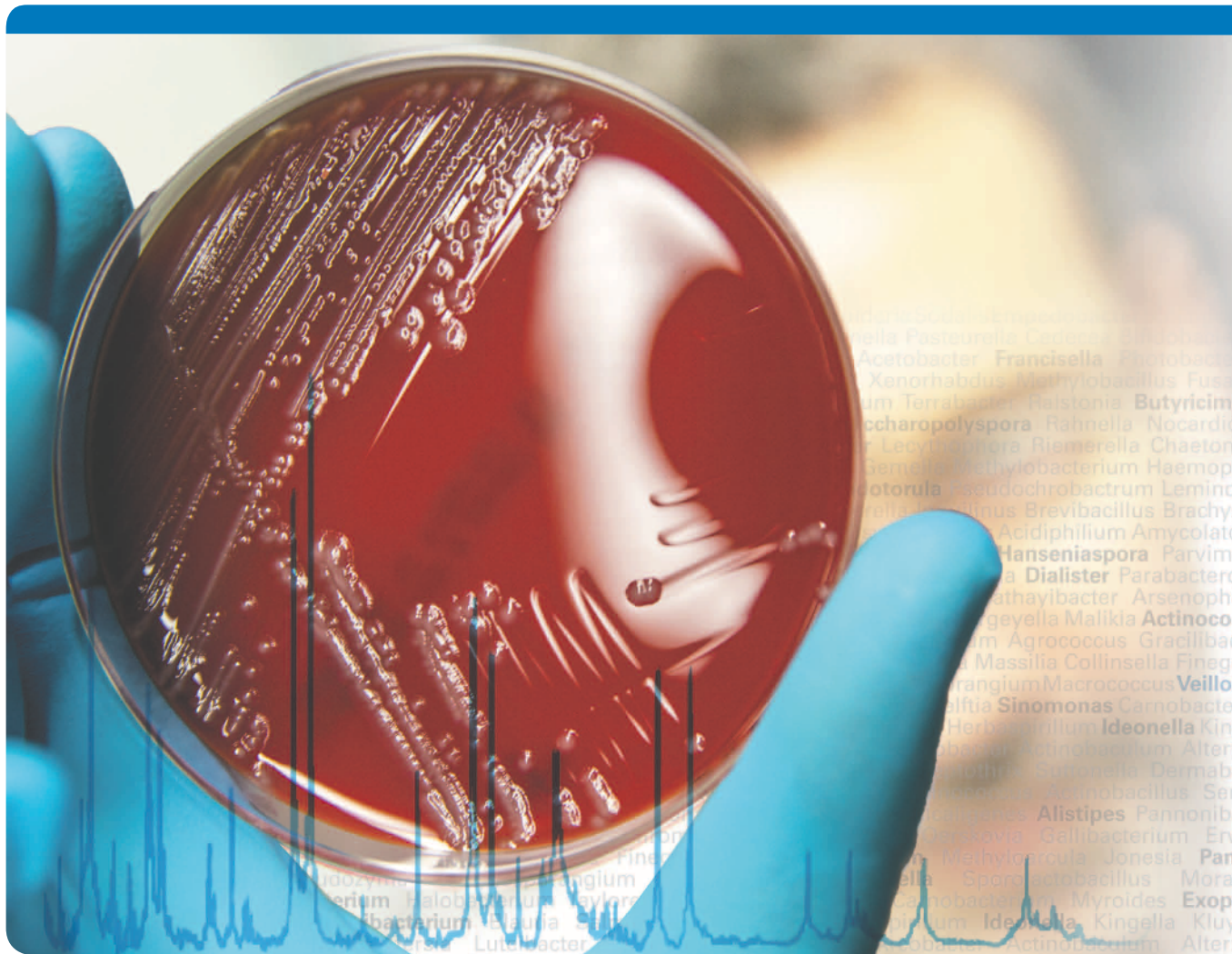




MALDI Biotyper CA System

- Clinical Application for Identification of Microorganisms



**In Microbiology,
Every Minute Counts**

The MALDI Biotyper CA 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 CA System. With its combination of performance and utility, the MALDI Biotyper CA System will revolutionize the way microbial identification is performed in the clinical microbiology laboratory.

- Accuracy comparable to Nucleic Acid Sequencing
- Much faster than traditional methods
- Cost effective
- Robust and easy to use
- A true benchtop system

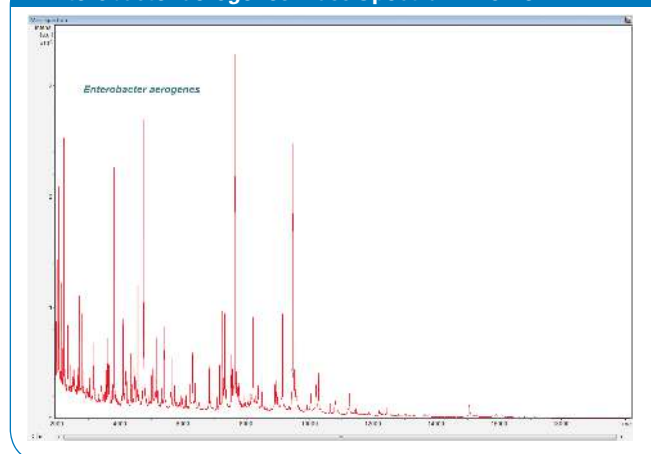
Identifying microorganisms by their molecular fingerprint

The MALDI Biotyper CA System identifies microorganisms using MALDI-TOF (Matrix Assisted Laser Desorption Ionization Time of Flight) Mass Spectrometry to measure a unique molecular fingerprint of an organism. Specifically, the MALDI Biotyper CA 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 FDA-cleared database to determine the identity of the microorganism.

***Enterobacter aerogenes* Mass Spectrum Profile**



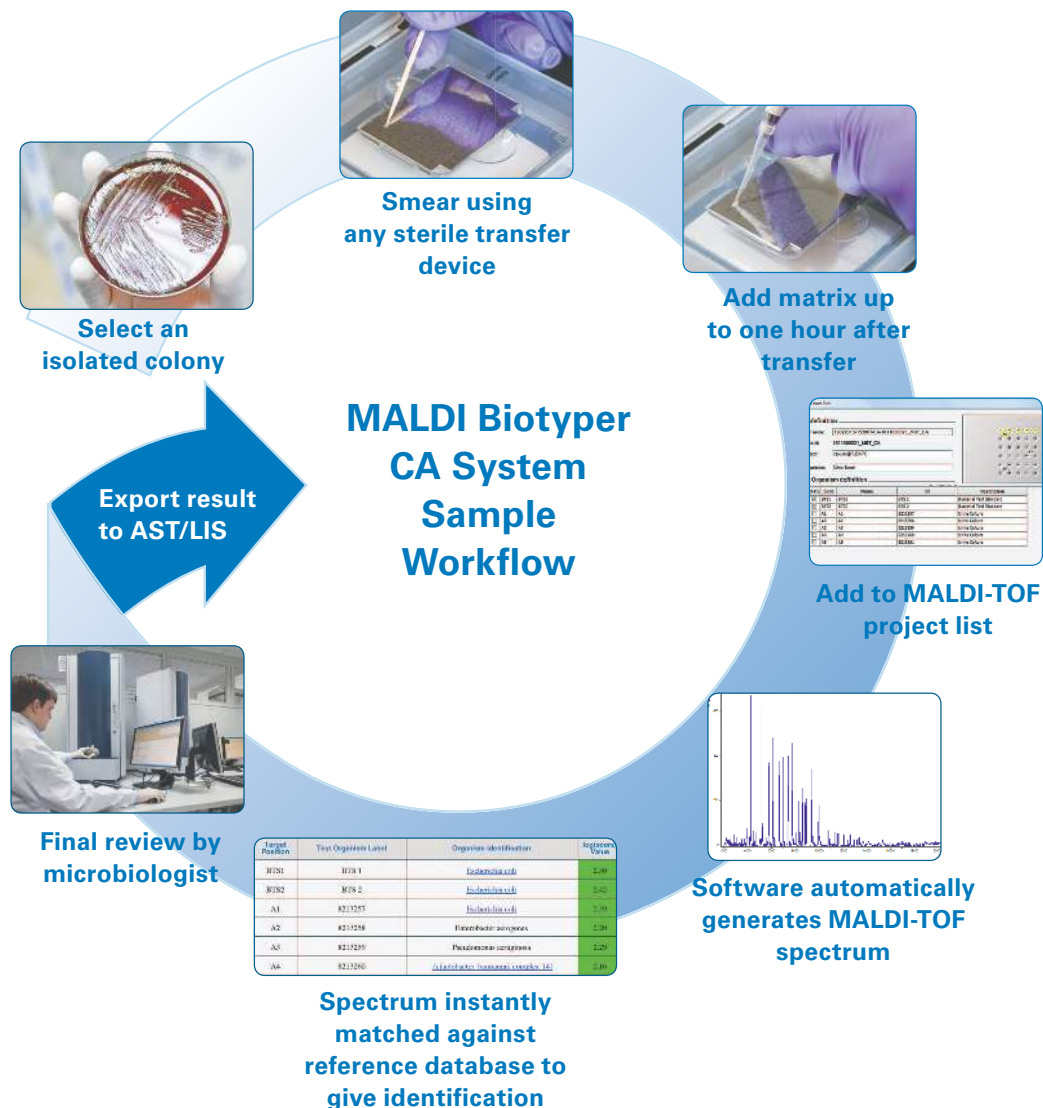
A Simple Procedure for a Sophisticated Platform

Innovative design leads to enhanced performance and productivity

The MALDI Biotyper CA System workflow has been designed to be as robust and easy to perform as possible. No previous experience with Mass Spectrometry is required. The workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications. Our dedicated microbiology software

automates the process of acquiring the mass spectrum and performing the data-base matching. A report is then generated showing the microbial identification in a very easy to interpret “traffic light” color scheme.

Typically no more than an isolated single colony from a culture plate is required, the entire procedure requires only a few minutes to complete providing a report showing the closest matches to the extensive library of microorganisms.



Easy to Use Software that is Dedicated to Microbiology

The wizard

A simple to use Real Time Classification wizard guides you through setting up samples for analysis in just a few easy steps.

Automatic Calibration and Quality Control Check

Create a new Run

Run definition

Run name: 12022013-152807-CA-1811000321_MBT_CA

Plate Id: 1811000321_MBT_CA

Creator: ca-user@FLEX-PC

Description: Urine Bench

Test Organism definition

	BTS	Spot	Name	Id	Description
1	☒	BTS1	BTS1	BTS 1	Bacterial Test Standard
2	☒	BTS2	BTS2	BTS 2	Bacterial Test Standard
3	☐	A1	A1	8213257	Urine Culture
	☐	A2	A2	8213258	Urine Culture
	☐	A3	A3	8213259	Urine Culture
	☐	A4	A4	8213260	Urine Culture
7	☐	A5	A5	8213261	Urine Culture



The MALDI Biotyper CA System microflex LT/SH mass spectrometer is automatically checked using US IVD BTS (Bacterial Test Standard) before each use. When the check is successful, the system automatically begins the measurement process.

Run Results Report

Target Position	Test Organism Label	Organism Identification	log(score) Value
BTS1	BTS 1	Escherichia coli	2.50
BTS2	BTS 2	Escherichia coli	2.42
A1	8213257	Escherichia coli	2.39
A2	8213258	Enterobacter aerogenes	2.20
A3	8213259	Pseudomonas aeruginosa	2.00
A4	8213260	Acinetobacter baumannii complex [4]	2.16
A5	8213261	Proteus vulgaris_group	2.45

After the acquisition of the spectral data has been completed, a Run Results Report can be generated. The resultant report for each sample shows the best match along with the respective matching score.

Organism identification hints can also be viewed via a hyperlink.

Rigorous and Sophisticated Data Analysis Assures Accuracy

Meaning of score values

The spectrum of the unknown test organism, acquired through the MALDI Biotyper CA System Software, is electronically transformed into the peak list. Using a biostatistical algorithm, this peak list is compared to reference peak lists of organisms in the reference database and a log(score) value between 0.00 and 3.00 is calculated.

The higher the log(score) value, the higher the degree of similarity to a given organism in the reference FDA-cleared database. A log(score) value of ≥ 2.00 can be considered an excellent probability for test organism identification at the species level.

The main spectra concept: a reference database developed with the user in mind

Reference database entries in the MALDI Biotyper CA 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.

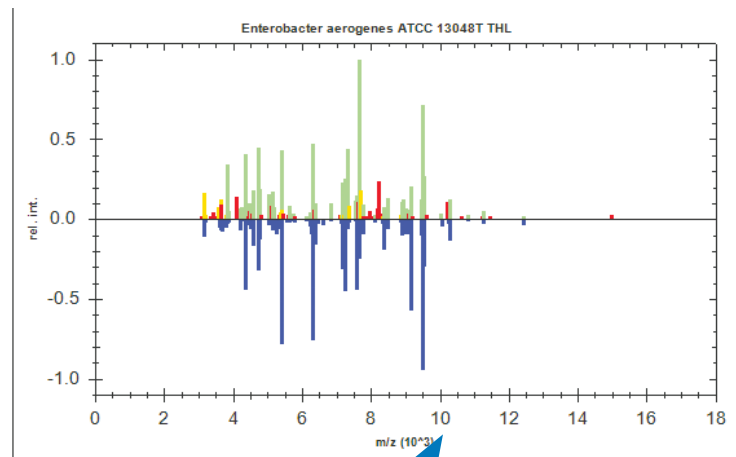
An unbiased sophisticated algorithm creates the MSP completely unsupervised by extracting information about peak position, intensity and frequency, while employing very effective de-noising and patented mass corrections to the peak data.

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

Score Values

Range	Interpretation	Color
2.00 - 3.00	High Confidence Identification	Green
1.70 - 1.99	Low Confidence Identification 1. If this log(score) is obtained on a direct transfer, follow with extraction preparation [see User Manual] 2. If this log(score) is obtained on an extracted test organism, report sample as "Low Confidence Identification"	Yellow
< 1.70	No Organism Identification Possible [refer to troubleshooting section in User Manual] 1. If this log(score) is obtained on a direct transfer, follow with extraction preparation [see User Manual] 2. If this log(score) is obtained on an extracted test organism, report sample as "No Identification"	Red

Reference Strain

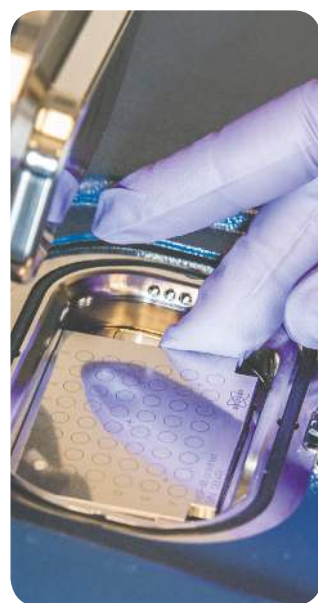


The Best Technology from the Market Leader in MALDI-TOF



The MALDI Biotyper CA System was developed by Bruker, the industry leader in MALDI-TOF technology. These systems were designed as robust, compact, high performance platforms intended for extensive and routine usage. Many outstanding features have been incorporated into the MALDI Biotyper CA System to enhance performance, simplify operation, and extend system lifetime and utility.

- A true bench-top system—A smart compact design that packs a punch with a throughput of 192 samples an hour. The small access chamber allows for a rapid target insertion that eliminates waiting time between runs. Requires only a 110 V electrical outlet with very minimal heat output.
- Silent and pleasant operation—With WhisperMode™ you really have a system that can sit on a bench next to you almost silently. By eliminating noisy oil-based vacuum pumps, the vacuum system is not only quiet, but virtually maintenance free.
- Greatly enhanced sensitivity—With the most sensitive detector technology available (FlashDetector™) you will benefit from having the same high performance technology as large research grade instruments.



Powerful and Reliable Performance— Benchtop Convenience

microflex LT/SH Mass Spectrometer Dimensions and Operating Parameters

LxWxH:	510 x 680 x 1093 mm [20.1" x 26.8" x 43"]
Weight:	84 kg (185 lb) net weight
Noise:	< 30 dB under normal operating conditions
Temp Range:	10-30°C (50-86°F)
Operating Humidity:	15-85% non-condensing @ 30°C

Full spectrum resolution

Patented, intelligent pulsed Ion Extraction across a wide protein mass range. This unique technology enhances peak

resolution and separation, and mitigates the need for unnecessarily long and bulky instrument flight tubes.

MALDI Biotyper CA System and Components

Components

The standard MALDI Biotyper CA System contains the following components:

- microflex LT/SH mass spectrometer [P/N: 269944]
- MALDI Biotyper CA System desktop computer running under Windows® 7 [P/N: 604941]
- MALDI Biotyper CA System software [P/N: 604512]
- US IVD 48 Spot Target [P/N: 604532]
- US IVD BTS [P/N: 604530]
- US IVD HCCA portioned [P/N: 604531]
- Package Insert, MALDI Biotyper CA System User Manual [P/N: 603291]
- Uninterruptible Power Supply (UPS) [P/N: 601463]

Instrument: microflex LT/SH Mass Spectrometer

- Nitrogen Laser with 60Hz repetition rate
- Full Spectrum Resolution (FSR) with broadband focusing mode (PAN™)
- FlashDetector™
- WhisperMode™
- Oil-free membrane pre-vacuum pump and turbo pump

Indication for use

The Bruker Daltonics, Inc. MALDI Biotyper CA System is a qualitative in vitro diagnostic mass spectrometer system for the identification of Gram-negative bacterial colonies cultured from human specimens using matrix-assisted laser desorption/ionization time of flight (MALDI-TOF) mass spectrometry technology.

The MALDI Biotyper CA System is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of Gram-negative bacterial infections.

The following organisms are claimed:

Achromobacter xylosoxidans
Acinetobacter lwoffii
Acinetobacter radioresistens
Acinetobacter ursingii

Acinetobacter baumannii complex

Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter nosocomialis
Acinetobacter pittii

Aeromonas sp

Aeromonas allosaccharophila
Aeromonas caviae
Aeromonas culicicola
Aeromonas hydrophila
Aeromonas ichthiosmia
Aeromonas veronii
Aeromonas sobria
Alcaligenes faecalis
Burkholderia gladioli
Burkholderia multivorans

Burkholderia cepacia complex

Burkholderia ambifaria
Burkholderia anthina
Burkholderia cenocepacia
Burkholderia cepacia
Burkholderia diffusa
Burkholderia dolosa
Burkholderia lata
Burkholderia latens
Burkholderia metallica
Burkholderia pyrrocinia
Burkholderia seminalis
Burkholderia stabilis
Burkholderia vietnamiensis

Citrobacter amalonaticus complex

Citrobacter amalonaticus
Citrobacter farmeri

Citrobacter freundii complex

Citrobacter braakii
Citrobacter freundii
Citrobacter gillenii
Citrobacter murlinae
Citrobacter werkmanii
Citrobacter youngae
Citrobacter rodentium
Citrobacter sedlakii

Citrobacter koseri

Eikenella corrodens

Enterobacter aerogenes

Enterobacter cloacae complex

Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter cloacae
Enterobacter hormaechei
Enterobacter kobei
Enterobacter ludwigii
Escherichia coli
Haemophilus influenzae
Haemophilus parainfluenzae

Hafnia alvei
Klebsiella pneumoniae
Klebsiella oxytoca / *Raoultella ornithinolytica*
Moraxella sg_Branhamella catarrhalis
Moraxella sg_Moraxella osloensis
Morganella morganii
Pantoea agglomerans
Pasteurella multocida
Proteus mirabilis

Proteus vulgaris group

Proteus hauseri
Proteus penneri
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa

Pseudomonas fluorescens group

Pseudomonas azotoformans
Pseudomonas brenneri
Pseudomonas cedrina
Pseudomonas congelans
Pseudomonas corrugata
Pseudomonas extremorientalis
Pseudomonas fluorescens
Pseudomonas gessardii
Pseudomonas libanensis
Pseudomonas mandelii
Pseudomonas marginalis
Pseudomonas migulae
Pseudomonas mucidolens
Pseudomonas orientalis
Pseudomonas poae
Pseudomonas rhodesiae
Pseudomonas synxantha
Pseudomonas tolaasii
Pseudomonas trivialis
Pseudomonas veronii

Pseudomonas putida group

Pseudomonas fulva
Pseudomonas montellii
Pseudomonas mosselii
Pseudomonas plecoglossicida
Pseudomonas putida

Salmonella sp

Salmonella enterica ssp arizonae
Salmonella enterica ssp bongori
Salmonella enterica ssp diarizonae
Salmonella enterica ssp enterica
Salmonella enterica ssp houtenae
Salmonella enterica ssp indica
Salmonella enterica ssp salamae
Serratia liquefaciens
Serratia marcescens
Stenotrophomonas maltophilia
Yersinia enterocolitica
Yersinia pseudotuberculosis



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