



MICROBIAL SOLUTIONS

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## Accugenix<sup>®</sup> Microbial Identification & Strain Typing Services

Charles River's Accugenix<sup>®</sup> microbial ID and strain typing services offer unparalleled accuracy with the most relevant reference libraries of bacteria, filamentous fungi, and yeasts. We've driven the development and adoption of the most progressive technologies to improve our clients' environmental monitoring, reduce their costs, and protect their brands. Our flexible solutions allow clients to outsource to our experts or use our services in-house.

### Areas of Expertise Include:

- Accugenix<sup>®</sup> Libraries
- AccuBLAST<sup>®</sup> Sequencing Data Analysis
- Tracking and Trending Data Management
- AccuGENX-ID<sup>®</sup> Microbial Sequencing
- Access<sup>®</sup> MALDI-TOF System
- AccuPedia<sup>™</sup> Database
- AccuPRO-ID<sup>®</sup> MALDI-TOF Identification
- AccuGENX-ST<sup>®</sup> Strain Typing

### Why Is Accuracy So Important?

Accurate identification of environmental isolates improves reporting capabilities, facilitating full investigation of root causes for contamination and informed decision-making. With accurate data, it is possible to fully understand issues that arise and develop an appropriate plan to reduce production recovery time and minimize the impact to the supply chain cycle.

### The Charles River Difference

Charles River Laboratories has invested in the technology, instrumentation, and expertise to conquer genotypic- and proteotypic-based testing methods, process validation, cGMP compliance, and other rigorous regulatory standards at the global level. With a focus on building relationships and delivering the highest quality service, our team of scientists and technical experts can accelerate our clients' transition to more sophisticated microbial identification solutions and simplify business practices to support compliance initiatives, all at affordable pricing.

EVERY STEP OF THE WAY

Partnering with Charles River can help:

- Decrease the cost per reportable result while increasing accuracy of identifications
- Improve operational efficiencies while reducing compliance risk
- Offset the capital investment costs of upgrading technologies with our contract laboratory services
- Streamline environmental monitoring processes through innovative data management applications
- Protect brands, and more importantly, consumers or patients, while improving micro QC program quality

### **The Accugenix® Libraries**

The industry's most comprehensive and up-to-date databases for environmental isolates, our Accugenix® reference libraries contain more than 14,000 entries for bacteria, filamentous fungi, yeast, and other relevant isolates found in today's manufacturing environments. As we continue to partner with clients to identify unknown samples, our databases continue to grow, making Accugenix® unmatched for breadth and accuracy.

### **AccuGENX-ID® Microbial Sequencing**

Comparative DNA sequencing of the 16S rRNA gene in bacteria and the ITS2 rRNA region in fungi is recognized across the industry as the most accurate and reproducible method for identifying unknown microorganisms. AccuGENX-ID® utilizes this technology through our BacSeq identification for bacteria and FunITS identification for fungi. Our sequencing technique is independent of the health or growth conditions of the isolate; samples can be viable or nonviable cultures or simply genomic DNA from a microbe. For each sample submitted for identification, the resulting DNA sequence is compared against our validated libraries for bacteria and fungi.

AccuGENX-ID® is the ideal solution for aseptic-filled products, cleanrooms, bioburden, and contamination investigations, achieving maximum accuracy with minimum hassle and delivering rapid and reproducible results in as little as six hours.

### **AccuPRO-ID® MALDI-TOF Microbial Identification**

AccuPRO-ID® MALDI-TOF service offers a first-in-industry polyphasic approach to microbial identification. As the earliest contract laboratory to adopt MALDI-TOF technology for identification of bacteria, we offer an industry-leading MALDI-TOF library that is focused on bacteria, filamentous fungi, and yeast relevant to production environments. This extensive library is backed up by our AccuGENX-ID® 16S and ITS2 rDNA sequencing method at no additional cost.

Providing higher accuracy rates and faster results, AccuPRO-ID® MALDI-TOF service is a less expensive option for environmental monitoring programs. The service is far superior to antiquated biochemical identification systems as it offers greater accuracy compared to phenotypic results.

### **AccuBLAST® Sequencing Data Analysis**

Our AccuBLAST® service is designed exclusively for customers who have purchased the MicroSEQ® identification system and are not confident in the identifications made by the automated system. The AccuBLAST® service employs our own unrivaled sequence libraries and expert data analysis to generate meaningful reports, allowing us to deliver IDs more quickly and accurately.

## **Tracking and Trending Data Management**

Complementing our Accugenix® solutions, is our value-added tracking and trending data management software. This innovative tool generates the sophisticated reports you need to drive decision making, allowing you to address issues, prove 21 CFR Part 11 compliance, and strengthen your overall environmental monitoring program.

## **AccuPedia™ Database**

Located within Tracking & Trending, AccuPedia™ provides an informational database of microorganisms and their characteristics that provides valuable insight into your flora. This key reference tool provides a deeper understanding of organisms to assist with risk assessments, finding root cause, and confident operational decisions from investigations to product release.

## **Strain Typing with AccuGENX-ST®**

In production facilities, it is often necessary to determine the source of a contamination, ascertain if a certain production strain is the correct one, or establish the “normal” flora for the facility. Our strain typing service makes it possible to reliably track and trend some of the most difficult microorganisms encountered in aseptic and non-sterile production facilities. AccuGENX-ST®, a cGMP service for single- or multilocus sequence typing, combined with the accuracy of our AccuGENX-ID® rDNA genotypic identification, solves these issues.

## **The Axxess® MALDI-TOF System**

The Axxess® MALDI-TOF System features the precision of the Bruker MALDI Biotyper instrument with the industry-leading Accugenix® proprietary microbial libraries and reporting through a secure online network. Based on MALDI-TOF mass spectrometry, the MALDI Biotyper has become widely accepted across industry segments as the next generation of microbial identification. While conventional biochemical identification requires time-consuming incubation and ancillary precursory tests, the Axxess® system allows for instantaneous identification of isolated colonies from a plate. Any samples not identified can always be sent to our facilities for identification at no additional cost. The Axxess® solution includes all the Accugenix® library updates and curation, our secure online Tracking and Trending data management reports, backup identification services if the instrument requires service, and ongoing customer training and support.

## Accugenix® Microbial Identification Services

Product Line	Product	Turnaround Time	Code	
AccuGENX-ID®	AccuGENX-ID® bacteria (16S 500bp)	Same day	BacSeq-0	
		1 day	BacSeq-1	
		2 day	BacSeq-2	
		5 day	BacSeq-5	
	AccuGENX-ID® fungi (ITS2)	Same day	FunITS-0	
		1 day	FunITS-1	
		2 day	FunITS-2	
		5 day	FunITS-5	
	AccuGENX-ID® ProSeq	1 day	PROSEQ-1	
		5 day	PROSEQ-5	
	AccuPRO-ID®	AccuPRO-ID® bacteria and yeast	Same day	AccuPRO-ID-0
			1 day	AccuPRO-ID-1
2 day			AccuPRO-ID-2	
5 day			AccuPRO-ID-5	
AccuPRO-ID® filamentous fungi		5 day	AccuFUN-ID-5	
AccuBLAST®	AccuBLAST® analysis of 16S raw data sequence files	Same day	AccuBLAST-0	
		1 day	AccuBLAST-1	
		2 day	AccuBLAST-2	
AccuGENX-ST®	AccuGENX-ST® sequence-based strain typing	5 day	AccuGENX-ST-5	
	AccuGENX-XGST® multi-locus sequence-based strain typing	5 day	AccuGENX-XGST-5	
Access® MALDI-TOF System	<b>Access® sirius one MALDI Biotyper package</b> Access® Sirius one MALDI Biotyper package Starter kit for MALDI-TOF MS Barcode scanner for MALDI Biotyper Reference physiocare pack (tips and pipettes) Software package MALDI Biotyper Compass HT Compliance Assistance Module		AXC750	
	<b>Access® sirius MALDI Biotyper package</b> The sirius package includes all the features and accessories as the Access® sirius one MALDI Biotyper package, with the added benefit of both positive and negative ion mode for microbial identifications and future applications.		AXC850	
	<b>Access® Startup Package</b> The Access® Startup Package is available with the initial Access® instrument purchase. It includes the Bruker IQ/OQ/PQ, Charles River SQ/MV, and Access® authorization and licensing fee for one year.		AXC8000	
	<b>Conidia IDFP fungi agar plates, 20 pack</b>		AXC320	