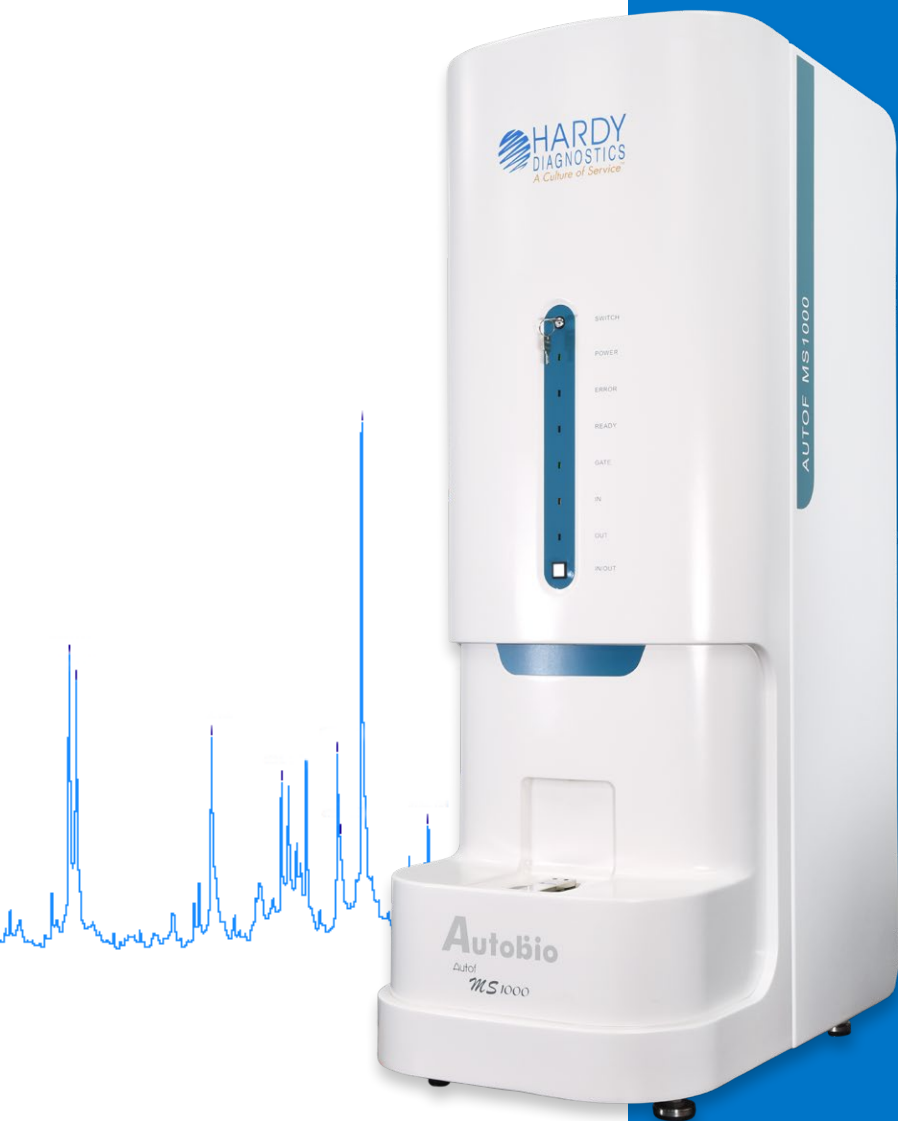


MALDI-TOF

Matrix-Assisted Laser Desorption/Ionization

Time-Of-Flight



Autobio

 **HARDY**
DIAGNOSTICS
A Culture of Service™

AUTOMATED MASS SPECTROMETRY MICROBIAL IDENTIFICATION SYSTEM

Hardy Diagnostics is proud to introduce the Autof ms1000*

Identification of microorganisms to the species level is the principle **objective** in microbiology.¹ For many years, such a feat has been accomplished through laborious biochemical assays. While advancements in nucleic acid sequencing technologies have enabled highly specific detection rates of microorganisms, these technologies are too **time-consuming** and **costly** to be commonplace.²

The **Autof ms1000** provides **automated**, **high-speed** and **high-confidence identification** and taxonomical **classification** of bacteria, yeasts, fungi, and filamentous fungi based on proteomic profiling. Numerous studies have demonstrated the **higher accuracy**, **faster time-to-result**, and **lower cost** provided by MALDI-TOF technology when compared to classical methods.^{3,4,5}



Features:

- Faster time-to-result when compared to conventional methods and PCR⁶
- Accuracy similar to nucleic acid sequencing technologies⁷
- Cost effective⁸
- Robust, intuitive software, supporting 21 CFR part 11 compliance
- Installation Qualification/Operation Qualification-Performance Verification support
- LIMS/LIS connectivity and support
- Database of approximately 5,000 species created with over 15,000 strains
- Can identify 96 samples in less than 20 minutes hands-on time

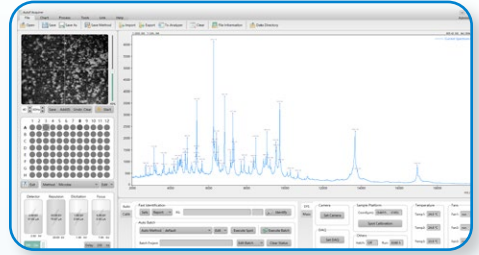
Cat. no. MS1000

1. <https://www.ncbi.nlm.nih.gov/books/NBK8406/> 2. <https://pubmed.ncbi.nlm.nih.gov/24822116/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986882/> 4. <https://pubmed.ncbi.nlm.nih.gov/31116624/>
5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5228263/> 6. <https://pubmed.ncbi.nlm.nih.gov/31116624/>
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986882/> 8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5228263/>

INTUITIVE SOFTWARE

Easy-to-use software provides a friendly user experience. The Autof Acquirer has been designed to comply with the rigors and standards of a regulated working environment.

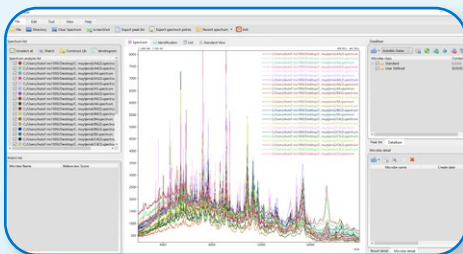
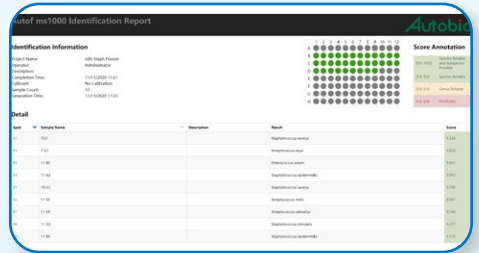
- Authentication
- User management
- Data archiving



Range	Description	Color
9.500 - 10.000	Reliable species	Green
9.000 - 9.499	Reliable species identification result	Green
6.000 - 8.999	Reliable genus identification result	Yellow
0.000 - 5.999	No reliable identification result	Red

Easy-to-read, color coded score annotations indicate the degree of confidence in each identification result.

Following the acquisition of spectral profiles, an identification report is automatically generated. A summary of sample locations, names, descriptions, results, and scores will be displayed.



Laboratories that need to create their own local database can do so with a companion software application.

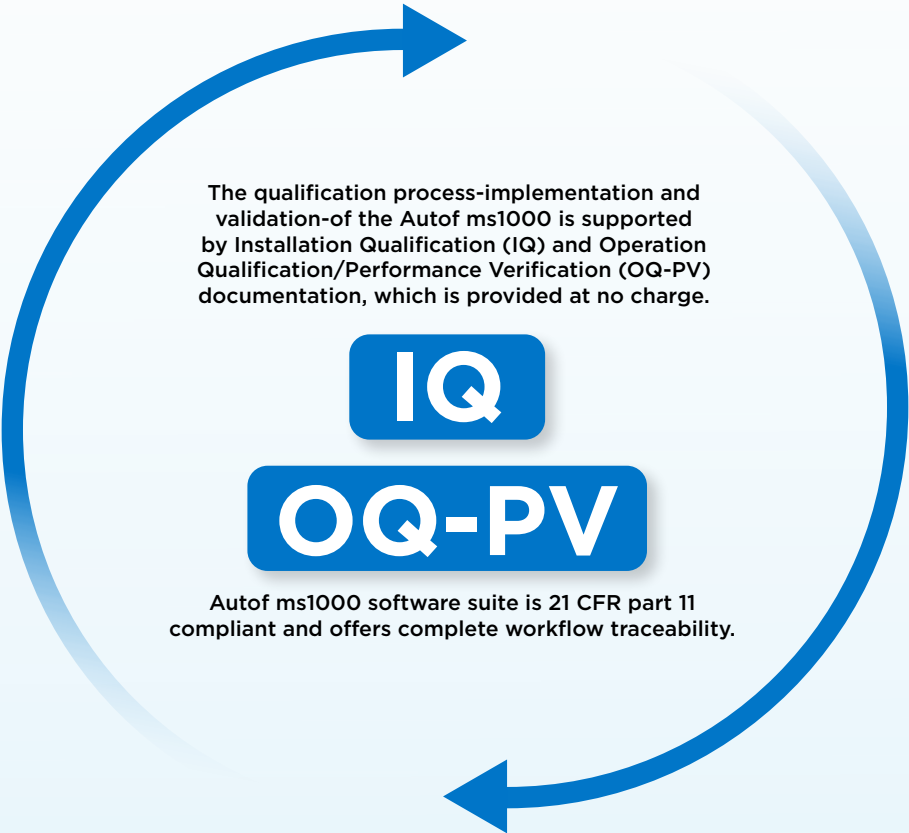
THE PROCESS

SINGLE COLONY | SINGLE SPOT | SINGLE DROP



- Unique Rapid Identification function displays a test result in 0.1 seconds for a single sample
- Average identification (acquisition and data analysis) time for 96 samples is 17.5 minutes
- Batch function available to edit and identify samples in a fully customizable format
- Access to LIMS/LIS system; reports release automatically

FREE ASSISTANCE WITH QUALIFICATION OF THE AUTOF MS1000



The qualification process-implementation and validation-of the Autof ms1000 is supported by Installation Qualification (IQ) and Operation Qualification/Performance Verification (OQ-PV) documentation, which is provided at no charge.

IQ

OQ-PV

Autof ms1000 software suite is 21 CFR part 11 compliant and offers complete workflow traceability.

IQ: Verification process that ensures the Autof ms1000 has been properly delivered and installed by way of an approved system and specification checklist.

OQ-PV: A collection of test cases employed to verify that the Autof ms1000 and its subsystems perform as expected as defined by the functional requirements specifications.

ROBUST DATABASE

The Autof ms1000 has the **most expansive database** in the industry. Created with more than **15,000 strains**, each with more than **5 reference spectra**, averaging more than **10 strains per species**, the database of the Autof ms1000 provides **highly accurate results**.

Local database includes a total of **1,003 Genera**, **4,943 Species**, and **15,993 Strains**



Gram +



Gram -



Yeast



Filamentous Fungi



Mycobacteria

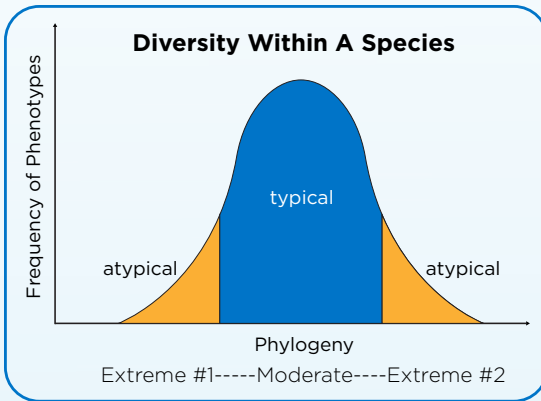
- 1,869 Gram + species
- 2,173 Gram - species
- 166 Mycobacteria species
- 249 Yeast strains
- 460 Filamentous Fungi Species

As part of the partnership, **Hardy Diagnostics** and **Autobio Diagnostics Co. LTD.** are constantly **augmenting** the **Autof ms1000 database**. New strains and species are constantly being added, **improving** upon the **reliability** and **accuracy** of the system.

The **Autof ms1000** database contains a multitude of reference strains from:

- Varying geographic regions of the world
- Different specimen types
- Different culture media types
- Different growth conditions

Criteria that captures the natural phylogenetic diversity within a species.



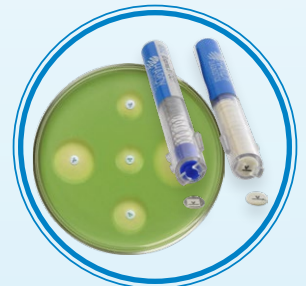
Hardy Diagnostics offers a comprehensive solution to your microbiology needs.



Culture



Identification



**Antimicrobial
Susceptibility Testing
(AST)**



Hardy Diagnostics adheres to cGMP, is licensed by the FDA as a medical device manufacturer, and its quality management system is ISO 13485 certified.

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