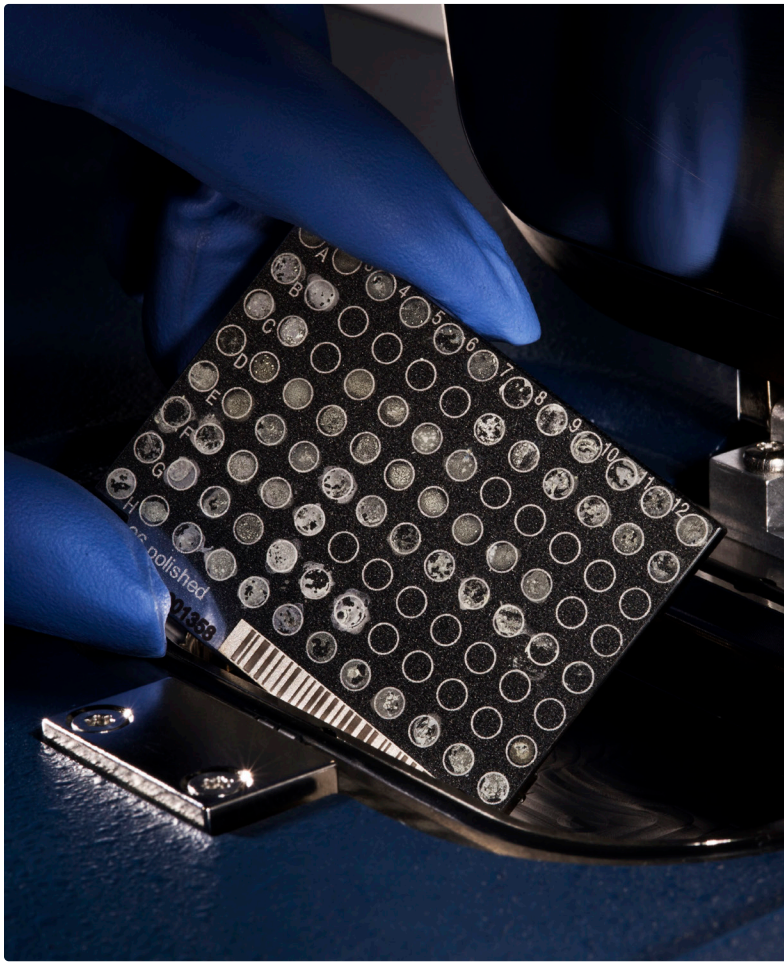
QC Microbial Solutions

charles river

Accugenix® Axcess® MALDI-TOF Microbial Identification System



Explore this solution in-depth

Visit criver.com/axcess →

The Axcess® System combines the precision of MALDI-TOF technology with the industry-leading Accugenix® proprietary microbial libraries and reporting over a secure online network.

Sirius One Model

Sirius Model

The Axcess® Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) System is designed for microbial identification testing in pharmaceutical, medical device, and consumer care industries. The proprietary MALDI database is optimized for environmental monitoring (EM) in product manufacturing facilities as opposed to clinical applications.

While conventional identification takes time-consuming incubation and ancillary precursory tests, the Axcess® System allows for instantaneous identification of isolated colonies from a plate. The delivery of rapid identification of unknown microorganisms in just minutes enables users to confirm the quality of their product and quickly respond to potential contamination events in the production facility.

Axcess® MALDI-TOF System Advantages

Bruker MALDI-TOF Instrument with Biotyper Software: Automated self-cleaning, silent bench-top system with enhanced peak resolution, sensitivity, and performance.

Accugenix® MALDI-TOF Reference Library: The largest curated and validated database focused on identification of microorganisms in aseptic and non-sterile manufacturing environments. Our validated Accugenix® microbial identification databases are continuously updated to reflect the ever-evolving microbial world, where taxonomic changes and new species are described daily.

Accugenix® MALDI-TOF Identification Reports: Clear ID interpretation allows you to make confident operational decisions.

No-Match Sample Guarantee: Complimentary AccuGENX-ID® service to test samples that fail to yield a successful species identification.

Method Validation: Our method validation, derived from USP <1113>, is an integral process used to establish that the Axcess® system works as intended and performs according to specifications.

Fungal Samples: Axcess customers can perform fungal sample identification using Conidia IDFP agar plates. Samples that do not generate an identification can be sent to one of our Accugenix laboratories using our AccuGENX-ID® FunITS fungal sequencing service. Samples should be sent on Conidia plates, but can be sent on other media for an additional cost.

Backup Identification Service: In the remote chance that your MALDI-TOF instrument goes down and requires service, you can send your samples to Accugenix for identification at a very low rate while using the same methodology and database.

Security: Our IT approach is purposely designed with multiple redundancies to protect your data and to ensure continuity of service 24/7.

Tracking & Trending and AccuPedia™: The Accugenix Customer Web Portal makes it easy to get a glimpse of your environmental control data, past and present. Filterable reports help you note significant changes in microbial flora when investigating excursions or conducting root cause determinations. The AccuPedia™ microbial characteristic database is a key reference tool designed to help you understand the impact of your facility's microflora.

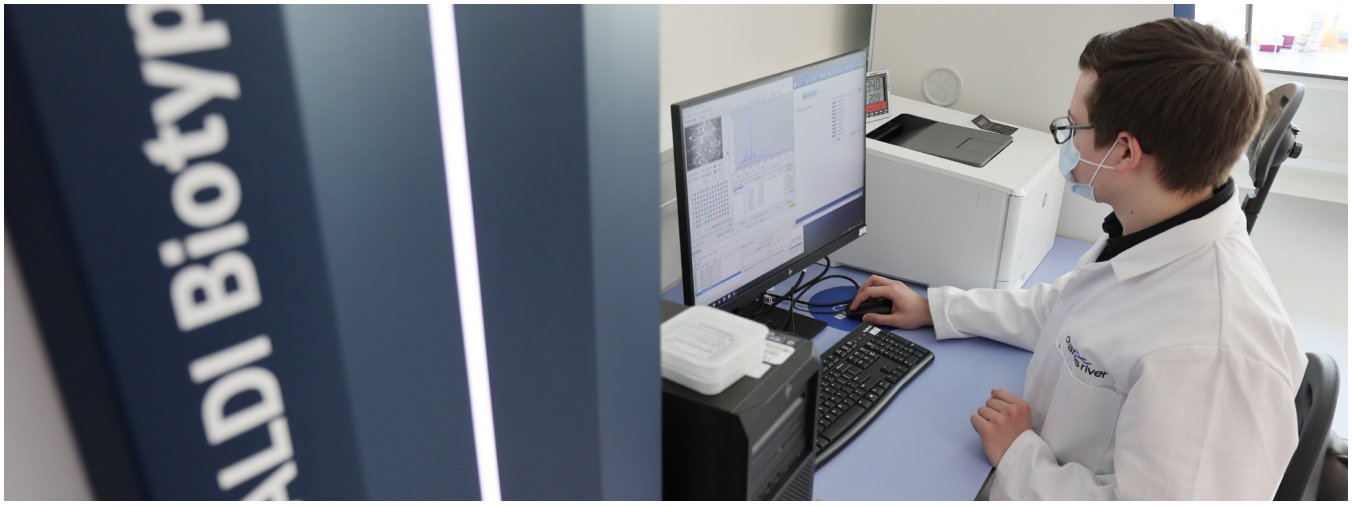
System Throughput: Workflow analysis has shown that four target plates containing 96 spots each can yield results in 60 minutes (15 minutes/target plate), compared to competitive MALDI-TOF systems that can take up to 180 minutes for the same workload or phenotypic systems that can take up to 18 hours of incubation time for biochemical reactions to occur.

Axcess® System Site Preparation Guide

The following are equipment and consumables that will be needed to use the Axcess System, but are NOT included with its purchase. It is recommended that users have these items in place prior to installing the Axcess System.

Material Not Provided		
Required	**Equipment**	Chemical fume hood or ventilated enclosure
		Incubator(s)
		-20 °C freezer
		4 °C refrigerator
		Microcentrifuge
		Vortexer
		Sonicator (depending on target cleaning method)
		Three single-channel pipettes (1-10 µL, 20-200 µL, and 100-1,000 µL)[1]
		General lab equipment (e.g., beaker, bottles, microcentrifuge tube rack, glass dishes)
		MALDI-TOF target plates (steel or disposable)
	Consumables	Matrix
		Bacterial test standard
		Chemicals (e.g., water, acetonitrile, trifluoroacetic acid, ethanol, methanol, formic acid)
		General microbiology supplies (e.g., growth media, biohazard bags, gloves, microcentrifuge tubes, inoculation loops, Kimwipes®, swabs, pipette tips)
Recommended/Optional		Biosafety cabinet
		Uninterruptible power supply

[1] Note: Three Eppendorf® pipettes are included when a MALDI-TOF instrument is purchased as part of the Axcess® System.



A major component of the Axcess MALDI-TOF System is the benchtop mass spectrometer. Please be aware of the following specifications that must be accommodated in order to properly install and utilize this equipment.

Instrument Specifications

Packaged Instrument	**Size (D x W x H)**	Depth: 31 in (787 mm) Width: 47 in (1194 mm) Height: 55 in (1397 mm)
	Weight	335 lbs (151.9 kg)
Instrument	**Size (D x W x H)**	Depth: 28 in (711 mm) Width: 20 in (508 mm) Height: 42 in (1067 mm)
	Weight	165.4 lb (75 kg)
Clearances	**Instrument**	Left and Right: 20 in (508 mm) Behind: 8 in (203 mm) Total Depth: 36 in (914 mm)
	Bruker Instrument Controller	Additional 40 in (1,016 mm) required next to the instrument to house the Bruker instrument controller
Environment	**Operating Temperature**	61-86 °F (16-30 °C) with temperature variations at less than 3 °C/hr, and where analytical specifications are met at 64-76 °F (18-24 °C)
	Operating Humidity	20-75% non-condensing at +86° F (+30 °C)
	Maximum Altitude	6,600 ft (2,000 m)
Power	**Usage**	Up to 400 W (1,364 BTU/hr), plus any power dissipated by the associated Bruker
	Supply	Requires an input of 204 VAC to 230 VAC (50/60 Hz) and must be powered with either: • 110 VAC in North America • 230 VAC or 240 VAC in Europe and Australia
Internet	**Connectivity**	Requires an internet connection Minimum Speed: 1.5 Mbps (T1), Recommended Speed: 10 Mbps[1]

[1] Internet bandwidth/speed may affect the response time of the Axcess® System, particularly the time required for report generation.

Description of Service Agreements for the Axcess® MALDI-TOF System

The annual service agreement consists of the following features. Annual service provides the optimum performance of the instrument and is serviced by Bruker. Please confirm if these service agreements and features are available in your location.

Coverage	Std. Warranty	Warranty plus CARE, AXC700	Complete CARE, AXC900	Complete CARE Priority, AXC1000	Complete CARE Priority Plus, AXC1100
Parts (excludes consumables)	Parts	Parts	Parts	Parts	Parts
On-Site Response Time[1]	None	1 business day	Avg. 3 business days	2 business days	1 business day
Emergency Visits	Unlimited	Unlimited	Unlimited	Unlimited	Unlimited
PM Visits[2]	None	1 cleaning, if necessary	1 PM	1 PM	1 PM
Depot Unit Dispatch[3]	No	Yes	No	No	Yes
Compass flexControl/ flexAnalysis[4] **(all upgrades)**	Included	Included	Included	Included	Included
MBT Software Requiring New License (MBT Compass Explorer)	Included	Included	Included	Included	Included
Hotline Access[5]	Included	Included	Included	Included	Included
9:00 a.m.– 9:00 p.m. ET Weekdays, Weekends and Holidays	Included	Included	Included	Included	Included
Saturday On-Site Support	No	Yes	No	No	Yes
Instrument Controller Coverage Including Monitor/Printer	Yes	Yes	No	No	Yes
Annual OQ/PV[6] **with Contract Add**	N/A	N/A	Inquire	Inquire	Inquire

General Notes:

1. Response time calculation does not include weekends or holidays, and begins after the determination via remote WebEx diagnostics that an on-site response is required. Remote diagnostics via WebEx link (VPN connection) REQUIRED.
2. Cleaning and PM visits require 12-24 hours of downtime, and will be scheduled at mutually agreeable times. Includes one additional PM or cleaning if necessary and diagnosed by a Bruker remote support engineer.
3. Depot Unit Dispatch (microflex™): In the event a required repair would require over three business days of downtime, a microflex™ unit can be sent out overnight. The customer unit would be swapped out for the dispatched unit and test processing can continue until the customer unit is fixed (on-site or at the factory).
4. FA/FC/Compass is the flexAnalysis and flexControl software for mass spectrometer control. The MBT Compass and Explorer software is used for setting up identification runs and doing more detailed analysis of results for microbial identification. No-charge upgrades are included only as long as they are compatible with the customer's existing hardware; if hardware or instrument upgrades are required for a software upgrade, such hardware or instrument upgrades are not included.
5. MALDI Biotyper Hotline: (877) 410-2211, access code 724.
6. Only available for systems for which IQ and OQ/PV was included with the initial purchase. Note that some routine operations such as cleaning, adjustment of the laser power or detector voltage, or adjustment of the pulsed ion extraction (PIE) voltage are considered routine adjustments and do not require performance of a full OQ/PV, just a simple check of performance with the Bacterial Test Standard (BTS) used for calibration and validation.
7. All service activities are performed by Bruker Daltonics GmbH & Co. KG or their certified service provider.

General Note on Warranty:

Instrument is under warranty during the first year of installation. The standard warranty included with instrument purchase does not include any response time guarantees or cleaning visits. The standard warranty can be upgraded to include response time guarantees and service by upgrading to any of the warranty packages noted above. Please contact your account specialist for details.

Final MSA terms and conditions will be quoted prior to purchase, and the terms and conditions in this document are for informational purposes only and subject to change at any time.

Axcess® MALDI-TOF System

Product Line	Product	Code
Axcess® MALDI-TOF System	**Axcess® sirius one MALDI Biotyper package** 1-year warranty Starter kit of reagents for MALDI-TOF MS Barcode scanner for MALDI Biotyper Reference physiocare pack (tips and pipettes) Software package MALDI Biotyper Compass HT Compliance Assistance Module for data integrity	AXC750
	Axcess® sirius MALDI Biotyper package The sirius package includes all the features and accessories as the Axcess® sirius one MALDI Biotyper package, with the added benefit of both positive and negative ion mode for microbial identifications and future applications.	AXC850
Axcess® MALDI Biotyper-CM Reagents	Bacterial test standard (BTS)	AXC115
	Matrix HCCA	AXC155
	Conidia IDFP fungi agar plates, 20-pack	AXC320
	MSP 96 steel target plate	AXC9605
	MSP adapter for MALDI Biotarget	AXC4800AD
	MALDI Biotarget 96 disposable target plate 20/pk	AXC9600D
Axcess® Plans	**Axcess® Startup Package** The Axcess® Startup Package is available with the initial Axcess® instrument purchase. It includes the Bruker IQ/OQ/PQ, Charles River SQ/MV, and Axcess® authorization and licensing fee for one year. *The Startup package begins when the Axcess® Complete Validation is completed and runs for 1 year. A renewal contract will be issued at the end of the Startup Package.	AXC8000
	OR	
	Axcess® Premium Plan The charge applies to samples run by the customer which result in an identification. All samples ran at Accugenix® under the No Match Sample Guarantee will be charged the classification fee.	AXCESS-10
	*Contact your Account Specialist to review coverage for each service package.	

Request more information about Axcess® on criver.com/axcess. Contact us for personalized help.

criver.com/contact-us | askcharlesriver@crl.com

charles river