

IVD



Expert Insights

- MALDI Mass Spectrometry Advances Biomedical Clinical Applications

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Scientists at the MEDILYS Laborgesellschaft improve medical laboratory services with the Bruker MALDI Biotyper® sirius



Working with Bruker

Sebastian Bussmann, Deputy Head Technician at MEDILYS Laborgesellschaft, has worked in partnership with Bruker to expand the laboratory's technical capabilities for its medical laboratory services with the MALDI Biotyper sirius. He describes this relationship:

“Our Bruker instrumentation has delivered exactly what we needed in our laboratory, particularly the high throughput and reliability required to serve our clinicians and patients. But I’m equally impressed with the customer service we’ve received from Bruker. They’ve helped us numerous times – whenever we have an issue or need some guidance. Because of their support, I’m a huge Bruker fan.”

Medical laboratory services at MEDILYS

One of Europe’s largest clinical laboratories, MEDILYS Laborgesellschaft, provides a wide range of laboratory diagnostics and hospital hygiene services. The lab is a subsidiary of the Asklepios Kliniken Group (Asklepios GmbH & Co. KGaA), one of the biggest private-sector clinic operators in Germany with 170 healthcare facilities and 2.6 million treated patients in 2020.

MEDILYS completes more than 10 million analyses and produces more than 18 million clinically relevant findings each year. The laboratory serves the hospitals of Asklepios, as well as other hospitals and medical practices in Northern Germany. The laboratory’s extensive list of services include:

- Bacteriology
- Hemostasiology
- Infection serology
- Clinical chemistry
- Medicines & drugs
- Molecular genetics
- Special immunohematology
- Transfusion medicine
- Hygiene
- Quality management

MEDILYS’s experienced team of 20 doctors and scientists work with more than 120 medical-technical assistants to ensure the best possible medical laboratory care for its patients, focusing on providing around the clock, quality-oriented, reliable and fast analyses. Sebastian Bussmann, Deputy Head Technician at MEDILYS, describes the laboratory’s vision:

“MEDILYS employs a variety of excellently trained experts in various specialist areas. We work closely together on an interdisciplinary basis to offer the best possible analysis and to cover a wide range of services. The experience of our laboratory doctors ensures that our clinicians receive accurate data and practical advice to determine the right therapies for patients.”

The nature of clinical work requires MEDILYS to stay abreast of advances in technology, which has included continuous innovations in mass spectrometry (MS) over the past decade. Mr. Bussmann explains:

“Medical analyses require educating ourselves on the latest scientific innovations. We always need to challenge what we’re doing and find ways to improve. The fast and accurate identification of bacterial pathogens is essential to patient health and outcome. MS has shown significant advances in technology and new methodologies in this field, making it an extremely powerful tool for clinical work.

To maintain our high level of professional competence, we constantly search for the best tools to help our clinicians and patients, as well as solutions that will provide fast, reliable results”

MEDILYS recently invested in Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) MS instrumentation from Bruker to identify microbes reliably and rapidly, in a cost-effective manner.

Advances in microbiology

As many countries across the world are challenged with a rising number of multi-drug resistant (MDR) organisms, the need for rapid and accurate detection of antimicrobial resistance has grown. MALDI-TOF technology is recognized as a reliable, reproducible method to rapidly identify microorganisms directly from culture plates and positive blood cultures (PBCs).

Microorganism identification to the species level is a key task of microbiology. Traditionally, this process has been achieved by carrying out labor-intensive and time-consuming biochemical assays. Though current sequencing technologies may provide very precise insights, they are still far too slow and expensive for clinical settings where high throughput and reliability are essential.

Now the standard in microorganism identification, MALDI-TOF provides an innovative, molecular-based MS identification method that enables faster and more efficient analysis than conventional assays or sequencing. MALDI-TOF MS determines the unique proteomic fingerprint of an organism, and then matches characteristic patterns with an extensive reference library to determine the organism’s identity.

The latest advances have resulted in new robust, compact high-performance platforms intended for extensive and routine use in the microbiology laboratory. Mr. Bussmann explains the impact of these MALDI-TOF technology advances on the service offerings of the MEDILYS laboratory:

“To provide the highest levels of patient care, we are constantly working on improving all processes. Laboratory medicine makes an important, and often even decisive, contribution to the detection of diseases, so that therapy can be initiated in a short time. We were interested in expanding our use of MS, and we knew MALDI-TOF was a technique that could improve our ability to provide the data our clinicians need. Fast and reliable laboratory analyses provide clinicians with indispensable information for further treatment. So, we began to test new MALDI-TOF instrumentation to find the solution that worked for us.”

MALDI Biotyper® sirius modular system

After extensive testing, MEDILYS recently invested in the IVD-CE certified Bruker MALDI Biotyper (MBT) sirius modular system. The MBT sirius is a microbial identification system based on MALDI-TOF MS, allowing unbiased identification of microorganisms within a few minutes down to the species level. The MBT sirius allows for the identification of thousands of different microbial species. This capability, combined with automated detection of specific resistances in one workflow, makes the instrument a powerful tool in clinical microbiology laboratories. The MBT sirius is an easy, rapid, robust, high-throughput, cost-effective and efficient identification technology, ideally suited to microbial laboratories and designed to be configured according to individual laboratory needs. Mr. Bussmann describes the initial impression of the MEDILYS team after validating the system:

“We looked at capability of the MALDI Biotyper sirius IVD system to provide high-speed, high-confidence identification and taxonomical classification of bacteria and yeasts. We were impressed with the instrument’s workflow, which proved to be both efficient and easy. Best of all, no previous experience with MS is required, which makes it easier for us to integrate into a clinical laboratory. 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. Due to its broad range of applications, speed of analysis and low sample processing costs, the MBT sirius is ideally suited to our needs for microorganism identification."

Specifically, the MBT sirius measures highly abundant proteins that are found in all microorganisms. The characteristic patterns of these proteins are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive IVD-CE certified reference library (Figure 1). Typically, sample preparation takes an average hands-on time of ~20 seconds for one isolate and less than 20 minutes for 95 isolates. The time to result, including sample preparation, for 95 isolates and one quality control sample is typically less than 40 minutes.

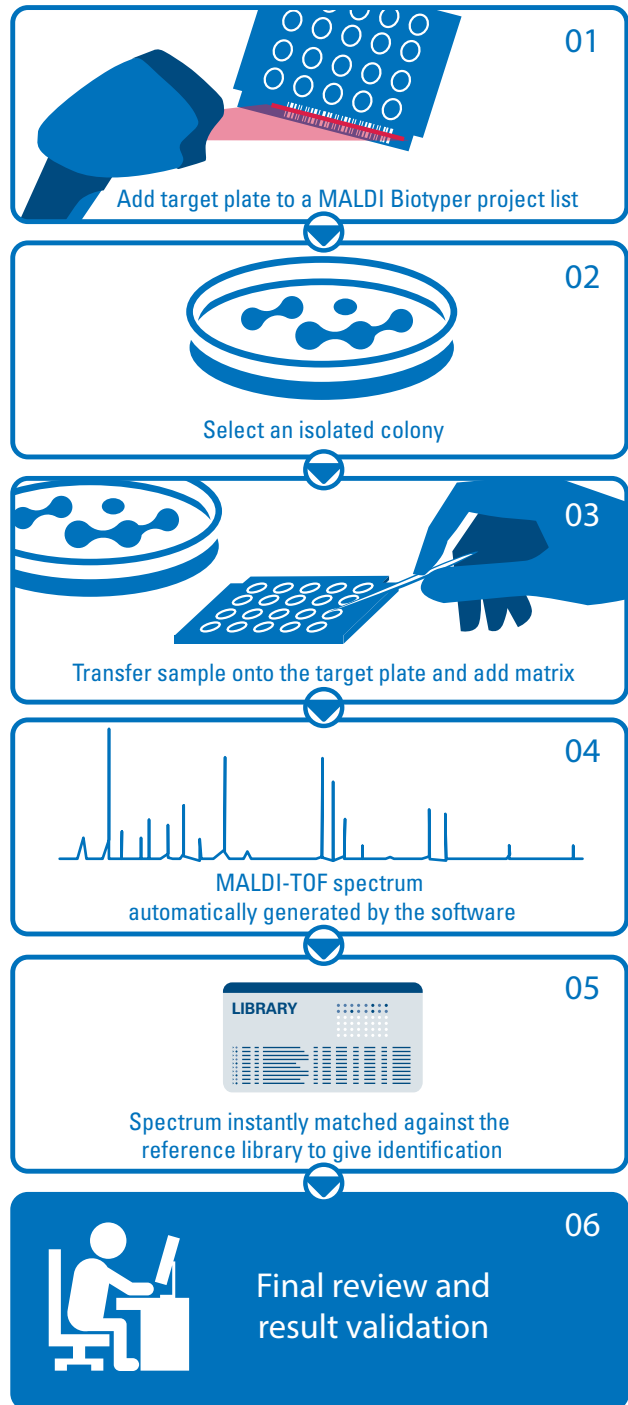



Figure 1: Typical workflow of the Bruker MALDI Biotyper sirius IVD solution



Bruker's dedicated microbiology software automates the process of acquiring the mass spectrum and performing the match against the extensive IVD-CE certified reference library. Continuous expansion of the MBT IVD reference library ensures that all clinically relevant microorganisms are easily identified, and more challenging organisms are included as well. The results, presented using a "traffic light" color scheme, are easy to interpret. Mr. Bussmann describes the impact of the MALDI Biotyper sirius's high-throughput capabilities on the MEDILYS laboratory service offerings:

"Classical biochemical techniques based on different metabolic characteristics of microorganisms typically take hours or even days, and often lack specificity. Using the MALDI Biotyper sirius, we can go from culture to identification within minutes."

Numerous studies have demonstrated the higher accuracy, faster time-to-result and lower costs provided by the Bruker MBT sirius compared to classical methods.^{1,2,3} The system offered MEDILYS the advantage of throughput speed, something which this busy hospital lab values in its work as reduced confirmation and identification times enable prompt optimization of antimicrobial therapy, thereby providing patients the best possible chance to recover from infectious disease.

The lab runs this type of analyses on about 33,000 samples per month, typically with a 48 to 72 hour turnaround time. Mr. Bussmann describes the benefits of the MALDI Biotyper sirius for the laboratory:

"We were impressed with the trial results. Our tests found the MALDI Biotyper sirius was the fastest, particularly for blood cultures.

And faster results mean that our clinicians can provide faster therapy to the patients. Timely alterations of therapeutic treatment are particularly vital. These improvements also enabled our laboratory personnel to reallocate their time to other key tasks, which was another advantage in cost effectiveness, as well as in time management for our staff members."



Scientists at the MEDILYS Laborgesellschaft with the small footprint MALDI Biotyper® sirius IVD System (visible at the back left hand side of the image)

Working with Bruker

The decision to invest in the Bruker MBT sirius was based on more than the instrument's performance. Bruker's commitment to customer service and the working relationship between the two organizations were other key elements of the decision-making process. Mr. Bussmann describes the installation and support services that MEDILYS received from Bruker after the purchase of the MBT sirius:

"We've had a very positive experience working with Bruker. In addition to the company's high-quality instruments, we enjoy working with Bruker because we have a great relationship with the applications support team. The installation went very smoothly, and it was easy to switch to this new technology. That's important in a busy clinical laboratory setting, because we need to get up and running quickly. Their engineers really understand the technology, and they're always willing to help."

"One year, our MALDI Biotyper system went down, and during the repair period, Bruker arranged for our target plates to be sent to Bruker for identification, so our lab could carry on working. We were hugely impressed by this level of service."

The support from the Bruker team after the installation of the MBT sirius has continued to leave a positive impression on the MEDILYS team. Mr. Bussmann describes how Bruker's emphasis on customer service influenced the clinical laboratory's decision to invest in the instrumentation:

"While the quality of the MBT sirius is obviously an important part of the decision, it was the integrity and collaboration of their technical support that made the decision easy. It's a very powerful combination. I would definitely recommend Bruker to my peers for these reasons."

Further developments

The MEDILYS team anticipates MALDI-TOF MS will play an increasingly important role in the laboratory's identification of microorganisms, particularly as new pathogens are found. The precision of microorganism identification is critically dependent on the number of reference library entries, and the continuous updating of the Bruker IVD-CE certified reference library is vital for both the laboratory's current and future needs. Mr. Bussmann describes the importance of these constant updates for laboratory personnel:

"Clinical laboratories need to stay ahead of the game if they're going to help patients by identifying evolving therapies. We see our need for the MBT IVD-CE Reference Library expanding as the spread of uncommon, yet prolific pathogens expand. The faster we can identify these organisms, the better the outcome for our clinicians and patients."

As clinical laboratories provide a wide range of laboratory procedures that assist in the diagnosis, treatment and management of disease and public health, the MEDILYS team sees a higher purpose for their investments in analytical technology. Mr. Bussmann explains:

"Our investment in MALDI-TOF MS technology must not only meet the needs of the hospital and the clinicians, but also the needs of the patients. Improvements in patient outcomes was the basis for our investment in the MALDI Biotyper sirius and we see that investment continuing in the future. We needed to future-proof our laboratory as much as possible. We don't want to invest in anything that's not going to be supported later. Our laboratory instrumentation and software applications need to work for our patients today and tomorrow as well. That's why a partner like Bruker is so vital to our work."

For more information about MEDILYS Laborgesellschaft, please visit <https://www.medilys.de/>

For more information about the Bruker MALDI Biotyper sirius IVD System, please visit <https://www.bruker.com/en/products-and-solutions/microbiology-and-diagnostics/microbial-identification-for-clinical-laboratories-ivd-ce/maldi-biotyper-sirius-ivd.html>

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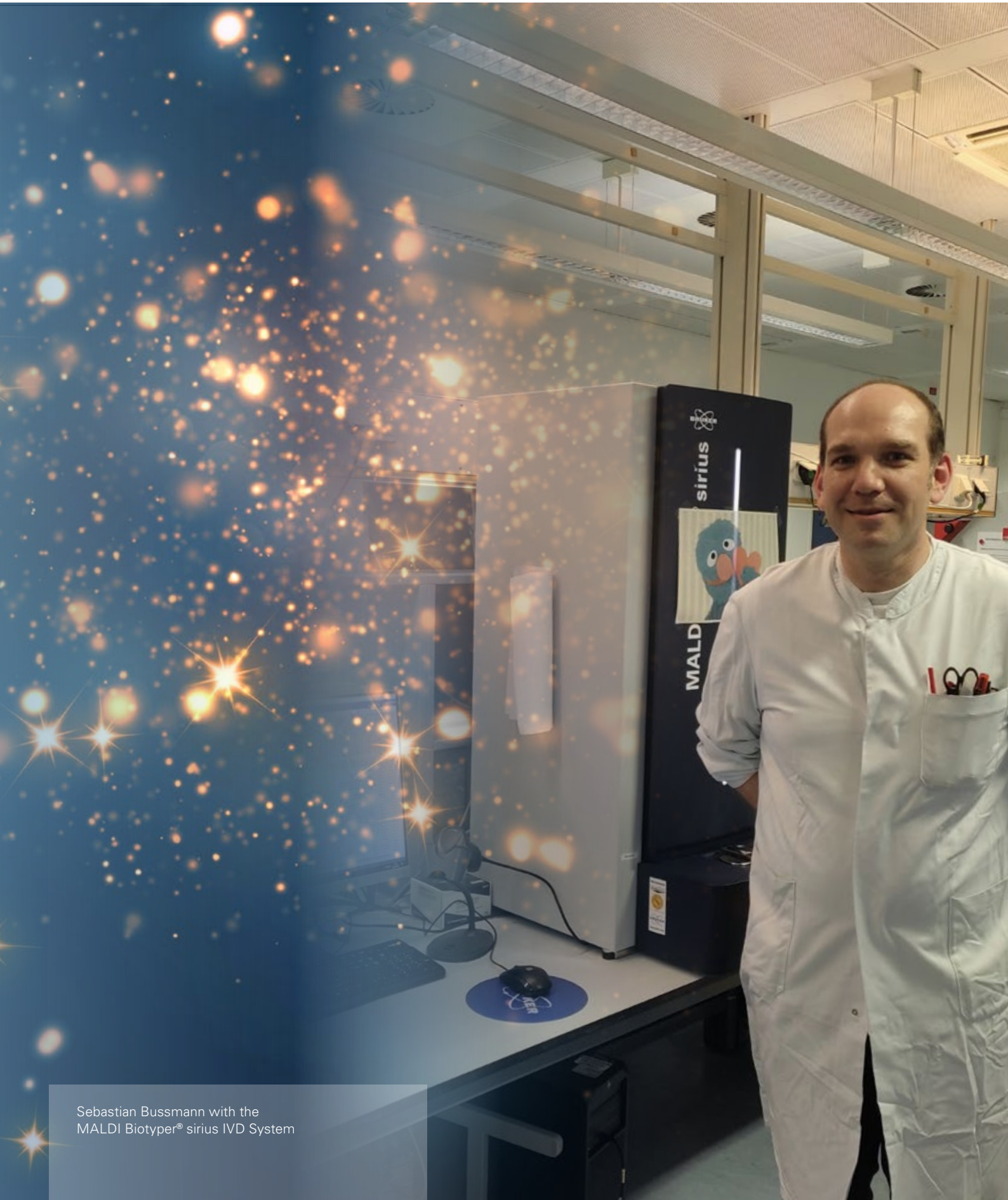
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² Evaluation of the Bruker MALDI Biotyper for Identification of Gram-Positive Rods: Development of a Diagnostic Algorithm for the Clinical Laboratory. Bettina Schulthess, Guido V. Bloemberg, Reinhard Zbinden, Erik C. Böttger, Michael Hombach. *Journal of Clinical Microbiology* Mar 2014, 52 (4) 1089-1097; DOI: 10.1128/JCM.02399-13

³ Multicenter Evaluation of the Bruker MALDI Biotyper CA System for the Identification of Clinical Aerobic Gram-Negative Bacterial Isolates. Matthew L. Faron, Blake W. Buchan, Josh Hyke, Neil Madisen, Jennifer L. Lillie, Paul A. Granato, et al. *PLoS ONE* Nov 2015, 10(11): e0141350. DOI: 10.1371/journal.pone.0141350



MALDI Biotyper® sirius



Sebastian Bussmann with the
MALDI Biotyper® sirius IVD System

Expert Insights

About MEDILYS Labgesellschaft mbH

MEDILYS provides a wide range of medical laboratory services for the hospitals of Asklepios Kliniken Hamburg GmbH, other hospitals in Northern Germany and for medical practices. In the fields of clinical chemistry, infection serology, hemostasiology, immunohematology and molecular genetics, the laboratory performs around 14 million analyses per year. In addition, they process around 360,000 submissions for bacteriological diagnostics. The experienced team of doctors, scientists and medical-technical assistants ensures the best possible medical laboratory care for customers around the clock, quality-oriented, reliable and fast.

About Bruker Corporation

Bruker is enabling scientists to make breakthrough discoveries and develop new applications that improve the quality of human life. Bruker's high-performance scientific instruments and high-value analytical and diagnostic solutions enable scientists to explore life and materials at molecular, cellular and microscopic levels. In close cooperation with our customers, Bruker is enabling innovation, improved productivity and customer success in life science molecular research, in applied and pharma applications, in microscopy and nanoanalysis, and in industrial applications, as well as in cell biology, preclinical imaging, clinical phenomics and proteomics research and clinical microbiology.

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