



news digest #011

Rapid microbial identification in pharmaceutical laboratories

Rapid and accurate identification of microorganisms is an essential part of the drug discovery and development process. Contaminants can be found in a diverse range of materials including ingredients, pharmaceutical water, the manufacturing environment, intermediates, and finished products. Identifying microorganisms is essential to understand the microbial environment of a pharmaceutical lab, monitoring the effectiveness of microbiological control and investigating fermentation strains and bio-collection populations.

As demand to bring drugs to market faster continues to rise, the pharmaceutical industry is experiencing unprecedented growth. A recent industry report predicts that pharmaceutical manufacturing will grow rapidly with a compound annual growth rate of 11.34% by 2028. To keep pace with the demand to bring drugs to market, new solutions are needed. The Bruker MALDI Biotyper®, based on MALDI-TOF mass spectrometry (MS), is transforming the modern pharmaceutical microbiology lab by providing a rapid, cost-effective and specific microbial identification based on colony material.

Removing traditional barriers

Traditional analytical methods offer limited specificity for bacterial and fungal identification and confirmation. Growth-based incubation is slow and relies on known evaluation schemes. Biochemical identifications show weaknesses for some microbial genera or at species-level and do not reach the precision achieved with the MALDI Biotyper. Molecular techniques like PCR and sequencing are often used in parallel but are limited by the number of available assays. There can be a high cost per sample and lengthy time to result, especially if sequencing is not carried out in-house.

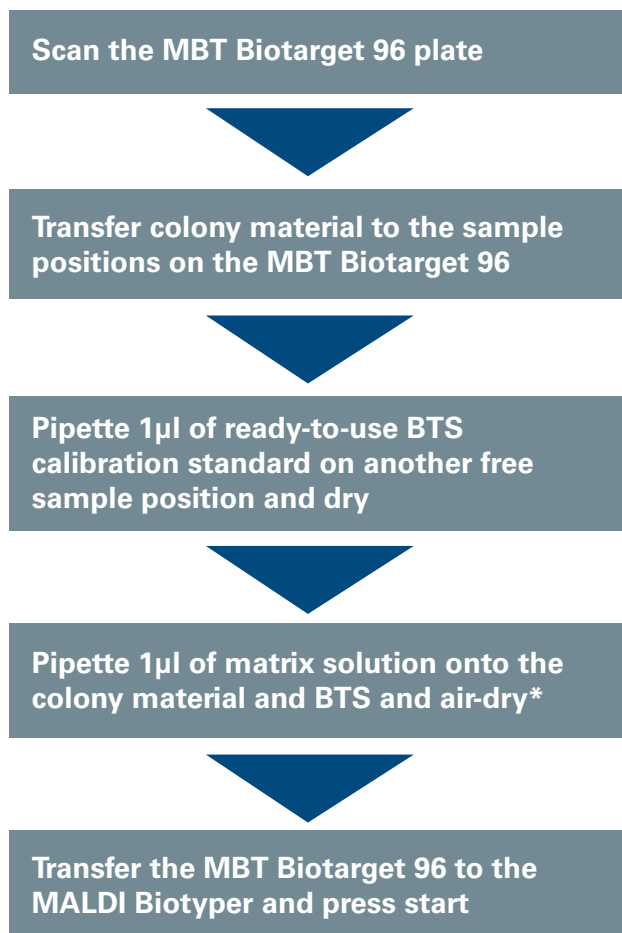
MALDI-TOF MS is a rapid, protein-based identification method. Analysis by the MALDI Biotyper returns a spectrum based on the ribosomal proteins of bacteria, yeasts and fungi. This spectrum, a microbial fingerprint, is then automatically compared with the MALDI Biotyper reference library of more than 4,700 species, using the system software to provide a match.

This rapid solution returns results for 96 samples in 30 minutes, including sample preparation starting from culture.

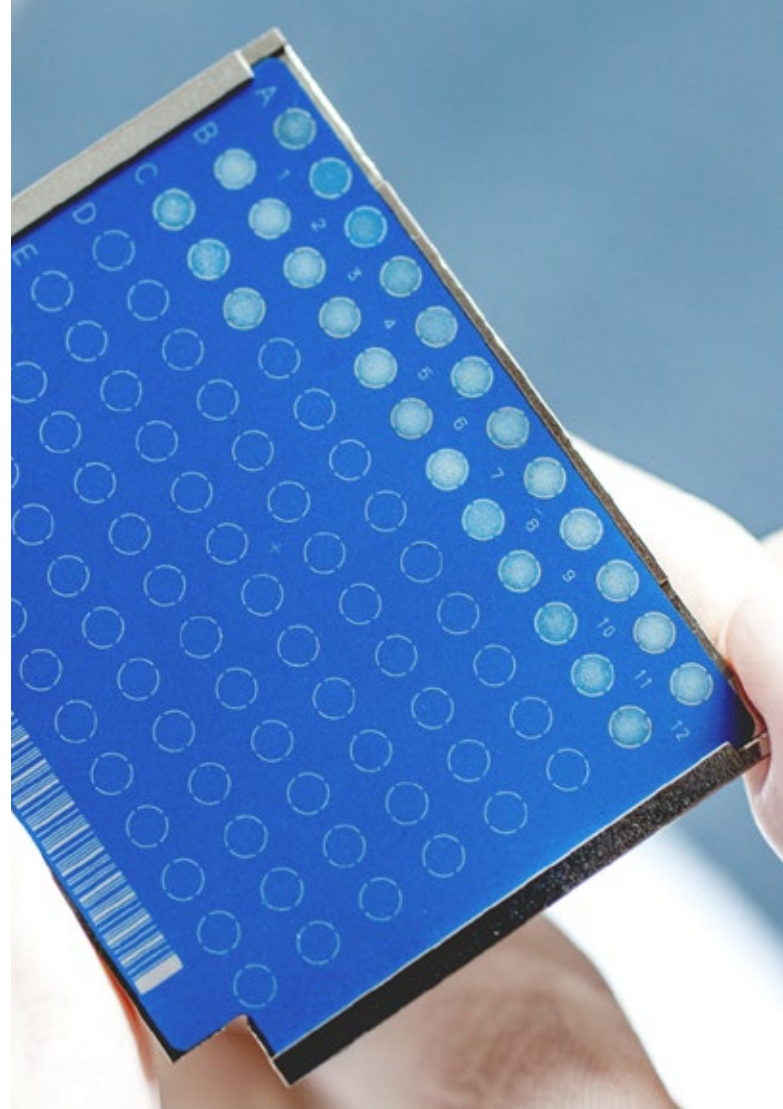
Rapid implementation

MALDI-TOF detection offers a simple workflow with the advantage of an easy set-up and use in the lab, with minimal training. Its software performs and controls the entire analysis, including rapid vacuum creation, calibration, laser treatment of samples, spectra generation and species identification.

Starting with fresh colony material, there are five simple steps:



*Optional use of the MBT FAST™ Shuttle, a small benchtop device, which creates the perfect environment for optimized, standardized and therefore reproducible matrix crystallization and faster drying



MBT Biotarget 96 with samples readily prepared to be analysed by the MALDI Biotyper

High performance

The MALDI Biotyper outperforms biochemical testing systems and is often superior to sequencing or PCR in terms of speed of identification starting from colony material, easy training and robustness of the method. In no time, the MALDI Biotyper provides reliable identification results of Gram-positive and Gram-negative bacteria, covering a broad range from airborne, waterborne, animal or plant origin to pathogenic ones. The system enables as well quick identification of yeast in industrial production, spoilage yeast or yeast in biofilms.

Rapid and reliable identification of filamentous fungi is essential for pharmaceutical microbiology, and the MALDI Biotyper overcomes typical limitations of classical identification by microscopy or biochemical assays. The system can run fungal and bacterial sample analysis simultaneously, and a dedicated add-on reference library adds improved identification for most common fungi found in industrial and in medical applications.

Further reading

Read more about the potential of MALDI-TOF MS in industrial applications:

- S K Urwyler *et al.*: Advantage of MALDI-TOF-MS over biochemical-based phenotyping for microbial identification illustrated on industrial applications, 2016. Lett Appl Microbiol. [doi: 10.1111/lam.12526](https://doi.org/10.1111/lam.12526)
- K El-Bouri *et al.*: Comparison of bacterial identification by MALDI-TOF mass spectrometry and conventional diagnostic microbiology methods: agreement, speed and cost implications, 2012. Br J Biomed Sci. [PMID: 22872927](https://pubmed.ncbi.nlm.nih.gov/22872927/)

Read more about the potential of MALDI-TOF MS in the identification of filamentous fungi:

- Claudia Honsig *et al.*: Identification of Filamentous Fungi by MALDI-TOF Mass Spectrometry: Evaluation of Three Different Sample Preparation Methods and Validation of an In-House Species Cutoff, 2022. J Fungi (Basel). [doi: 10.3390/jof8040383](https://doi.org/10.3390/jof8040383)
- Natacha Motteu *et al.*: Implementation of MALDI-TOF Mass Spectrometry to Identify Fungi From the Indoor Environment as an Added Value to the Classical Morphology-Based Identification Tool, 2022. Front Allergy. [doi: 10.3389/falgy.2022.826148](https://doi.org/10.3389/falgy.2022.826148)

References

- i Environmental monitoring: identify, track and trend microbial isolates, Rapid Microbiology, accessed 21 June 2022. <https://www.rapidmicrobiology.com/test-method/environmental-monitoring-identify-track-and-trend-microbial-isolates>
- ii Grand View Research: Pharmaceutical Manufacturing Market Size, Share & Trends Analysis Report By Molecule Type, By Drug Development Type, By Formulation, By Routes of Administration, By Sales Channel, By Age Group, And Segment Forecasts, 2021-2028. <https://www.grandviewresearch.com/industry-analysis/pharmaceutical-manufacturing-market>



MALDI Biotyper sirius System

Not for use in clinical diagnostic procedures.
Please contact your local representative for availability in your country.

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