



Mastering Microbial Identification with Accugenix®

**A blueprint for
control, confidence,
and compliance**

Pioneering Excellence

for over 35 years

Foreword by Beth Burke, Sr. Director of Laboratory Development, Delaware, US

It's been over three decades of building the Accugenix® service portfolio in a tightly regulated environment, which made it possible to become a world leader in microbial identification. The founder's vision for the privately owned company in 1990 was to supply the most accurate, reliable, and reproducible microbial identifications for sterile and non-sterile product manufacturing companies.

The passion for never-ending optimization and betterment paved the way to grow into a large corporation with **9 globally harmonized laboratories**.

Our unique laboratory process optimization strategy transformed us into a provider with the fastest turnaround times for microbial identification, resulting in **620,000 samples being processed yearly for over 6,000 clients**.

The backbone of our microbial identification technology is the large, curated, industry leading organism libraries. These libraries contain over **17,300 MALDI and 14,600 sequencing entries** based on samples currently being recovered in pharmaceutical and home and personal care facilities globally.

We love inviting customers to tour our Accugenix facilities around the world so that they can truly feel the welcoming atmosphere and how we have thoughtfully designed our labs around workflow

and precision. The expertise and customer centricity of our people at Accugenix is what strengthens our relationship with our clients daily and helps us ensure our clients overcome challenging times in the industry.

I'm incredibly proud to work with such a talented group of people to develop market leading solutions for you to keep up with increasing demands for testing, and excited to showcase our end-to-end service offerings that contribute to the development of tomorrow's ground-breaking drugs and therapies.

Perfected for Routine Use

MALDI-TOF: The most cost-effective proteotypic method testing service for fast, reliable results

Environmental stress on microorganisms can create a high degree of phenotypic variability, and microbial identification methods that rely on phenotypic characteristics often provide inaccurate and inconsistent identifications. These methods are now considered antiquated and inefficient in today's regulated environments. Modern proteotypic methods set the new standard for reliability and repeatability by using molecular protein signatures from bacteria and fungi.



Services

MALDI-TOF Microbial Identification for Bacteria and Yeast with **AccuPRO-ID[®]**

MALDI-TOF Microbial Identification for Filamentous Fungi with **AccuFUN-ID[®]**





Accugenix leverages Matrix-Assisted Laser Desorption/Ionization Time-Of-Flight Mass Spectrometry (MALDI-TOF MS) to provide fast, reliable, and cost-effective microbial identification, ideal for those still using phenotypic methods or requiring routine identification.

The AccuPRO-ID® MALDI-TOF service compares unique protein spectral fingerprints of organisms to the validated Accugenix MALDI database.

Our comprehensive, validated, and frequently updated organism database with **over 17,300 entries** - representing over **5,900 species** - supports robust species-level bacterial and fungal identification.



Cost-Efficient Advantage

Reduce time, labor, and internal costs by outsourcing



Seamless Workflow

A streamlined process to eliminate complex assay steps



Extensive Microbial Library

Identify a wide range of microorganisms in environmental monitoring samples



Enhanced Regulatory Compliance

cGMP compliant and ISO 17025-accredited processes



Superior Performance

Outperform your existing phenotypic method



Improved Accuracy

Industry-leading proteotypic species-level ID rate



Backed with DNA Sequencing Technology

Samples not identified with AccuPRO-ID are sequenced free of charge



Conidia ID Plates for Filamentous Fungi

Designed for higher ID rates with faster mold growth that's easy to harvest



Axcess[®] the Power of Our Library In-House

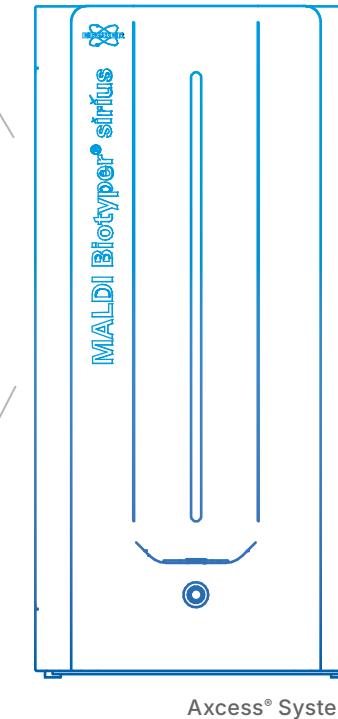
Speed and convenience at your fingertips

Gain complete control and make faster, more confident operational decisions while optimizing efficiency and minimizing unexpected costs, especially for high-throughput labs that demand seamless, delay-free manufacturing.

The Axcess[®] Microbial Identification System maximizes the precision of the Bruker MALDI Biotyper by combining it with our extensive Accugenix library to create a platform with unmatched speed, accuracy, and most importantly, the capability to identify a wide range of industry organisms.

Trusted Technology with a Twist

Leverage an easy-to-use benchtop MALDI system, requiring no more than a single colony to obtain a species-level ID



Best-in-Class Database

The largest industry-sourced MALDI-TOF microbial database, curated using manufacturing facility isolates from around the world

Rapid Results. Simple Prep.

Run up to 96 samples in just 15 minutes, compared to 18+ hours required by most phenotypic and PCR systems

Data Security and Insights
Gain peace of mind with encrypted sample data and LIMS integration. Curate and customize via Tracking and Trending reports in our Customer Web Portal

No Match? No Problem.

In the off chance your isolate isn't in our library, send it to us for complimentary AccuGENX-ID[®] sequencing service

Unveil the Unknown Through Sequencing

Superior-resolution microbial identification through DNA Sequencing

Beyond routine identification, Sanger sequencing technology provides species-level accuracy from the start. AccuGENX-ID is ideal for critical processes, regulated environments, and microbial investigations, where accuracy and informed decisions are non-negotiable.

Species-level ID for your most critical needs

Ensured microbial identification accuracy

of bacteria by using the 16S ribosomal RNA (rRNA) gene and of fungi with the Internal Transcribed Spacer region (ITS2)

Over 14,600 organism entries

for conclusive data interpretation and decisive action within our validated, continuously curated, and proprietary sequencing libraries

96% species-level ID rate

to provide you with the most accurate information from routine EM to investigations to root cause analysis

The industry's highest reportable rate

enabling you to implement appropriate actions in response to microbial excursions

Precise phylogenetic analysis

by our dedicated and experienced technical teams



Services

Microbial Sequencing for Bacteria with **AccuGENX-ID® BacSeq**

Microbial Sequencing for Mold and Yeast with **AccuGENX-ID® FunITS**

Analysis of Raw Sequence Data with **AccuBLAST®**

Speciation Within Bacterial Groups and Complexes using Protein-Coding Gene Sequencing with **AccuGENX-ID® ProSeq**

Differentiating Same-Species Members

with strain level precision

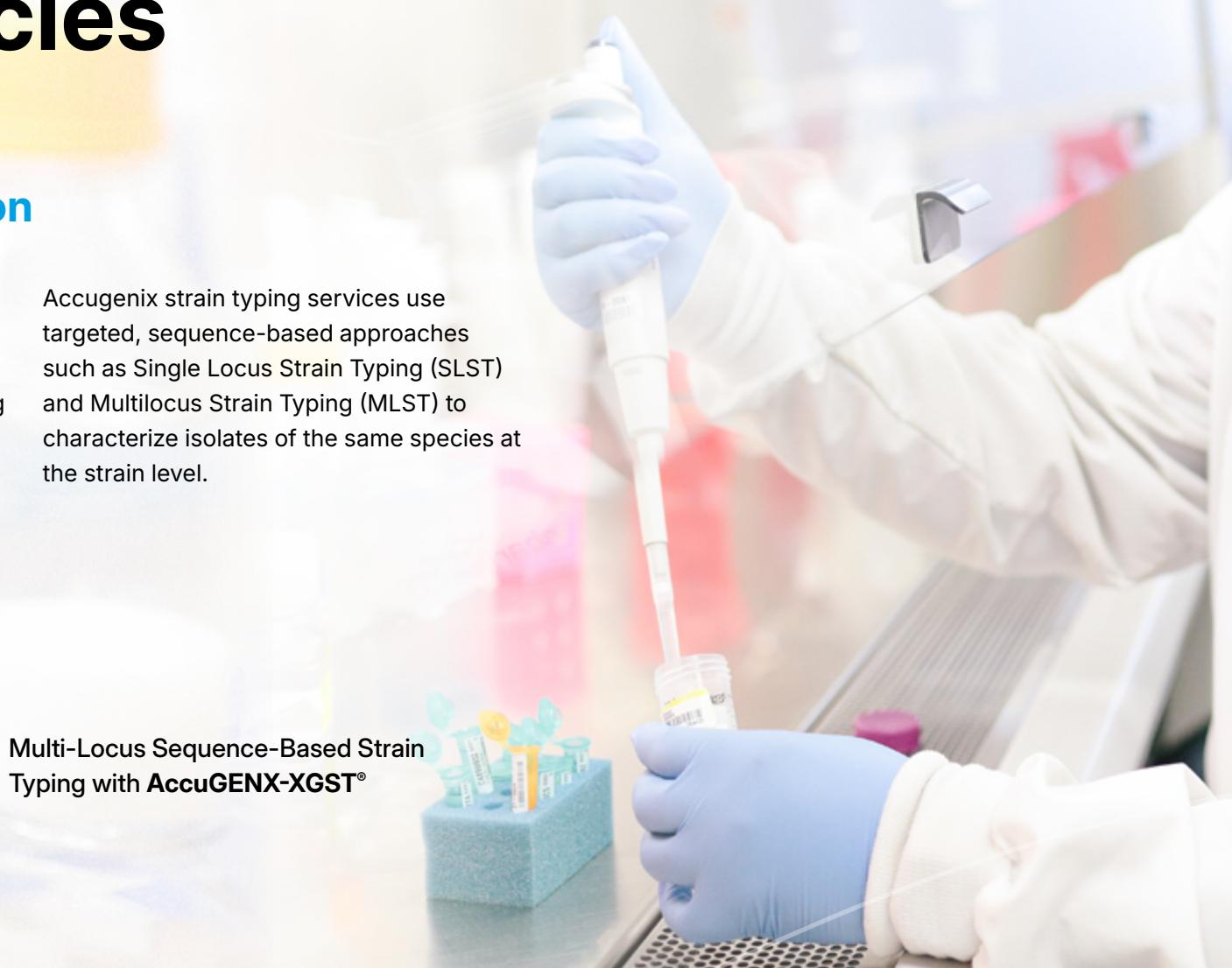
Get the full picture if standard identification methods are not enough when recurring contamination and persistent problematic organisms disrupt your process. Strain typing provides the deeper resolution needed to uncover the true root cause, helping you eliminate the issue at its source and prevent future occurrences.



Services

Sequence-Based Strain Typing
with **AccuGENX-ST®**

Multi-Locus Sequence-Based Strain
Typing with **AccuGENX-XGST®**



Harness unprecedented

Data-Driven Insights with Next-Generation Sequencing (NGS)

Comprehensively analyze your microbial populations

NGS for bacteria and fungi provides a critical understanding of microbial populations in pure or mixed samples, perfectly complementing your contamination control strategies.

Targeted Amplicon Sequencing (TAS)

services provide opportunities for identification results from challenging investigative samples by moving beyond the limitations of traditional Sanger sequencing approaches.

Whole Genome Sequencing (WGS)

enables in-depth exploration of strain diversity, strain identification, and comparative genomic analyses to support your microbial and process control workflows.



Services

NGS-Based Bacterial and Fungal Identification by Targeted Amplicon Sequencing with **Accugenix® TAS**

NGS-Based Inferred Strain Typing by Whole Genome Sequencing for Bacteria and Fungi with **Accugenix® WGS**

Plasmid NGS-Based Whole Genome Sequencing with **Accugenix® PLS**

From IDs to Insights

Identifications that power informed decisions

Track isolate history or monitor in real-time with the complimentary Accugenix Tracking and Trending Environmental Monitoring Software.

Ditch error-prone spreadsheets for modern data management tools that reduce contamination risks in manufacturing. Get comprehensive tracking and trending solutions with enhanced microbial environmental monitoring software, accessible via the Customer Web Portal.

Software designed to comply with 21 CFR Part 11 regulations and GAMP5 standards:

- A documented record of all identified environmental isolates over time for trend analysis
- Real-time, automatic aggregation of data into reports
- Informational database of microorganisms and characteristics via AccuPedia™ tool
- Data encryption and user login/password protection
- Tailored notifications of objectionable organisms unique to your facility
- Customizable report view with sorting and filtering options
- Analyze Gram reaction, cell morphology, and specific species
- Examine the frequency of organism occurrence for cleaning and sterility validations



Access the Accugenix Mobile App Anytime, Anywhere

Receive instant alerts on sample status, ID report readiness, and organism identification. Avoid the wait and quickly contact us via the 'Help' feature for support or inquiries.



Simplified EMPQ Testing and Reporting

Outsource and let us take it off your plate

Rely on us to streamline your Environmental Monitoring Performance Qualification (EMPQ). Avoid the complexity of managing the sheer amount of identification testing required when qualifying a new or existing cleanroom. We've simplified this critical aspect with a comprehensive testing bundle, complete with customized reports.

Service packages are designed based on real-world QC feedback to make EMPQs faster, smarter, and more effective.



Resource Optimization
Free your team from manual, resource-draining tasks so you can focus on core priorities



Decisions Made Simple
Generate actionable insights from simplified, curated reports



Regulatory Confidence
Evidence-based documentation ensuring compliance readiness



Over three decades of

Transforming Data into Actionable Decisions

Your global contamination control partner

Accugenix microbial identification goes beyond just providing an ID—it's a collaboration rooted in expertise and exceptional customer support. We deliver precise, meaningful results that empower you with actionable contamination control strategies, ensuring confidence in every identification.

A Network of 9 Globally Harmonized Laboratories at Your Fingertips

- Consisting of ISO-certified laboratories
- Seamless support for multinational companies standardizing their microbial ID programs
- Decades of technical research-backed experience

Strategic Support, Every Step of the Way

- A multilingual, dedicated global technical support team
- Clear and actionable reporting tailored to your unique needs
- Access to the AccuPedia database for microbial insights and taxonomy

Team Empowerment Through Technology and Resources

- Intuitive Customer Web Portal for real-time tracking, testing status and results
- Comprehensive guides and tutorials for sample preparation and shipping
- Multiple preparation methods for tailored solutions



Accugenix®

Identification Services

Product Line	Product	Turnaround Time	Code
AccuPRO-ID®	AccuPRO-ID® MALDI-TOF Microbial Identification Service for Bacteria and Yeast	Same-day	AccuPRO-ID-0
		1-day	AccuPRO-ID-1
		2-day	AccuPRO-ID-2
		5-day	AccuPRO-ID-5
AccuBLAST®	AccuPRO-ID® MALDI-TOF Microbial Identification for Filamentous Fungi	5-day	AccuFUN-ID-5
	AccuBLAST® Analysis of 16S Raw Data Sequence Files Sequence data analysis and identification report generation from .ab1 data files	Same-day	AccuBLAST-0
		1-day	AccuBLAST-1
AccuGENX-ST®		2-day	AccuBLAST-2
AccuGENX-ST® Sequence-Based Strain Typing	5-day	AccuGENX-ST-5	
AccuGENX-XGST®	AccuGENX-XGST® Multi-Locus Sequence-Based Strain Typing 7 gene MLST with sequence type and alleles	5-day	AccuGENX-XGST-5
		Inquire	SP-STF-01-10

Product Line	Product	Turnaround Time	Code
AccuGENX-ID®	AccuGENX-ID® Bacteria (16S 500bp) DNA Sequencing of the 16S rRNA Gene in Bacteria	Same-day	BACSEQ-0
		1-day	BACSEQ-1
		2-day	BACSEQ-2
		5-day	BACSEQ-5
		Same-day	FunITS-0
AccuGENX-ID®	AccuGENX-ID® Fungi (ITS2) DNA Sequencing of the ITS2 Region in Fungi	1-day	FunITS-1
		2-day	FunITS-2
		5-day	FunITS-5
		1-day	PROSEQ-1
		5-day	PROSEQ-5
Specialized Sequencing Reports	Alignments, comparisons, and/or phylogenetic trees for customer-specified samples	2-day	CompSeq-2

Accugenix®

NGS Services and Custom Libraries

Product Line	Product	Turnaround Time	Code
Accugenix® PLS	Plasmid NGS-Based Whole Genome Sequencing No DNA Extraction	10-day 20-day	NGS-PLSMD-NO- EXT-10 NGS-PLSMD-NO- EXT-20
	Plasmid NGS-Based Whole Genome Sequencing Includes DNA extraction	10-day 20-day	NGS-PLSMD-10 NGS-PLSMD-20
	Custom Bioinformatics for Accugenix®, NGS, Hourly Rate	Inquire	NGS-BIOINF-20
	Development of Customer-Specific Library	Inquire	SP-CLB-01-10

Product Line	Product	Turnaround Time	Code
Accugenix® TAS	NGS-Based Bacterial Identification by Targeted Amplicon Sequencing, 16S	20-day	NGS-TAS-16S-20
	NGS-Based Fungal Identification by Targeted Amplicon Sequencing, ITS2	20-day	NGS-TAS-ITS-20
	NGS-Based Fungal Identification of Fall-Through Samples by Targeted Amplicon Sequencing, ITS2	20-day	NGS-TAS-ITS- FT-20
	NGS-Based Bacterial Identification of Fall-Through Samples by Targeted Amplicon Sequencing, 16S	20-day	NGS-TAS-16S- FT-20
Accugenix® WGS	NGS-Based Inferred Strain Typing by Whole Genome Sequencing for Bacterial Samples	20-day	NGS-WGS-ST- BAC-20
	NGS-Based Inferred Strain Typing by Whole Genome Sequencing for Fungal Samples	20-day	NGS-WGS-ST- FUN-20

Accugenix® NGS services are currently not GMP. Please contact your local sales representative for more information.

Axcess®

MALDI-TOF System

Product Line	Product	Code
Axcess® MALDI-TOF System	Axcess® 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
	Axcess® Sirius MALDI Biotyper Package The Sirius package includes all the features and accessories of 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
	Bacterial Test Standard (BTS)	AXC115
	Matrix HCCA	AXC155
	MSP Adapter for MALDI Biotarget	AXC4800AD
Axcess® MALDI Biotyper-CM Reagents and Accessories	MALDI Biotarget 96 Disposable Target Plate (pack of 20)	AXC9600D
	Conidia IDFP Fungi Agar Plates (pack of 20)	AXC320
	Uninterruptible Power Supply 115V (US only)	AXC525

Product Line	Product	Code
Required with Purchase	Axcess® Start up Package (year 1) The Axcess® Start up 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. Required with Axcess® MALDI-TOF System purchase.	AXC8000
	Annual Licensing Fee For Axcess® Renewals (year 2 and beyond)	AXC2002
	Annual OQ-PV with Service Agreement	AXC400B
	Annual OQ-PV without Service Agreement	AXC404B
Axcess® Service and Support*	Axcess® System Target Cleaning Method Validation	AXC501
	Software Qualification/Methods Validation	AXC502
	Warranty Plus (additional instrument coverage during first year)	AXC700
	Complete CARE Contract	AXC900
	Complete CARE Contract Priority	AXC1000
	Complete CARE Contract Priority Plus	AXC1100
	On-Site Training (per day)	TS200

*Contact your local Charles River representative to review service package availability and coverage.



Join over 6,000 companies
that already rely on us for their
microbial identification.

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