style="list-style-type: none"> • 200 Hz repetition rate • ~400 samples/hr • 500 million laser shots
Vacuum system	Original vacuum system <ul style="list-style-type: none"> • fast target exchange 	New high-performance vacuum system <ul style="list-style-type: none"> • three times greater pumping capacity • even faster target exchange • less down-time after maintenance
L x W x H	530 x 680 x 1093 mm / 20.9" x 26.8" x 43"	530 x 680 x 1093 mm / 20.9" x 26.8" x 43"
Weight	84 kg / 185 lb	99 kg / 218 lb
Common features	Perpetual 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 / 110 V	

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

MALDI Biotyper System Overview

Microbial Identification Applications

- Gram +/- bacteria, yeasts, filamentous fungi, mycobacteria

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 operating system
- MBT Compass & MBT Explorer Software plus MBT Compass Library
- MBT Subtyping Module

Optional Libraries

- MBT Mycobacteria Suite
- MBT Filamentous Fungi Library

Consumables and Ancillaries

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

Accessories for workflow optimization

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

Qualification

- Recognized as an Official Method of Analysis by AOAC International
- ISO 16140-part 6 validated by MicroVal

Dimensions & Operating Parameters

microflex LT/SH smart

LxWxH:	530 x 680 x 1093 mm (20.9" x 26.8" x 43")
Weight:	99 kg (218 lb) net weight
Noise:	<60 dB
Temp Range:	16- 33°C (61-91°F)
Operating Humidity:	20-75% non-condensing @ 33°C (91°F)

microflex LT/SH

LxWxH:	530 x 680 x 1093 mm (20.9" x 26.8" x 43")
Weight:	84 kg (185 lb) net weight
Noise:	<50 dB
Temp Range:	16- 33°C (61-91°F)
Operating Humidity:	20-75% non-condensing @ 33°C (91°F)

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