Changing Pharmaceutical Microbiology

MALDI Biotyper®

Microbial identification with unequaled speed and accuracy

Innovation with Integrity

GP

Identification of microorganisms by their molecular fingerprint

Starting from colony material, the MALDI Biotyper identifies microorganisms using MALDI-TOF (Matrix-Assisted Laser Desorption/Ionization - Time of Flight) Mass Spectrometry to determine the unique molecular fingerprint of an organism.

The characteristic spectrum pattern of this fingerprint is used to reliably and accurately identify a particular microorganism by matching against thousands of reference spectra from microorganism strains.

Game-changing technology for optimal results

To help answer key challenges in microbiology, Bruker has utilized its many years of experience to create the truly groundbreaking MALDI Biotyper System (MBT). This revolutionary technology has allowed laboratories worldwide to achieve reliable, fast and efficient identification of a wide range of gram-negative and gram-positive bacteria, yeasts and molds, by an easy to operate, yet powerful benchtop system.

- NEW: Faster than ever, enabling analysis of up to 600 samples/hour
- NEW: A mighty mold solution for identification of hundreds of filamentous fungi species/species groups
- Accuracy comparable to Nucleic Acid Sequencing
- Faster than traditional methods and PCR
- Covering thousands of microorganisms
- Cost-effective
- Robust and easy to use
- Intuitive software, supporting 21 CFR part 11 compliance
- Easy to implement
- Optional workflow improvement tools
- Hosting interfaces for LIMS integration
- IQ - OQ/PV Support

Fast identification of microbial contaminants and biotechnological strains during quality and hygiene controls

With the MALDI Biotyper implemented in your workflow, specific identification of microorganisms is achieved within minutes. This can directly translate to significant cost savings by accelerated control of raw materials as well as quicker in-process QC, process environment and end-product testing.

Integrating the MALDI Biotyper into routine testing workflows results as well in a significant consolidation of resources, as it eliminates the burden of multiple steps and workstations required for DNA sequencing.

Additionally, the MALDI Biotyper delivers reliable information on species level, prior to further cluster analysis and strain discrimination which can be performed by Bruker's IR Biotyper®, by sequencing or other DNA fingerprinting techniques.

A simple procedure for a sophisticated and fast platform

Bacteria, yeast or mold: one workflow for all

The MALDI Biotyper system workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

Typically, no more than an isolated single colony from a culture plate is required. The hands-on time per isolate is only 20 seconds for nearly all microorganisms.

Our dedicated microbiology software fully automates the process of tuning, acquiring the mass spectrum and performing the match against the extensive reference library. The identification results, presented using a 'traffic light' color scheme, are effortless to interpret.

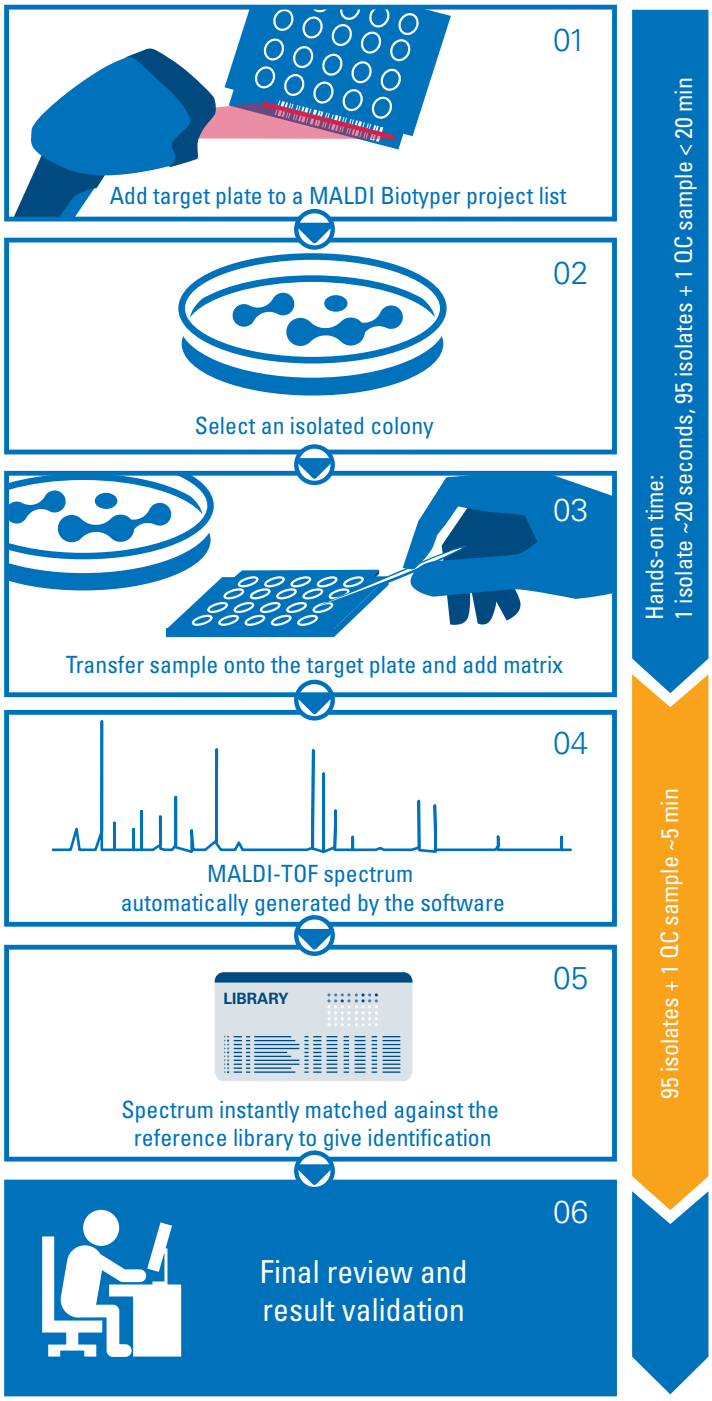
The MALDI Biotyper simplifies microbial identification, and facilitates and harmonizes the workflow with only one system.

Faster than ever

The new MBT Compass HT software dramatically shortens the time-to-result; analysis of 95 isolates and 1 QC sample results in a complete identification report within ~5 minutes.

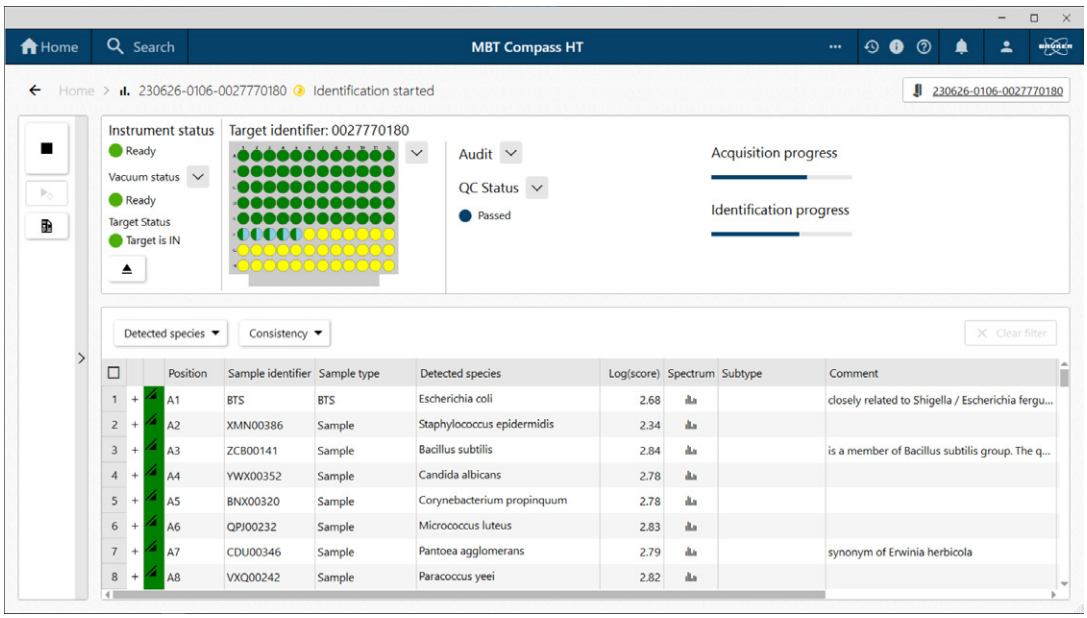
Sample preparation hands-on time:
- 1 isolate ~20 seconds
- 95 isolates < 20 min

System analysis time to result:
- 95 isolates + 1 QC sample ~5 min



Easy-to-use software

In just a few steps, the simple-to-use MBT Compass HT software guides users through the setup of samples for analysis.



A system suitability test (SST) with the Bruker Bacterial Test Standard (BTS), performed prior to every identification run, guarantees system performance, reproducibility and the fulfillment of local compliance criteria. Only after successful completion of the SST the system starts to acquire and process the sample data.

Range	Interpretation
2.00 - 3.00	High Confidence Identification
1.70 - 1.99	Low Confidence Identification
0.00 - 1.69	No Organism Identification Possible

Supporting 21 CFR part 11 compliance

Bruker understands the significance of regulatory compliance, particularly when it comes to electronic records and signatures. Our documentation supports your lab's adherence to 21 CFR Part 11 requirements, giving you the necessary tools to maintain data integrity and secure electronic records throughout the qualification process. The MBT Compass HT software has been designed to support compliance with the rules of regulated environments, addressing the following aspects:

- Authentication and user management
- User rights management
- Data integrity and archiving
- Audit trail including reason entry and timestamps
- Digital signatures

Integration with LIMS

The MALDI Biotyper allows for smooth integration with existing laboratory informatics. MALDI Biotyper results are converted into a format that can easily be exported to the LIMS.

The core of the MALDI Biotyper

A continuously updated reference library

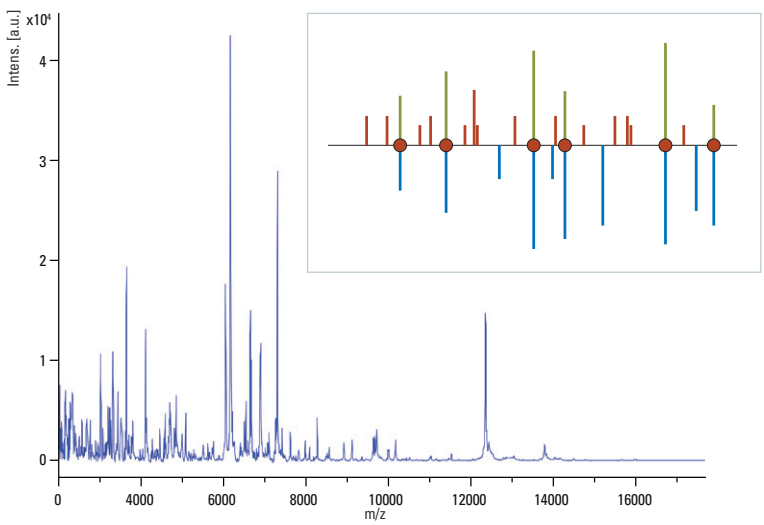
The principle behind identification of microorganisms with the MALDI Biotyper is the comparison of the mass spectrum of an unknown organism with a library of reference mass spectra. As the extent and quality of this library is key to successful identification results, Bruker is fully committed to the continuous development of the reference library. An active program of reference spectra generation culminates in regular library updates for MALDI Biotyper users. These updates are focused on recommendations from our collaboration partners from the industrial, veterinary and clinical field, including certified strain collections.

Create your own libraries and run your data comparison

Laboratories that need to create their own libraries can easily compile customized microorganism entries by software tools and share or export libraries. These might be libraries with site-specific isolates and/or entries for important starters used for production.

Our mighty solution for filamentous fungi

The MALDI Biotyper is perceived as the most promising alternative for molds identification. A dedicated MBT HT Filamentous Fungi Module, including a software module and a specific reference spectrum library, is available to facilitate the identification of this group of microorganisms. Bruker's simple and fast Mycelium Transfer (MyT) method can be used in most of the cases, when front mycelium is clearly visible and can be harvested easily. Hence, sample preparation is most often very straightforward, resulting in high identification success rates, directly from agar.



Identification of highly pathogenic microorganisms

A dedicated small library is available for identification of highly pathogenic species such as *Brucella melitensis*, *Vibrio cholerae* and *Clostridium botulinum.*

Taxonomy becomes easy

The metadata of the MALDI Biotyper Reference Library facilitate the access to taxonomical information, such as synonyms and taxonomical modifications.

The main spectra concept capturing true biological variability

Reference library entries in the MALDI Biotyper system are stored as Main Spectra (MSP). These MSPs are based on multiple measurements of a single defined strain to ensure that the true biological variability of an organism is reflected in the library.

Unknowns are then compared to the MSP library using a superior pattern-matching approach. This includes peak positions and intensities, ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

MALDI Biotyper System overview

Benchtop MALDI-TOF system

- **MALDI Biotyper sirius GP System***,
  with 200 Hz smartbeam™ laser and positive as well as negative ion detection

Routine identification of gram +/- bacteria, yeasts

Software
- MBT Compass HT software
- MBT Compass Library
- MBT HT Subtyping Module (optional)
- Security Related Library for identification of highly pathogenic microorganisms (optional)

Consumables
- Matrix HCCA-portioned
- Bacterial Test Standard
- MBT Biotarget 96

Accessories for workflow optimization & automation (optional)

- MBT Shuttle ergonomic target holder
- MBT FAST™ Shuttle for standardized and accelerated drying of matrix and other liquids
- MBT Pilot® for guided sample transfer
- MBT Galaxy® for automated application of HCCA matrix and formic acid

Filamentous fungi and Mycobacteria identification (optional)

Software
- MBT HT Filamentous Fungi Module
- MBT HT Mycobacteria Module

Consumables
- MBT Mycobacteria Kit

System implementation and qualification

- IQ and OQ/PV
- MBT HT Compliance Assistant Module to support 21 CFR part 11 compliance

* As an alternative, also the MALDI Biotyper sirius one GP System can be used.
Please contact your local Bruker sales representative for availability of the optional MBT system components in your country.

Qualification of the MALDI Biotyper

Experience peace of mind knowing that Bruker supports the qualification process of the MALDI Biotyper system in your pharmaceutical laboratory.

With Bruker's MALDI Biotyper system, you gain more than just a reliable and accurate microbial identification solution. Our commitment to providing the required documentation for IQ, OQ, and PV, coupled with support for 21 CFR Part 11 compliance, ensures a streamlined qualification process for your pharmaceutical laboratory.

Design Qualification

User Requirement Specifications (URS)
Functional Requirement Specifications (FRS)

DQ

Installation Qualification

System installation check
Specification check after installation

IQ

Operational Qualification

Verification of the system performance and reproducibility as specified before

OQ

Performance Qualification

The system performs consistently and provides reliable, appropriate results within the given laboratory setting under given validation criteria.

PQ

Enjoy smart and stress-free operation

A platform suited to your needs

Bruker offers laboratories the opportunity to choose the MALDI-TOF mass spectrometer that best fits their needs:

- The MALDI Biotyper sirius GP System with Bruker's proprietary lifetime* smartbeam™ solid state laser technology at 200 Hz repetition rate, and positive as well as negative ion mode. The additional capability of analysis in negative ion mode broadens the research applications, such as the analysis of lipids for e.g., resistance detection.
- The MALDI Biotyper sirius one GP System, with the same innovative improvements, smartbeam™ 200 Hz laser and positive ion detection only.

Resolution optimized for reliable profile matching

Overall, the resolution is an important performance parameter in MALDI-TOF mass spectrometry. A high resolution is desired for more precise analysis of samples, as it refers to the ability to distinguish between two closely spaced peaks in a mass spectrum. Thanks to Bruker's patented PAN™ resolution, the compact MALDI Biotyper achieves an optimal resolution over the relevant mass range of the mass spectral profile acquired from the unknown microorganisms. This accuracy is crucial when it comes to profile matching with thousands of reference spectra, for reliable identification of microorganisms.

Analysis of up to 600 samples/hr - Even shorter Time-to-Result

With Smart Spectra Acquisition™, data generation is accelerated by minimizing the number of laser shots per sample needed to acquire a meaningful spectrum. An additional benefit of this function is the optimal exploitation of the laser lifetime. System improvements, including the newest low-power electronics and a high-performance vacuum system, generate fast target exchange times for accelerated Time-to-Result - even faster than before.

The Time-to-Result is further shortened dramatically by the power of the new MBT Compass HT software, resulting in identification results popping up simultaneously with spectra acquisition, one by one, without delay.

An entirely filled MBT Biotarget 96, holding 95 isolates and 1 QC sample, results in a complete identification report in ~5 minutes. This analysis speed, combined with a superior fast target exchange, allows analysis of up to 600 samples/hour.

Continuous operation

The integrated ion source cleaning permits continuous high performance with minimized maintenance requirements. Cleaning the source using the separate IR-laser is performed easily by a few clicks in the software, without breaking vacuum.

The best technology from the experts in mass spectrometry

Bruker, a renowned leader in MALDI-TOF technology, recognizes the significance of designing robust, high-performance platforms that cater to extensive and routine usage in microbiology laboratories. Through continuous hardware development, we proudly present the 4th generation of Bruker's benchtop MALDI Biotyper systems that set new benchmarks in this field.

Our latest systems incorporate state-of-the-art low-power electronics and a high-performance vacuum system, resulting in rapid target exchange times for even faster Time-to-Result than ever before. These system improvements guarantee swift and precise identification of microorganisms, ensuring greater efficiency in your laboratory processes. At Bruker, we are committed to providing you with cutting-edge MALDI-TOF technology that empowers you to excel in your microbiology laboratory.

	MALDI Biotyper sirius GP System
Speed of analysis	▪ 95 isolates + 1 QC sample ~ 5 min to identification ▪ Identification of 600 samples/hr ▪ Identification results popping up simultaneously with spectra acquisition, one by one, without delay
Laser	Bruker's proprietary lifetime* smartbeam laser ▪ 200 Hz repetition rate ▪ At least 500 million laser shots are guaranteed
Polarity	Positive and negative ion mode
Mass range	Full functionality of a linear MALDI-TOF, with MALDI Biotyper applications focused to: ▪ 0-1.000 Da (resistance detection) ▪ 2.000-20.000 Da (microorganism identification)
Vacuum system	Oil-free membrane pre-vacuum pump and high capacity turbomolecular pump ▪ high pumping capacity, which in combination with a clever source design results in very fast target exchange ▪ minimal downtime after maintenance
Other features	LED strip to remotely observe system status Perpetual Ion Source™ with IR-laser self-cleaning functionality Whispermode™ <60 dB under normal operating conditions Patented PAN™ technology for high mass resolution over a wide mass range Latest low-power electronics protecting natural resources Voltage: 220 V / 110 V
Dimensions & Operating Parameters	L x W x H: 500 x 710 x 1070 mm / 19.7 x 28.0 x 42.2" Net weight: 75 kg / 165.4 lb Noise: < 60 dB Temp Range: 16 - 30°C / 61 - 86°F Operating Humidity: 20 - 75%, non-condensing

The MALDI Biotyper sirius one GP System comes with the same features but hosts only positive ion mode.

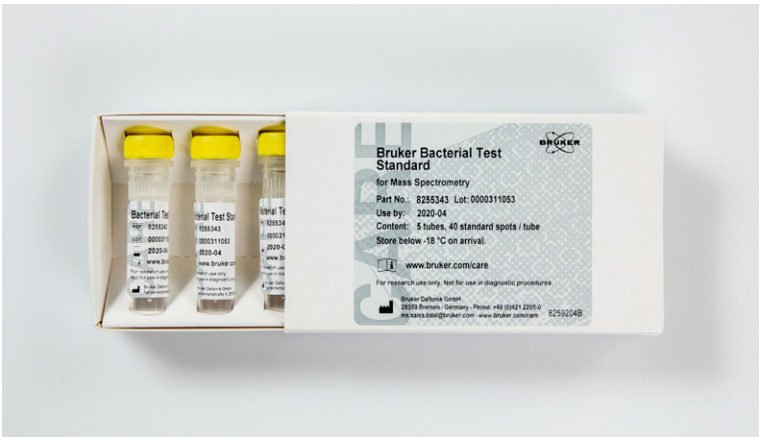
* Lifetime means: 500 million laser shots or seven years (whichever occurs first)

MBT consumables for basic identification

Bacterial Test Standard (BTS)

The BTS is an *E. coli* extract spiked with two high molecular weight proteins and has been developed for the quality control process of the MALDI Biotyper System. Its specific composition covers the entire mass range of proteins used for precise identification of microorganisms.

Content: One box consisting of 5 tubes providing 50 µL per tube / Part No. 8255343



HCCA Matrix, portioned

The instant HCCA matrix enables easy and convenient preparation of HCCA matrix solutions. The matrix is soluble in standard organic solvent, easy to handle, and enables highly sensitive measurements.

Content: One box consisting of 10 tubes providing 250 µL per tube / Part No. 8255344

Disposable MBT Biotargets

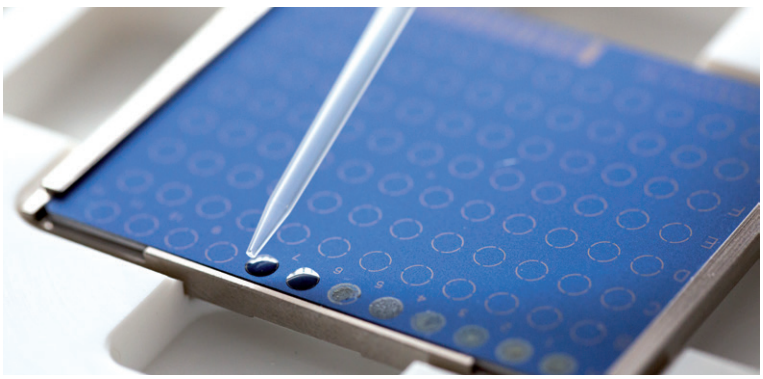
The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows.

MBT Biotarget 96

Set of 20 individually barcoded MALDI Biotyper target plates, 96 positions each / Part No. 1840375

MSP adapter for MBT Biotarget 96

Adapter required to use MBT Biotargets with MALDI Biotyper Systems / Part No. 8267615

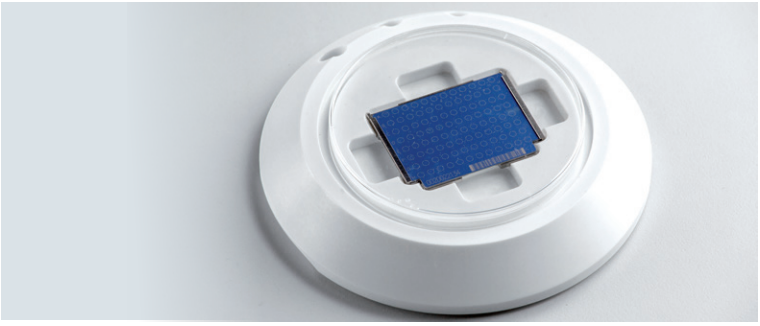


MBT workflow accessories

MBT Shuttle Target Holder

The MBT Shuttle target holder is used to securely hold MBT Biotargets during the sample preparation process. The secure grip, non-slip rubber feet and ergonomic shape make sample preparation easier.

One target holder / Part No. 1847032



MBT FAST™ Shuttle

Standardized and accelerated drying of MALDI Biotyper matrix and other liquid reagents

Part No. 1872847

MBT Pilot®

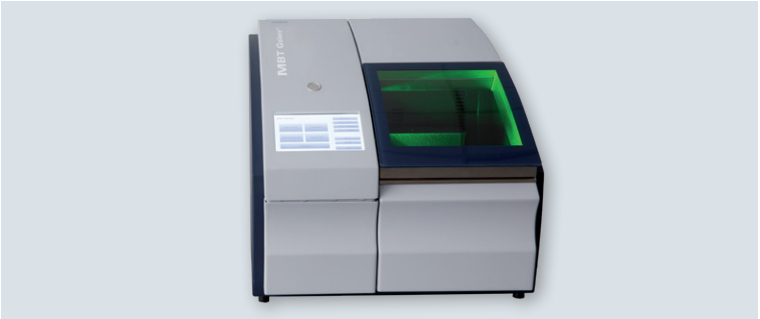
The MBT Pilot facilitates correct sample positioning through patented microprojection technology by indicating the next free MALDI target plate position.

Part No. 1822041

MBT Galaxy®

The MBT Galaxy, for automated application of HCCA matrix and formic acid, frees laboratory personnel from cumbersome pipetting while ensuring the highest preparation quality under controlled conditions and complete traceability in a paperless workflow.

Part No. 1821269



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

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