

# Clinical Microbiology

3.1, 3.2, 3.2.1

## MALDI Biotyper

- Fast & Accurate Identification of Microorganisms

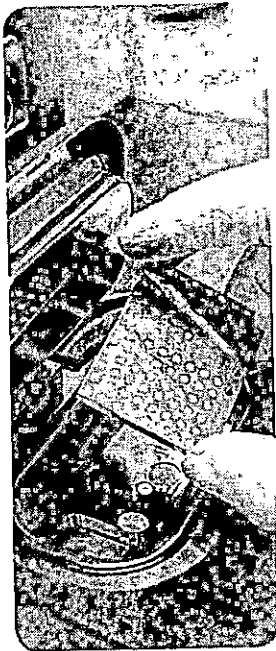
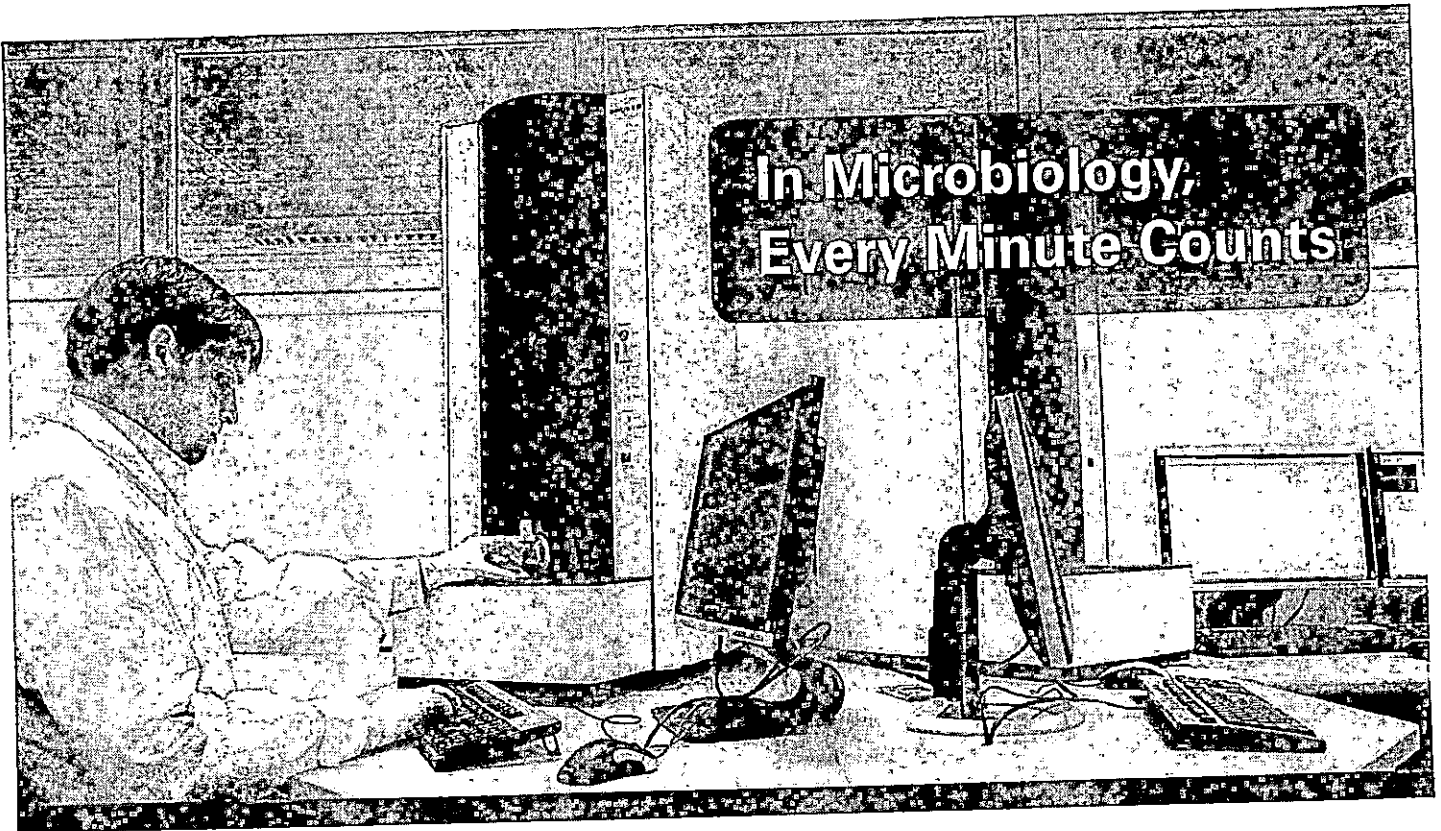
Innovation with Integrity

MALDI-TOF

บริษัท เทคโนโลยี ฟูนิค จำกัด  
 100 หมู่ 10 ต.บางพลีใหญ่ อ.บางพลี จ.สมุทรปราการ  
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๓. ลงชื่อ.....





**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 ground breaking MALDI Biotyper system. With its combination of performance and utility, the MALDI Biotyper has changed the way microbial identification is done in laboratories around the world.

**Identifying Microorganisms by Their Molecular Fingerprint**

The MALDI Biotyper 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 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 open database to determine the identity of the microorganism down to the species level.

**The MALDI Biotyper System:**

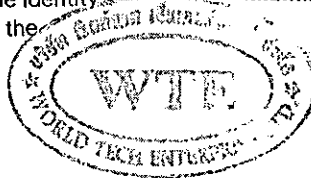
- Highly Accurate
- Applicable to a Wide Range of Microorganisms
- Much Faster than Traditional Methods
- Cost Effective
- Robust and Easy to Use

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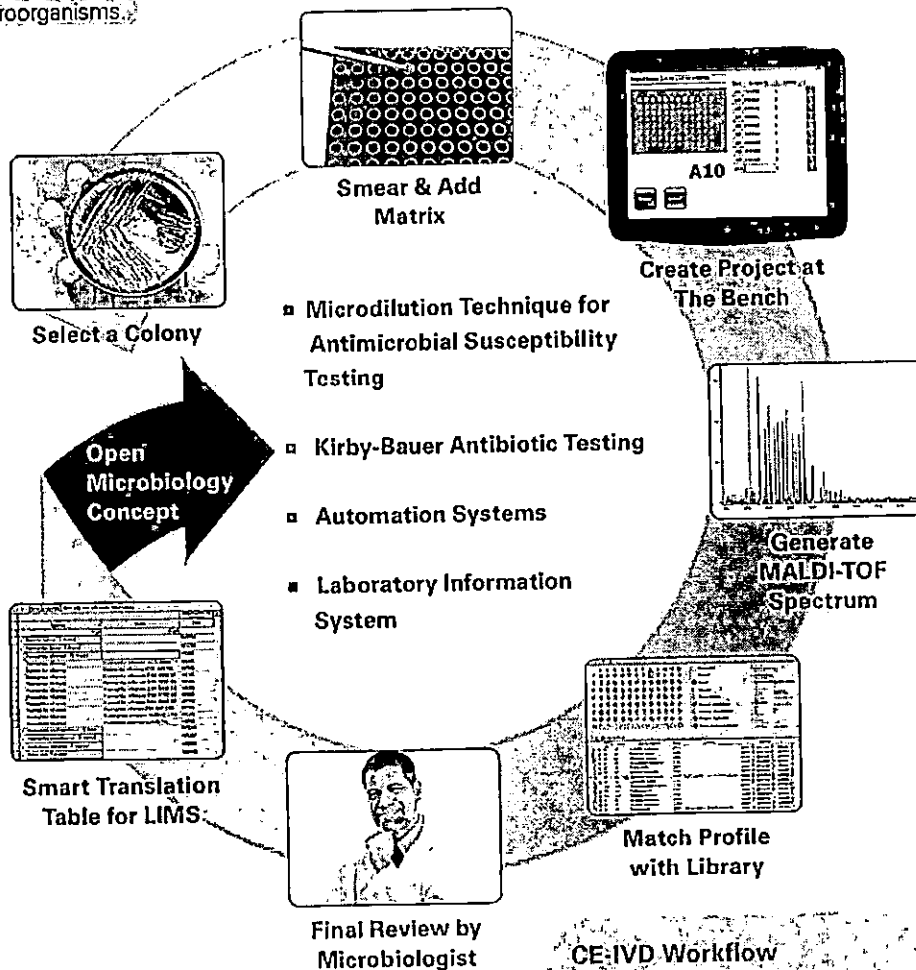


# A Simple Procedure for A Sophisticated Platform

Innovative Design Leads to Enhanced Performance and Productivity

3.1 The MALDI Biotyper 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 species identifications; our dedicated microbiology software automates the process of acquiring the mass spectrum, and performing the library matching, providing a report showing the closest matches to the extensive library of microorganisms.

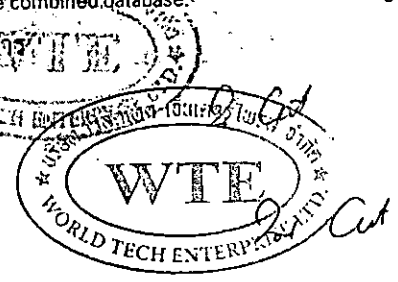
Typically, no more than a single colony from a plate or a small aliquot from a broth is required; the entire procedure requires only a few minutes to complete. Additional workflows are also available for the processing of positive blood cultures as well as other traditionally difficult to analyze groups of organisms including fungi and mycobacterium.

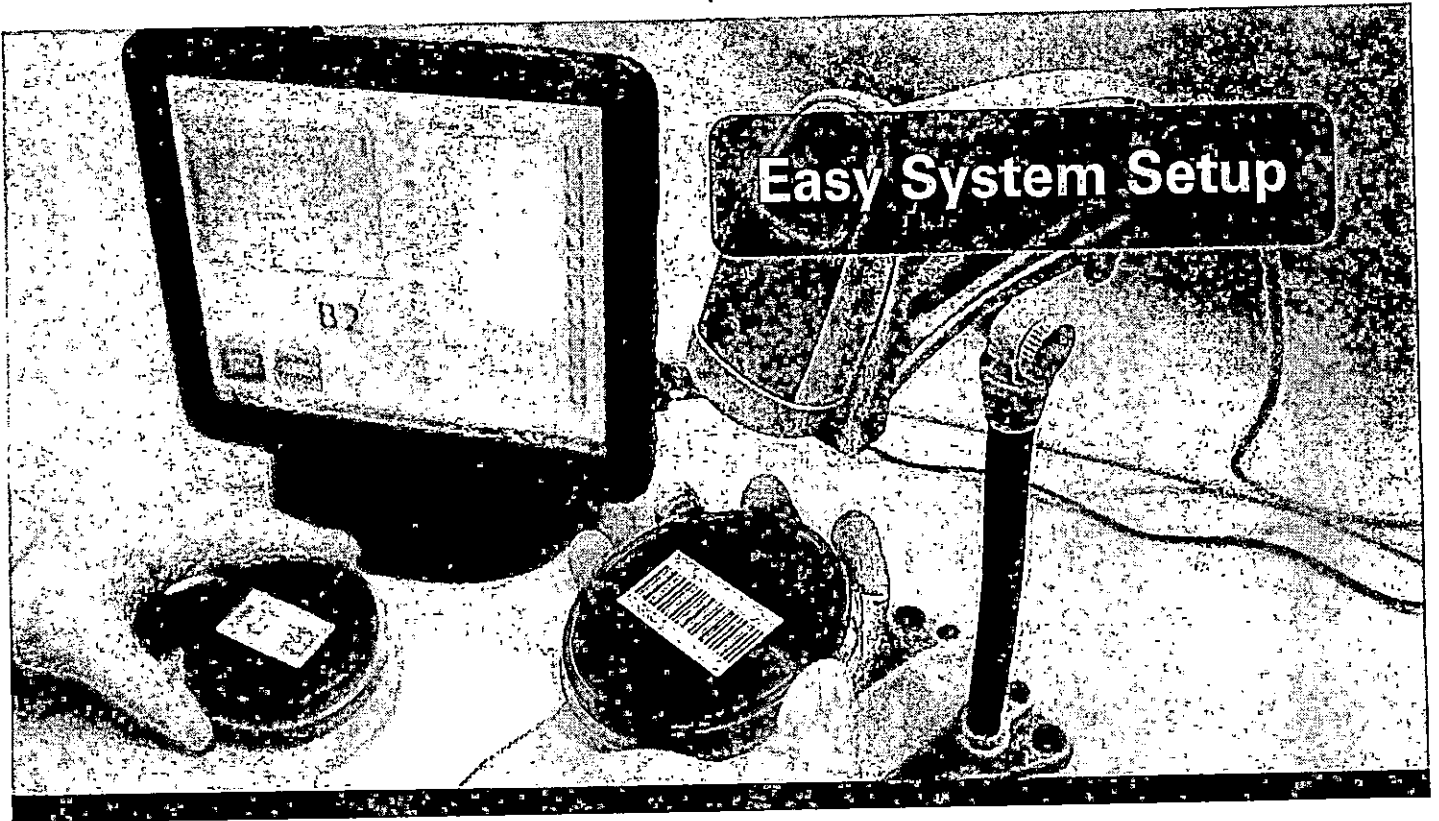


**CE:IVD Workflow**  
 A fully validated workflow according to the European Union IVD Directive 98/79/EC is also available and utilizes a list of the same strains contained within the combined database.

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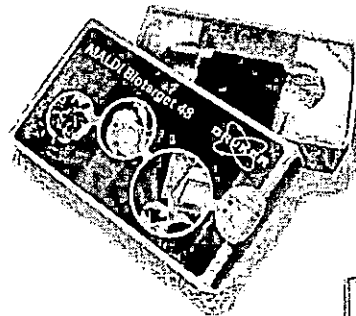




## A Workflow that Empowers Microbiology Laboratories

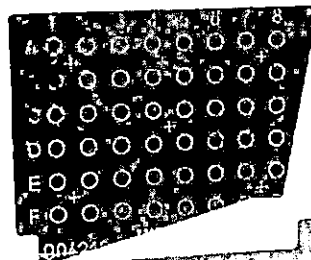
### Choosing the Right Sample Platform

Bruker offers a selection of bar-coded, disposable, or reusable 24, 48, or 96 position Sample Targets to best suit your individual requirements. All sample positions can be randomly accessed by the system, in any combination, for maximum assay flexibility.



### Have an Urgent Sample?

No problem. Just pause the running project, exchange the sample target, and get results in a few minutes. The unique system design facilitates on-the-fly changes to handle urgent samples.



### Matches Your Sample Project

With on board barcode reading, the MALDI Biotyper matches your sample with its corresponding target, ensuring you never analyse the wrong samples.



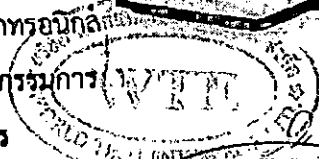
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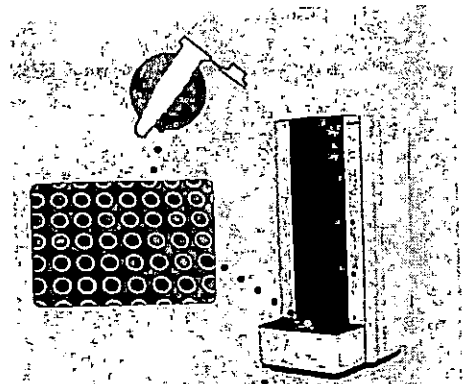
# Make A Difference in Analyzing Positive Blood Cultures

## MALDI Sepsityper™ Kit

Using the MALDI Sepsityper Kit in combination with the MALDI Biotyper, can result in a 70-90% identification rate in positive blood culture samples.

This high confidence result is available much earlier than with conventional technology. Use of the Sepsityper Kit can typically save at least one day in the time-to-result for the crucial identification step in analyzing blood borne infections.

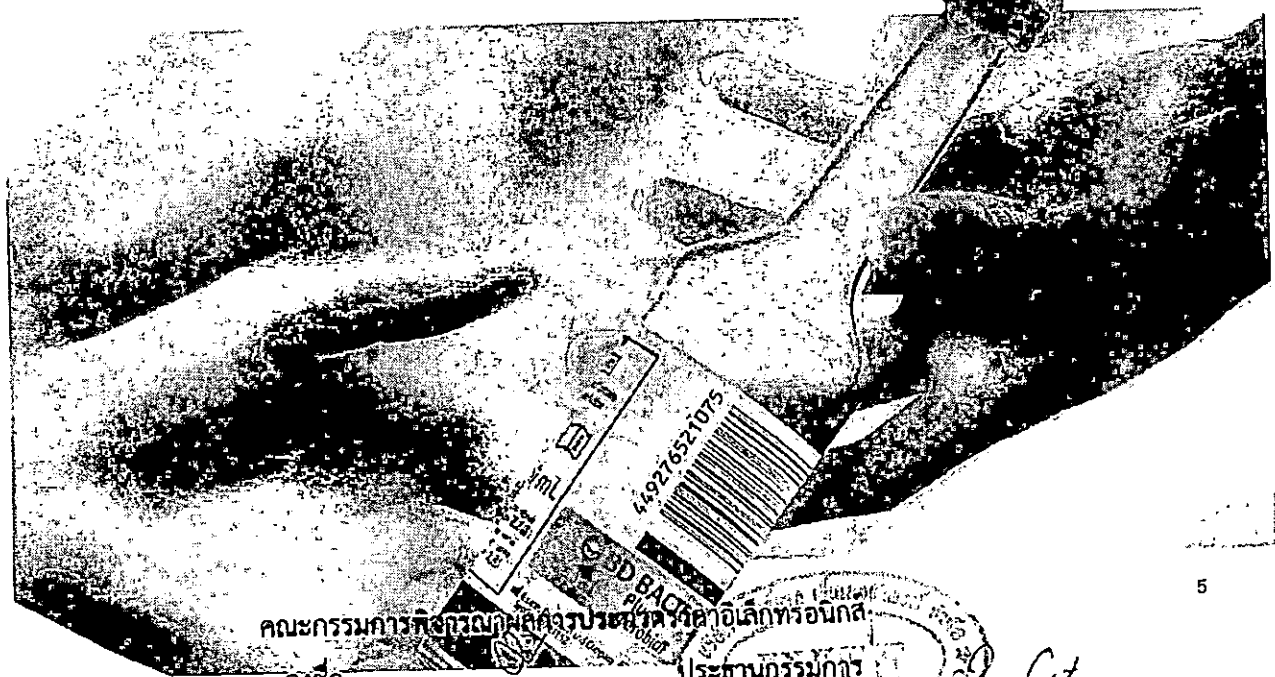
The efficient pathway for fast, reliable, unambiguous species identification from positive blood culture bottles



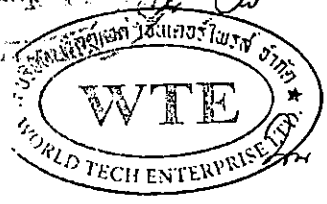
### Result Overview

Sample ID	Species	Confidence
1	Staphylococcus aureus	95%
2	Staphylococcus aureus	95%
3	Staphylococcus aureus	95%
4	Staphylococcus aureus	95%
5	Staphylococcus aureus	95%
6	Staphylococcus aureus	95%
7	Staphylococcus aureus	95%
8	Staphylococcus aureus	95%
9	Staphylococcus aureus	95%
10	Staphylococcus aureus	95%

- 1 Harvest 1 ml blood culture liquid in a test tube
- 2 Add Lysis Buffer and centrifuge
- 3 Add Washing Buffer and centrifuge
- 4 Suspend pellet in water
- 5 Standard Bruker extraction protocol for MALDI bacterial profiling
- 6 Spotting of 1µl extract onto MALDI target, overlay with HCCA matrix
- 7 MALDI-TOF measurement
- 8 Receive Result, ID



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# Easy to Use Software That's Dedicated to Microbiology

3.2.10

**MALDI Biotyper Realtime Classification Wizard**

**Analyte Placement**  
Please specify the target positions for your analytes by drawing a rectangle, clicking on row/column names or directly on the appropriate spots. Analytes are inserted using the Insert key or with Add Analytes from the context menu. Available target spots are shown in hollow. Spots containing analytes of the current project are white (not yet measured) or green (already measured). Please fill in the ID column if it is empty.

	1	2	3	4	5	6	7	8	9	10	11	12
A	<input type="checkbox"/>											
B												
C												
D												
E												
F												
G												
H												

Position	Chip	Creation Date	Name [opt. ID]	Bacterial Test Standard	Calibration	Description [optional]
A1	0	22/04/2011 16:39	A1	8213257		Blood Culture
A2	0	22/04/2011 16:39	A2	8213257		Blood Culture
A3	0	22/04/2011 16:39	A3	8213258		Blood Culture
A4	0	22/04/2011 16:39	A4	8213259		Blood Culture
A5	0	22/04/2011 16:39	A5	8213260		Blood Culture
A6	0	22/04/2011 16:39	A6	8213261		Blood Culture
A7	0	22/04/2011 16:39	A7	8213262		Blood Culture
A8	0	22/04/2011 16:39	A8	8213263		Blood Culture
A9	0	22/04/2011 16:39	A9	8213264		Blood Culture
A10	0	22/04/2011 16:39	A10	8213265		Blood Culture
A11	0	22/04/2011 16:39	A11	8213266		Blood Culture
A12	0	22/04/2011 16:39	A12	8213267		Blood Culture

Validation Position: **A10**

Buttons: Cancel, << Back, Next >>, Finish, Help

## The Wizard 3.2.10

A simple to use Real Time Classification wizard guides you through setting up a sample for analysis in just a few easy steps. Import sample information from LIMS or Excel or even enter it manually using a barcode reader.

## Automatic Calibration

Using the Bruker Bacterial Test Standard, you can select any position on your target, and the MALDI Biotyper will automatically calibrate the system.

## 3.2.10 Validate Your Results

The MALDI Biotyper expert system supports both the identification and validation of results. Make better, more informed decisions with the help of "matching hints" and view relevant sample data or information from your LIMS.

<input type="radio"/>	Not occupied
<input type="radio"/>	Prepared
<input type="radio"/>	Abated
<input type="radio"/>	Measured
<input type="radio"/>	Zeidno spectrum
<input type="radio"/>	Measured, classified green
<input type="radio"/>	Measured, classified yellow
<input type="radio"/>	Measured, classified red
<input type="radio"/>	Zeidno spectrum, not classified

Position	Name	Detected Species	Score	Comment	Validation
A2	A2	Acidiphilium acidophilum	2712		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A3	A3	Cupriavidu necator	2215		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A4	A4	Aerobacter sulfureus	2595		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A5	A5	Microbacterium marisnigricum	2342		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A6	A6	Protinus nishiki	2415		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A7	A7	no reliable identification	1261		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A8	A8	Haloconus halodentificans	1051		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A9	A9	Lactobacillus rossiae	2392		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A10	A10	Methylobacterium thiooxidans	1794		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A11	A11	Xanthomonas pisi	2417		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
A12	A12	Clavidium pallidipes	2105		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
B1	B1	no reliable identification	1303		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
B2	B2	no reliable identification	1303		species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
B3	B3	Escherichia coli	2441	closely related to Shigella and not de	species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
B4	B4	Escherichia coli	2479	closely related to Shigella and not de	species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>
B5	B5	Escherichia coli	2470	closely related to Shigella and not de	species <input type="radio"/> genus only <input type="radio"/> unknown <input type="radio"/>

Connecting to flexControl successful | Server: localhost Port: 7080

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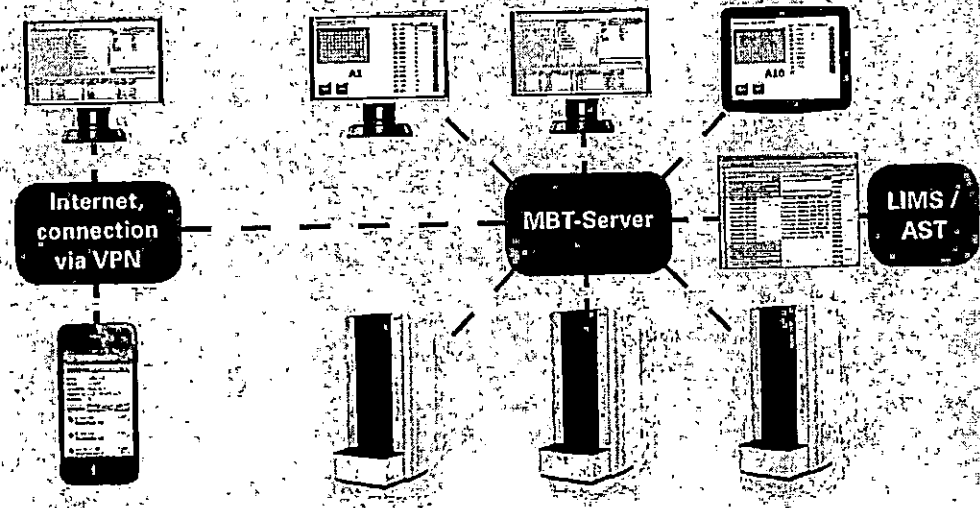
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# ...With A Powerful & Flexible Data System Architecture

## MBT Client Server Architecture



### Direct Connection to LIMS

All LIMS integration is handled by the MBT Server. CSV and ASTM are supported as exchange formats and have established connections to many LIMS providers.

### Easy Integration with Laboratory Informatics

The central MALDI Biotyper Server manages all requests for information and stores all data. The Server also manage requests and processes data from several instruments or remote clients. Installation of remote clients on existing computers in the laboratory is supported. This enables system set up and operation directly from the lab bench, or allows for the validation of an already completed run.

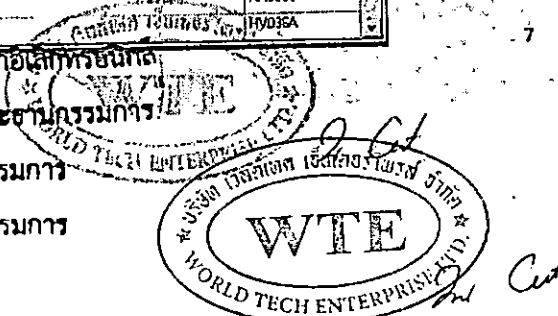
### Translate Your Results

Using the customizable smart translation tool, the thousands of species covered by the MALDI Biotyper are automatically converted into a format that a LIS, an expert system, or an AST System can understand.

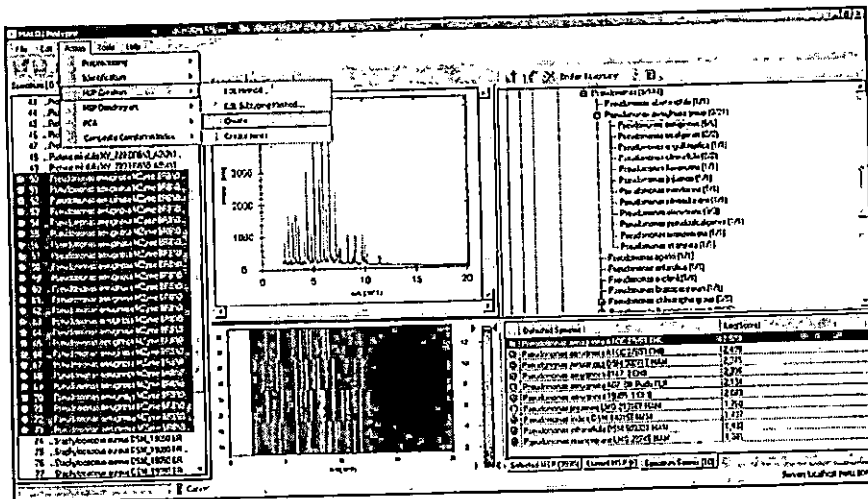
Species	Name	Abbreviation for Laboratory
Grimonia holzschii - 1 strain(s)		GH0363
Haemophilus ducreyi - 1 strain(s)		HD0364
Haemophilus influenzae - 10 strain(s)		HI0365
Haemophilus influenzae	Haemophilus influenzae ATCC 35056 TH	HI0365
Haemophilus influenzae	Haemophilus influenzae ATCC 9006 THL	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 10000 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 10001 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 11121 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 11959 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 4690T DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 9599 DSM	HI0365
Haemophilus influenzae	Haemophilus influenzae HU30410.1 PN	HI0365
Haemophilus influenzae	Haemophilus influenzae bes5130 THL	HI0365
Haemophilus parahaemolyticus - 5 strain(s)		HP0366
Haemophilus parainfluenzae - 5 strain(s)		HP0367
Haemophilus parainfluenzae - 1 strain(s)		HP0368
Hafnia alvei - 7 strain(s)		HA0369
Halorococcus volcanii - 1 strain(s)		HY036A

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# An Open Microbiology Platform and Database



## An Open and Comprehensive Database

3.2.11 MALDI Biotyper integrates a ready to use reference library of microorganisms comprising over 6,000 of individual entries of microorganisms. The library is constantly maintained and updated with contributions from many collaborating partners from countries around the world.

MSPs can be created and added to the database by users. This process is simple and highly automated within the software. MSP's can then be associated into their unique libraries with just a few additional mouse clicks.

The screenshot shows the MALDI Biotyper MSP Metadata Editor dialog box. It contains fields for Organism (Pseudomonas aeruginosa), Strain (ATCC 27853), Provided by (THL), Determined by (ATCC), Extraction Method (EDH FA), Matrix (HCCA), and Growing Conditions (according to http://www.lgcprochem.com). There is also a comment field and buttons for Edit, OK, Cancel, and Help.

## The Main Spectra Concept

Database entries in the MALDI Biotyper 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 library using a superior pattern matching approach which 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.

The screenshot shows the MALDI Biotyper Taxonomy Tree Editor. It displays a project structure with folders for 'Projects (0/271)', 'Fibrous Fungi Consortium (0/44)', and 'Mycobacterium consortium library (227/227)'. Below the tree, there are two tables: 'Unassigned MSPs (0)' and 'MSPs of Mycobacterium consortium library (227)'. The second table has columns for MSP Name, Creation, and Peak List Count.

MSP Name	Creation	Peak List Count
Mycobacteri	10.06.20	21
Mycobacteri	10.06.20	14
Mycobacteri	10.06.20	20
Mycobacteri	10.06.20	24
Mycobacteri	10.06.20	6
Mycobacteri	10.06.20	21

## Continuous Database Expansion and Expert Support

Bruker is fully committed to the future development of the database. An active program of library generation culminates in regular database updates for MALDI Biotyper users. These updates are especially focused in areas of major clinical importance.

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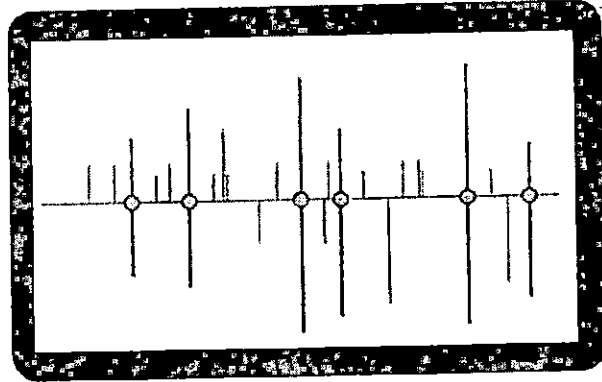




# Rigorous and Sophisticated Data Analysis Assures Accuracy

## Analyzing and Displaying Results

Sample data can be displayed against different reference strains. Sample data is displayed above the axis, while Reference data is displayed below in blue. Perfect matches between the sample data and the reference standard are indicated in green. Differences between the sample and reference are highlighted in red. Light blue indicates peaks found in the reference, but not the sample.



## Result Overview

Sample Name	Organism (with rank)	Score Value	Organism (second best match)	Score Value
Enterococcus faecalis ATCC 29212	Enterococcus faecalis	95.1	Enterococcus faecalis	95.1
Enterococcus faecalis ATCC 29212	Enterococcus faecalis	95.1	Enterococcus faecalis	95.1
Protonotaria sp. ATCC 35061	Protonotaria sp.	95.1	Protonotaria sp.	95.1
Protonotaria sp. ATCC 35061	Protonotaria sp.	95.1	Protonotaria sp.	95.1
Pseudomonas aeruginosa ATCC 27612	Pseudomonas aeruginosa	95.1	Pseudomonas aeruginosa	95.1

Rank (Quality)	Matched Pattern	Score Value	NCBI Identifier
1 (+++)	Pseudomonas aeruginosa ATCC 27612 THL	95.1	287
2 (+++)	Pseudomonas aeruginosa B147_2 CHB	95.1	282
3 (+++)	Pseudomonas aeruginosa DSM 50071T HAM	95.1	282
4 (++)	Pseudomonas aeruginosa ATCC 27833 CHB	95.1	282
5 (++)	Pseudomonas aeruginosa 19955_1 CHB	95.1	282
6 (++)	Pseudomonas aeruginosa A07_01 Padi FLR	95.1	282
7 (+)	Pseudomonas fluorescens LMG 31116T HAM	1.781	128516
8 (-)	Pseudomonas fluorescens DSM 50332T HAM	1.781	53408
9 (-)	Pseudomonas fluorescens DSM 14015T HAM	1.781	132635
10 (-)	Pseudomonas fluorescens LMG 3374T HAM	1.781	23412

## Scoring the Results

The resultant report for each sample shows the top two matches along with their respective matching score. The top ten matches, along with precise information about the closest matching strain, can also be displayed.

## Meaning of Score Values

Range	Description	Symbols	Color
2,300 ... 2,000	Highly probable species identification	(+++)	green
1,000 ... 1,299	Probable species identification	(++)	green
1,700 ... 1,599	probable genus identification	(+)	yellow
0,000 ... 1,499	Species not identified	(-)	red

## Meaning of Consistency Categories (A - C)

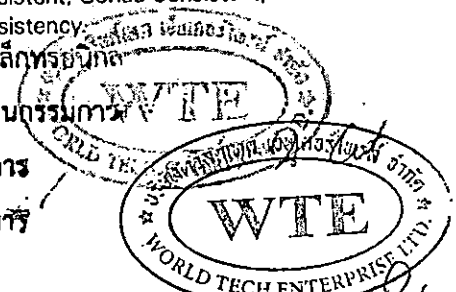
Category	Description
A	Species Consistency: The best match was classified as 'green' (see above). Further 'green' matches are of the same species as the first one. Further 'yellow' matches are at least of the same genus as the first one.
B	Genus Consistency: The best match was classified as 'green' or 'yellow' (see above). Further 'green' or 'yellow' matches have at least the same genus as the first one. The conditions of species consistency are not fulfilled.
C	No Consistency: Neither species nor genus consistency (Please check for synonyms of names or microbial mixture).

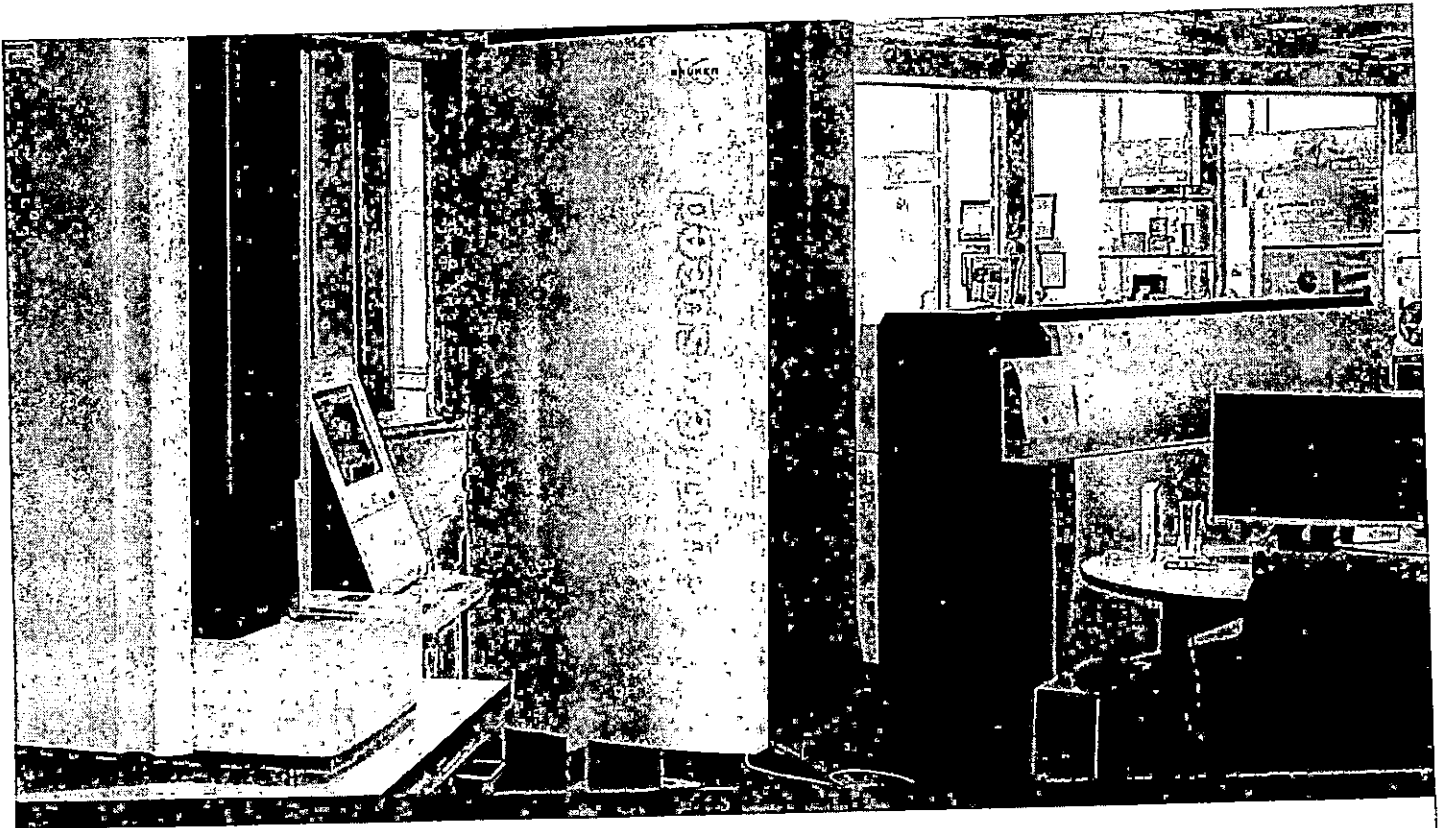
## Grading the Results

In addition to the score, the sample match result is also given a Consistency Category. This data parameter gives a indication of the degree of consistency. The categories are rated as Species Consistent, Genus Consistent, or No Consistency.

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## The Best Technology from The Market Leader in MALDI-TOF

### Bruker's FLEX™ Series of MALDI-TOF Instruments

The MALDI Biotyper is based on the well proven, industry leading FLEX Series of MALDI-TOF MS instruments.

These systems are designed as robust, compact, high performance platforms intended for extensive and routine usage.

Many features of these outstanding systems have been incorporated into the MALDI Biotyper to enhance performance, simplify operation, and extend system lifetime and utility.

#### ■ A True Bench Top System

A smart compact design that packs a punch. Employs the same high end electronics and developments from its big brothers.

#### ■ Silent and Pleasant Operation

With WhisperMode™ you really have a system that can sit on 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 can benefit from having the same high performance technology as large research grade instruments.

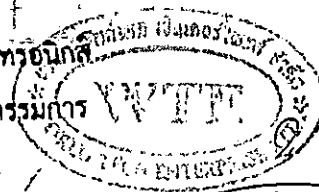
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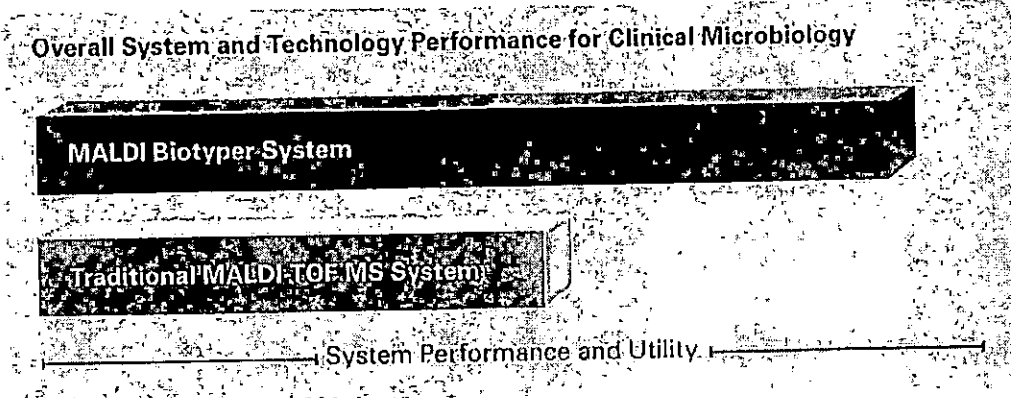
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# Size Doesn't Equal Performance



## 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.

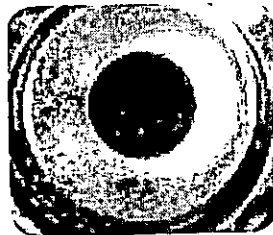
## Maximize Laboratory Productivity and Return on Investment

### Self Cleaning Source

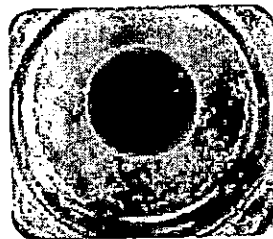
The Perpetual™ Ion Source\* is a unique, automated self cleaning instrument source. This technology enables routine maintenance of the system to insure peak performance in less than 15 minutes without the costly and time consuming need to break system vacuum.

3.2.3

\*Patent pending



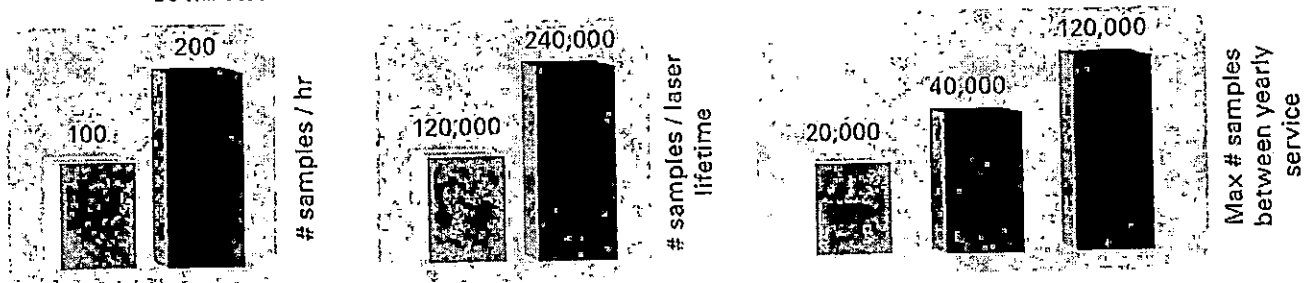
Before Cleaning



After Cleaning

### SmartSpectra™ Acquisition

This capability accelerates data acquisition speed by minimizing the time and amount of sample needed to generate a signal. Typically, 96 samples can be fully analyzed in well under 30 minutes.



Traditional MALDI-TOF MS

MBT + SmartSpectra

Traditional MALDI-TOF MS

MBT + SmartSpectra

Traditional MALDI-TOF MS

MBT + SmartSpectra

MBT + SmartSpectra + Self-Cleaning Source

คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ  
 ๒.ลงชื่อ.....กรรมการ  
 ๓.ลงชื่อ.....กรรมการ

