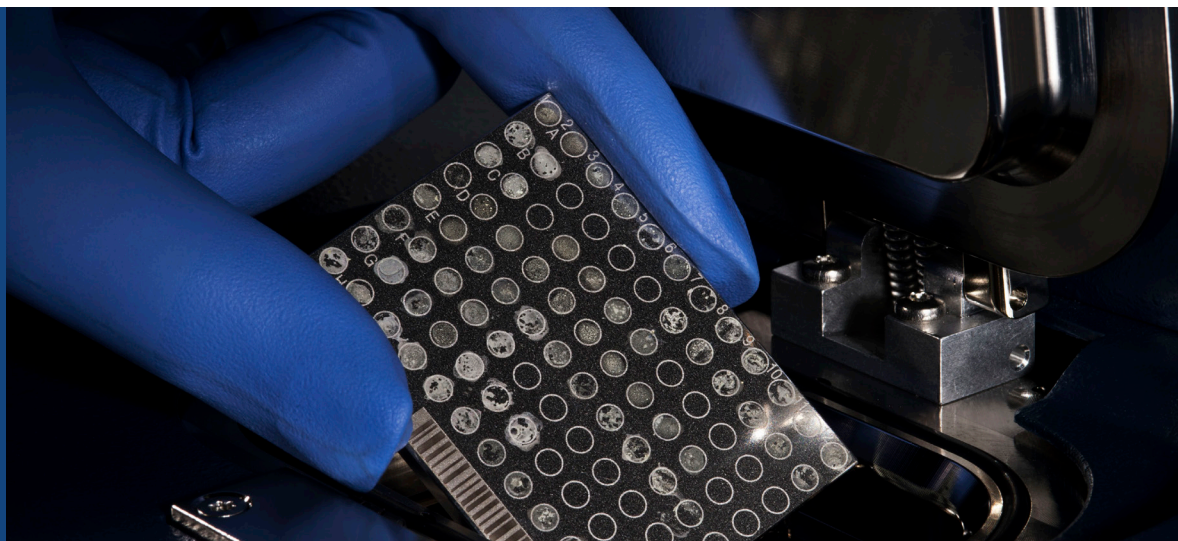


## Summary

Powered by the validated, industry-relevant Accugenix® proprietary libraries, the Axxess® System's MALDI-TOF technology generates rapid, accurate and reliable microbial identification information.



MICROBIAL SOLUTIONS

# Axxess® System IT Configurations and Security

## Access® System IT Configuration

The Charles River Axxess® System combines the precision of MALDI-TOF technology with the industry-leading Accugenix® proprietary microbial libraries over a secure online network. This document serves as a reference guide for clients wanting basic details on the IT specifications, configuration and data flow for the system.

The preferred installation set-up is to use the computer system provided by Bruker, HP z420, as the workstation. The computer delivered to the customer comes as a functional, approved and validated system, which guarantees that the system will work as intended after the installation.

## Why is the Bruker PC preferred?

The PC is a special production from HP® that has more RAM, additional fans, and comes equipped with a video-grabber and a digitizer exclusively produced for Bruker. This configuration, along with all device drivers, is tested and validated together with the control and the MBT software. Bruker has over 10 years of experience using HP® and Microsoft® software, along with their own software suite of products.



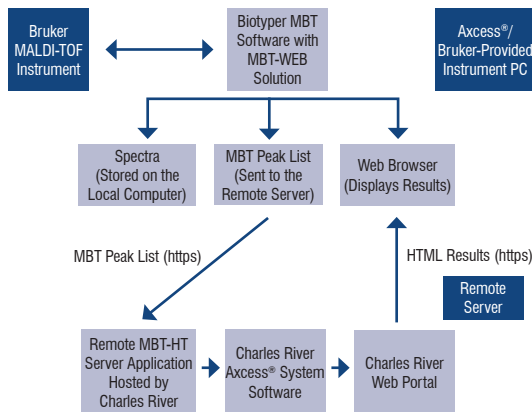
EVERY STEP OF THE WAY

## Installation

There are two standard installation configurations. These are described below, showing the basic data communication paths.

### Basic Installation

This is the basic recommended installation configuration, utilizing one computer attached to the Biotyper instrument. This computer comes with the purchase of the MALDI-TOF instrument.



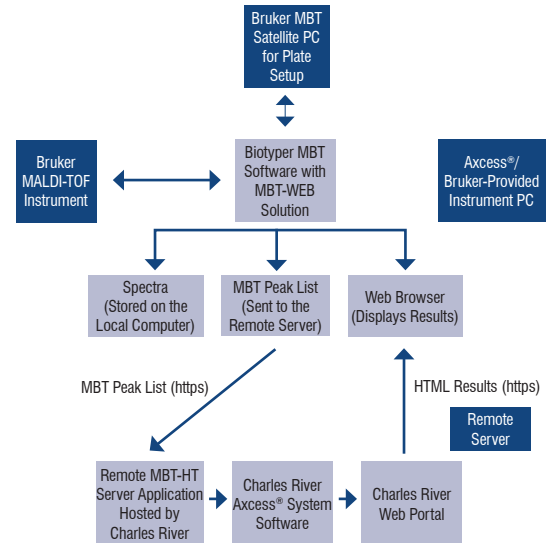
### PC Specifications (for both computers)

- CPU: Dual-core processor; e.g., Intel® Core™ or Intel® Xeon®
- Hard disk: At least 1 GB of free disk space
- Main memory: 16 GB RAM
- Operating system: Windows® 7 Professional with the latest Service Packs
- Graphic resolution: 1024 x 768 pixels, 256 colors or better (e.g., 1650 x 1080 with true colors)
- CD-ROM/DVD drive (only for installation)
- Microsoft.NET Framework 3.5 (will be installed at installation if not found on computer)
- Internet connection with up-to-date browser

### Optional Remote Satellite Installation

This option may be employed in a situation when a customer wants to set up a satellite laboratory for sample preparation and loading of the target plates, networked to the central laboratory where the actual MALDI-TOF identifications are performed (using the basic installation).

Note: The customer can supply the computer for the satellite laboratory, but it must meet the PC requirements outlined on the next page.



### Software Specifications

- The instrument PC comes with software pre-installed by Bruker. This is the MALDI Biotyper suite of applications – flexControl, RTC, Biotyper Server, etc.
- The optional remote/satellite PC needs to have the MBT-Satellite (RTC) software installed for remote target plate creation.

### Internet Connection

- Speed: Minimum of 1.5 Mbps
- Wi-Fi Option: Can be used, provided it is properly configured to meet internal security measures and established company policies with respect to data security, similar to a wired client connection.

### Alternatives for Satellite Laboratory PC Connection

- Recommended: On-site LAN network direct connection (http/https) – Minimum of 1 Mbps
- If the remote satellite PC and the MALDI PC are not connected by a network, Bruker offers the use of the MBT-Satellite software in “Offline” mode. In this scenario, the customer creates the plate and exports the file on the remote/satellite PC. This export text file is then sent (via email, CD, USB stick, etc.) to the MALDI PC and imported at the time of the run.

### Data Security

The Access® System is designed with data security and confidentiality considerations in mind. A general summary of the IT security pieces we have in place to protect our customers and their data is described below. If more details are required, we can have our IT staff address concerns in further detail.

### Data Security and Backup

In the course of Access® System operation, the client’s original source data (spectra) are never sent to the Charles River remote host. We do not receive these data and therefore cannot back them up and/or store them on the client’s behalf. It is important that clients protect the spectra produced both for calibrations and samples by assigning appropriate permissions to the folders that store spectra, thereby inhibiting unauthorized access to these files through the file system. It is also very important that clients back up the folders containing calibration and sample spectra on a routine basis. By securing and storing the original source data (the spectra), they will always have the original source data used to prepare their Access® System reports.

### Data Transmitted to the Remote Host

Spectra for the samples are not transmitted to our remote host. A condensed form of the spectra known as a MALDI Biotyper (MBT) Peak List is transferred to the remote host for processing. The MBT Peak List data retain all information that is pertinent to classification (library identification), providing everything necessary to produce a classification report. Along with the Peak List, the following information is sent to our server:


- Unique Serial Number of the client’s Bruker MALDI-TOF instrument, which is associated with the customer account name
- Operator ID – the name of the authenticated MBT operator who initiated the sample run
- Date and Time of the sample run
- For sample tracking integrity – the Target Plate Identification Number, Well Position, and Customer Sample ID (the text from the ID column of the Real-Time Classification Client Sample Definition table)

Access® System Identification Reports are made secure and confidential on the Charles River remote server in compliance with FDA 21 CFR Part 11. Charles River stores these report files (PDF) on permanent storage media for a minimum retention period of seven years, in compliance with FDA retention guidelines.

## Access® System Reports Traceability

Our reports meet the industry compliance requirements for traceability. Each report contains the authenticated user/operator running the samples, the target plate identifier (usually a bar-coded number), the serial number of the instrument, the unique customer-specified name (Project Name) of the run, and a unique identifier (UUID) that links the IRF to the sample run.

The figure below is an example of the Access® System Report.

	223 Lake Drive Newark, DE 19702 Phone +1.302.292.8888 FAX +1.302.292.8468 www.criver.com/accugenix	<b>Accugenix® access® Report</b>	
Customer:	<b>Valued Customer</b>	Account:	<b>999999 (ACC2)</b>
Address:	<b>1313 Mockingbird LN, Newark, DE, 19702</b>	ID Request Form#:	<b>876543</b>
Accugenix C#:	<b>C9876789 - 20160620999</b>	Due Date:	<b>2016-06-20</b>
Customer Sample ID:	<b>Sample ABC</b>		

Identification: **Oceanobacillus kimchii**  
 Confidence Level: **Species**

Quality	Top Species Match(es) for Organism	Score	Run Date/Time
+++	Oceanobacillus kimchii	2.176	2016-06-20 10:10:10
-	Oceanobacillus iheyensis	1.628	2016-06-20 10:10:10

Rank (Quality)	Top Ten Matched Patterns	Score	NCBI ID
1 ( +++)	Oceanobacillus kimchii ACC 1459282 ext ACC	2.176	<a href="#">746691</a>
2 ( +++)	Oceanobacillus kimchii ACC 1243723 ext ACC	1.948	<a href="#">746691</a>
3 ( - )	Oceanobacillus iheyensis ACC 1103202 ext ACC	1.628	<a href="#">182710</a>
4 ( - )	Oceanobacillus profundus ACC 1243722 ext ACC	1.610	<a href="#">372463</a>
5 ( - )	Oceanobacillus polygona ACC 2077627 ext ACC	1.556	<a href="#">1235259</a>
6 ( - )	Oceanobacillus iheyensis ACC 1426040 ext ACC	1.520	<a href="#">182710</a>
7 ( - )	Agromyces mediolanus DSM 20152T DSM	1.389	<a href="#">41986</a>
8 ( - )	Oceanobacillus oncorhynchi ACC 1475228 ext ACC	1.359	<a href="#">545501</a>
9 ( - )	Ornithinibacillus bavariensis ACC 1315428 ext ACC	1.305	<a href="#">545502</a>
10 ( - )	Corynebacterium sp 901600604 LBK	1.292	<a href="#">1716</a>

#### Meaning of Score Values

Range	Description	Symbols	Color
1.75 ... 3.000	probable species identification	( +++)	green
0.0 ... 1.749	not a reliable species identification	( - )	red

Not intended for in vitro diagnostic use.

Operator ID:	<b>cri-labtech</b>
Target Plate ID:	<b>10137256</b>
Instrument ID:	<b>264320.00390</b>
Project Name:	<b>160620-1010-035831</b>
Project UUID:	<b>b54c8251-bffc-0df9-367a-e65dfd602341</b>