VDGH
Verband der Diagnostica-Industrie

VDGH-WHITEPAPER

Point-of-care testing

A trend-setting development in laboratory diagnostics

Readers are requested to note that this is a translation for information purposes only. The original German text is legally binding.

Content

To the point

Our healthcare system is facing increasing challenges - from the shortage of skilled workers to demographic change and funding bottlenecks.

New applications in diagnostics and therapy can help to overcome these challenges. These include, in particular, immediate diagnostics close to the patient, also known as point-of-care testing (POCT). It comprises laboratory diagnostic tests that are carried out in close proximity to the patient in terms of time and space. A key feature is the immediate derivation of diagnostic and therapeutic consequences

The potential of patient-oriented immediate diagnostics as a trend-setting form of laboratory diagnostics can only be exploited if its possible applications and significance as a solution option for existing challenges in the healthcare system are recognized and acknowledged. This position paper is intended to contribute to this.

— **Challenges in healthcare:** The fundamental challenges facing our healthcare system will not become any smaller in the future, but will remain or even increase. Laboratory diagnostics enables targeted therapies for patients and thus controls care processes. In this respect, laboratory diagnostics can generate important solutions for current and future challenges.

— **Areas of application:** POCT is already firmly established in many areas, particularly in inpatient emergency and intensive care medicine, in emergency medical services, but also in outpatient medical care. Patient-oriented testing is used to diagnose diseases (also in the sense of rapid exclusion diagnostics), monitor treatment progress and control therapy for acute and chronic diseases.

— **Advantages:** Regardless of the existence of a laboratory infrastructure, POCT enables treatment processes to be designed efficiently thanks to immediate diagnostic results. This opens up many options, such as avoiding unnecessary hospital admissions or re-presentation at the doctor's surgery. Adherence and patient satisfaction can be increased.

— **Future:** Technological progress and digitalization offer considerable opportunities to make patient-oriented immediate diagnostics even more useful for patient care. It is always a question of the various laboratory diagnostic approaches working side by side.

— **General conditions:** The current framework conditions and incentive systems do not promote the development of POCT. As a result, its use falls short of what is possible and sensible. In further discussions, it is important to identify starting points and create measures that can make better use of the benefits of POCT. Point-of-care testing is the key to more efficient, patient-oriented healthcare and an effective means of combating the shortage of specialists and cost explosion in the healthcare system.

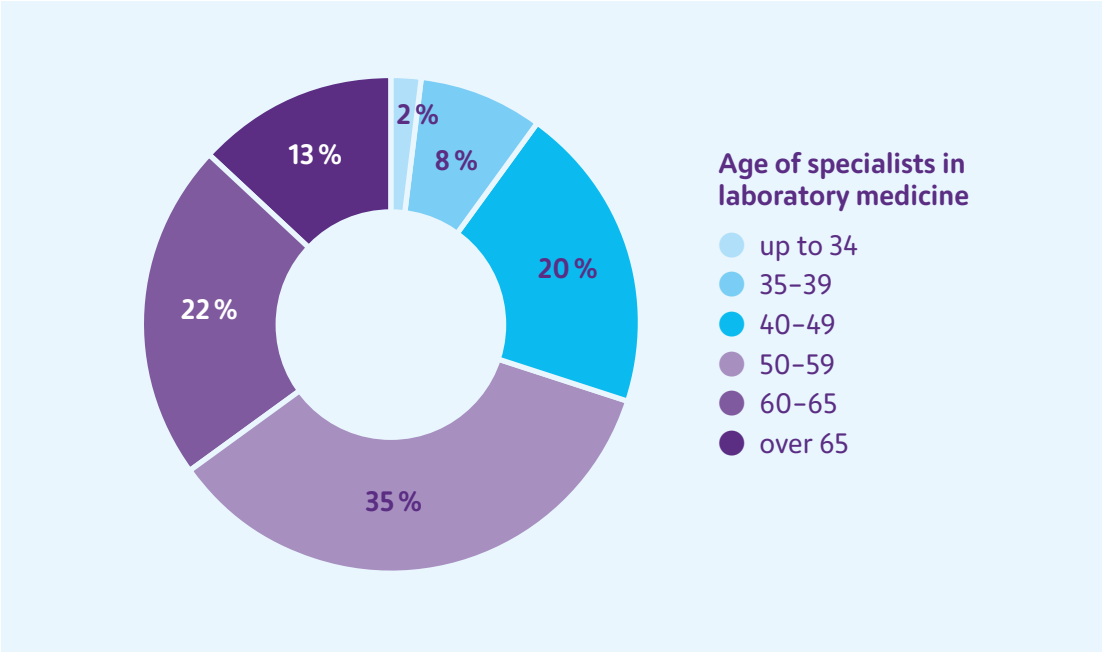
I. The challenges of healthcare: Why laboratory diagnostics are part of the solution

Healthcare systems around the world are facing major challenges. In developed countries such as Germany, medical care is increasingly being jeopardized by a shortage of specialists, rising demand for healthcare services and limited financial resources. A key driver here is demographic change, which is affecting individual countries and groups of countries differently. For European countries, the ageing of the population goes hand in hand with a growing demand for medical services, which is reinforced by the increase in diagnostic and therapeutic possibilities (medical progress). At the same time, the question arises as to how sufficient medical staff can be recruited. Financing in a health insurance system based on solidarity is reaching its limits in view of the already high tax and contribution burden. Last but not least, societies must also address the sustainability of healthcare in the face of advancing environmental and climate change.

The German healthcare sector is also becoming increasingly aware of and addressing these challenges. In particular, the competition for qualified personnel in the healthcare sector has reached a new level of urgency, and a shortage of skilled workers will be one of the key challenges in the healthcare sector in the coming decades. The dramatic nature of this development is exemplified by these publications:

- The Competence Center for Securing Skilled Workers at the German Economic Institute (IW) calculates that the healthcare sector is the industry most affected by the shortage of skilled workers in Germany. Around 47,400 positions could not be filled on average in 2023/2024[1]
- A study by management consultants PwC[2] predicts a dramatic shortage of up to 1.8 million workers by 2035, particularly in nursing and geriatric care. This would not only jeopardize medical care, but also Germany as a business location.
- The National Association of Statutory Health Insurance Physicians (KBV) sees an increasing discrepancy between supply and demand for doctors by 2030, which is not only the result of a lower number of doctors. A trend towards part-time work and employment instead of private practice will exacerbate the situation.[3]
- A study by the Robert Bosch Stiftung assumes that around 11,000 GP posts will be vacant in 2035. In almost 40 percent of rural districts, there is a risk of undersupply.[4]
- In an analysis of the age structure, the Professional Association of German Laboratory Doctors (BDL) shows that almost a third of all specialists in laboratory medicine are over 60 years old and as many as 72 percent are over 50.[5]

1 Frankfurter Allgemeine Zeitung 18.11.2024, p. 19: Most are missing in health
2 Skills shortage in the German healthcare sector 2022 - PwC [accessed 15.1.2025]
3 National Association of Statutory Health Insurance Physicians: KBV - Physician time shortage [accessed 15.1.2025]
4 Robert Bosch Stiftung: Health Centers for Germany | Robert Bosch Stiftung [accessed 15.1.2025]
5 Laboratory physician - Berufsverband Deutscher Laborärzte e. V. [Accessed 15.1.2025]



Source: Bundesärztekammer (2023) | Graphic: VDGH

These developments are also prompting decision-makers in politics and self-administration in the German healthcare system to take action. Different approaches to care are being discussed in order to ensure the provision of care in the future: These include, for example, the expansion of hospitals into regional care centers, primary care centers or the increased use of digitalization, including through telemedicine. However, it is not only structures that need to be changed in order to overcome the challenges. In view of personnel limitations, the extent to which tasks can be delegated within the healthcare professions and new players can be integrated must also be examined. All conceivable further developments in the healthcare system must be discussed from the perspective of patient orientation and the improvement of care.

Laboratory diagnostics is an indispensable part of modern healthcare. It accounts for no more than three percent of healthcare expenditure, but is the basis for 70 percent of all clinical diagnoses. This means that the medical decisions made on the basis of laboratory diagnostic results largely determine treatment procedures and the utilization of various service providers in the healthcare system. Laboratory diagnostics is therefore called upon to help identify solutions to the challenges facing our healthcare system

In-vitro diagnostics (“laboratory diagnostics”) takes various forms. They range from highly complex analyses, which are carried out in the laboratory doctor’s practice or in the central laboratory of the hospital, to self-application tests, which can be carried out by the lay-person. Point-of-care testing, the third most important application, lies somewhere in between. It is the focus of the following discussion.

II. Point-of-care testing: a clarification of terms

The terms "point-of-care testing" and "near-patient immediate diagnostics" have become established and are used synonymously in this paper. The term refers to in-vitro diagnostics that are used directly on the patient and provide rapid results.

These features of the POCT are essential[6]:

- Carrying out laboratory tests in close proximity to the patient
- Carrying out laboratory tests outside a central or satellite laboratory
- Simple or no sample preparation
- "Ready-to-use" reagents, e.g. as cassettes or "unit-use devices"
- Special measuring devices that are only intended and used for individual sample measurement
- No special laboratory medical qualification required for operating the measuring device
- Rapid availability of results
- Immediate derivation of a diagnosis or therapeutic consequences from the results

A key feature of point-of-care testing is the shortened time component. The so-called turnaround time (TAT) refers to the time between requesting the test and receiving the result. The TAT therefore includes the ordering of the laboratory diagnostic test, sample collection with allocation to the patient, sample transportation, laboratory receipt / sample acceptance, analysis and transmission and documentation of the findings. POCT has the clear advantage that the TAT can be greatly shortened - by eliminating the need for sample preparation, transportation, laboratory receipt and transmission of findings, which can take several days. POCT stands for the goal or the necessity of deriving the diagnosis immediately, identifying targeted therapies quickly and reliably, controlling treatment processes and, if necessary, initiating the transfer patients to necessary care areas.

POCT is a laboratory diagnostic test carried out by healthcare professionals in close physical and temporal proximity to the patient, but without being a self-test.

A key criterion of POCT is the immediate derivation of diagnostic and therapeutic consequences.

Point-of-care testing must be distinguished from tests for self-administration, so-called self-tests. Even though POC tests and self-tests have various things in common (often the rapid availability of the test result), they are fundamentally separate categories of in vitro diagnostics. The main difference is that in the case of self-tests, the use of the in vitro diagnostic (IVD) by the layperson is intended and legally permitted. Consequently, the self-administered IVD must also be suitable for laypersons in terms of handling and comprehensibility of the test result. This is guaranteed by detailed legal requirements for Europe-wide product approval (placing on the market) of corresponding tests. Prominent examples of self-tests are the regular measurement of glucose levels (blood sugar) by diabetes patients or the corona test (qualitative detection of the SARS-CoV-2 virus). Self-tests are not included in this analysis.

6 Junker, R., Petersmann, A., & Luppa, P. B. (2017). Relevance of POCT in healthcare. POCT-Patient-oriented laboratory diagnostics, 9-17.

In contrast, POC tests are always assigned to professional use. POC tests are also subject to specific regulations on placing on the market and market surveillance, which are laid down in European law in Regulation (EU) 2017/746 on in vitro diagnostic medical devices. In POCT, sampling and analysis is carried out by healthcare professionals. POCT often, but not always, requires an analyzer. In addition to the provisions of the EU Regulation, further specifications on POCT can be found in the "Guideline of the German Medical Association for Quality Assurance of Laboratory Medical Examinations - (Rili-BÄK)" and in DIN-ISO 22870.

III. Important areas of application for the POCT

POCT offers solutions for a variety of clinical issues and can improve diagnostic and therapeutic procedures in different areas of healthcare. Many of the diagnostic parameters for which POCT applications are available are not limited to a single area of healthcare delivery. Many tests are used in general practice as well as in emergency rooms, clinics or other areas to enable timely decisions. In the following, examples are presented that demonstrate the variety of possible applications of patient-oriented laboratory diagnostics from POCT.

Inpatient sector: when every minute counts

POCT is particularly important in anesthesia, intensive care and emergency medicine. Here, the rapid availability of measurement results and thus the rapid, adequate and targeted treatment of the patient is particularly important. Rapid laboratory diagnostics are essential for acute life-threatening conditions. Inpatient care with a highly differentiated hospital sector is therefore addressed. Emergency laboratory medicine is extensive and diverse. It is included in a large number of national and international medical guidelines and hospital checklists. The literature contains differentiations regarding the urgency for the determination of laboratory parameters based on the turnaround time (e.g. max. 15 minutes, max. 60 minutes, max. four hours[7]), which in turn determine the laboratory medicine options (POCT or central hospital laboratory).

In the inpatient setting, however, it is not just about rapid diagnostics in an emergency. Immediate diagnostics close to the patient also play an important role in monitoring (vital) parameters during operations and other medical procedures, as well as monitoring progress and therapy during the inpatient stay.

Rapid microbiological diagnostics also have their own importance. Germs that cause diseases (pathogens) cannot be easily detected when patients come into hospital. However, they can pose a considerable threat to all patients and hospital staff.

"For the determination of laboratory parameters in patients with a highly pathogenic disease, point-of-care laboratory devices are the ideal solution, precise and easy to handle."

Stefan Boxnick, Ltd. coordinator of the special isolation ward at Düsseldorf University Hospital

7 Position paper of the DGKL and the DIVI on the requirements for laboratory medicine in intensive care and emergency medicine [accessed 15.1.2025].

Risk-based or general admission screenings counteract this. They are an important basis for planning targeted treatments, for deciding on isolation measures and for the hospital's hygiene management.

These are the main areas of application for patient-oriented immediate diagnostics in hospitals:

— Emergency room
— Outpatient clinics
— Shock room, operating theater, recovery unit
— care unit
— Normal ward

Blood transfusion: safety at the patient's bedside

In Germany, 54 units of blood are transfused per 1,000 inhabitants every year. A very important point-of-care test is blood grouping prior to a blood transfusion. It is necessary in order to check the compatibility of the patient's blood with the donor's blood. For this purpose, freshly drawn blood from the recipient must be tested immediately before the transfusion. Optionally, the canned blood is also compared again with the declared blood group. Blood grouping is mandatory for transfusion in an emergency as well as for a planned blood transfusion and is the central instrument for protecting the patient from incompatibilities and potentially fatal mix-ups. The test with the so-called bed-side card can be carried out directly at the patient's bedside without additional laboratory equipment and without refrigeration and can be archived in the patient file.

Monitoring heparin therapy: precision in real time

The activated clotting time (ACT) is another example of the many possible applications of POCT in the inpatient sector. ACT is a coagulation parameter that can be determined close to the patient. ACT is measured close to the patient and in real time if the performance of coagulation tests in the laboratory is too time-consuming. ACT is mainly used to monitor the suitability of heparin therapy during invasive vascular procedures such as cardiopulmonary bypass and cardiac catheterization.

Rescue service: Rapid assistance begins even before the hospital

A quarter of all hospital cases are admitted by ambulance[8]. In total, more than 13 million calls are made to the public rescue service in Germany every year, of which around 62 percent are emergency rescues. While the average time to arrival of the rescue vehicle (e.g. ambulance) at the person seeking help is 8.7 minutes, the average prehospital time (time from requesting help to reaching the hospital) is 52 minutes.[9]

POCT provides important initial information about the patient's condition until they reach the hospital. For example, oxygen levels in the blood, electrolytes, blood sugar, cardiac stress or indications of internal bleeding can be checked directly on site. This information helps to make life-saving decisions before the patient arrives at the hospital. The diagnostic markers form a basis for decisions on therapeutic and organizational consequences for care. Preclinical POCT thus ideally supplements or relieves the burden on emergency analysis in hospital.

Medical practice: Determine relevant laboratory values in the presence of the patient

The use of immediate diagnostics close to the patient also has a wide range of benefits in the care provided by SHI-accredited physicians. Decisions can be made quickly on the basis of promptly available diagnostic values, e.g. for critical coagulation values (INR value), inflammation/infection values (e.g. CRP, procalcitonin) or NT-proBNP values for the exclusion or monitoring of heart failure. POCT also quickly provides vital information for acute decisions, e.g. when determining troponin. Troponin is a protein that is released into the blood in the event of damage to the heart muscle, such as a heart attack. The earlier a heart attack is detected and treatment started, the better the prognosis. The test is not only used in emergency rooms and intensive care units, but also in private practice, e.g. by cardiologists or GPs, so that a decision such as referral to hospital can be made quickly in the event of acute heart problems. This also reduces the rate of misdiagnosis, e.g. in the case of silent infarctions or atypical symptoms.

"In pre-hospital emergency medicine, we are dealing with patients we don't know, for whom we have no medical records and who are often unable to give us much information. It is therefore important to find out as much as possible about the patient in the first few minutes in order to make a quick diagnosis and initiate life-saving measures. This is where point-of-care blood gas analysis, alongside other diagnostic procedures such as ultrasound, is of paramount importance. This enables the DRF Luftrettung medical crews, for example, to provide patients with the best possible care at the scene and to make an even better choice of suitable destination hospital."

Dr. Bernd Landsleitner, Chief Helicopter Doctor for the Southeast Region of DRF Luftrettung

8 Rößler M. et al. (2024) Regional differences, recurrent utilization and costs of emergency medical services in Germany, ePAper of the BARMER Institute for Health Systems Research,

9 BASt - BASt reports - Analysis of the performance level in the rescue service for the years 2020 and 2021 [accessed 15.1.2025]

A different, but at least equally strong benefit aspect of POCT in the doctor's office lies in making treatment decisions in partnership, avoiding unnecessary reappointments and increasing patient satisfaction. This is illustrated by the following areas of application.

People with diabetes: making treatment success immediately visible

Around 11 million people in Germany have diabetes mellitus, and more than half a million adults develop the disease every year. In addition, there are an estimated 2 million previously undiagnosed cases. All people with type 1 diabetes (approx. 370,000) and more than 1.5 million type 2 diabetics are treated with insulin[10]. The burden of disease and the economic costs, also due to the large number of complications and secondary diseases, are enormous.

"Immediate diagnostics close to the patient helps the patient so that they only have to visit the practice once and can leave with a concrete result. It helps the treating doctor."

Dr. Cornelia Woitek, Chairwoman of the Professional Association of Registered Diabetologists Saxony e.V.

The possibility of determining the glucose level by self-measurement provides people with diabetes with information, supports health behavior and enables those affected to live well with their disease. Nevertheless, regular visits to a specialist family doctor or registered diabetologist essential. Regular measurement of the HbA1c value is medically indispensable for insulin-treated diabetes patients and strengthens compliance, as the patient learns whether their efforts to adopt healthy behavior or use insulin are successful. HbA1c is a "long-term blood glucose value" that allows conclusions to be drawn about the quality of blood glucose control over the last eight to twelve weeks. By measuring HbA1c as a POCT directly at the doctor's visit, the patient does not have to come back to the practice after the consultation to discuss the laboratory value. This saves unnecessary time and relieves the burden on doctors' surgeries, which are already full.

Informed decision-making: Testing before using antibiotics

Everyone probably knows the situation from their own experience: cough, cold, sore throat, fever. We drag ourselves to the doctor's surgery with a heavy cold, a "flu-like infection", hoping for relief and wanting to be given some medication. This is the reality millions of times over in GP surgeries and pediatric practices

However, antibiotics only help against bacteria and the infections they cause. Antibiotics are ineffective against viral infections, which include most colds, but are still frequently prescribed. A reliable distinction between bacterial and viral infections is made using laboratory diagnostic markers (CRP, procalcitonin). These markers can be determined in the

10 DDG Factsheet: Deutsche Diabetes Gesellschaft e.V. [Accessed 15.1.2025]

laboratory, the patient must then be called back to the GP or receive the laboratory results by telephone a day later. The alternative prescription of an antibiotic with the proviso that it should only be taken if a bacterial infection is confirmed is also an auxiliary solution.

POCT applications are available for CRP and procalcitonin for immediate use in the doctor's surgery. They enable time-critical and correct medication decisions to be made. The responsible handling of antibiotic prescriptions is effectively supported.

The benefits of POCT in the area of respiratory pathogens have been intensively investigated: Studies have shown that rapid PCR testing for respiratory pathogens leads to a reduction in hospital admissions[11] and a shorter hospital stay[12] as well as fewer doctor visits and referrals to specialists due to early diagnosis[13]. Patients who tested positive were also prescribed more antivirals (which are most effective within 2 to 5 days of symptom onset)[14]. In addition, patients who test negative are prescribed significantly fewer antibiotics, which leads to less antibiotic resistance[15,16,17].

The fight against antibiotic resistance: Diagnosis before therapy

The excessive or unindicated use of antibiotics is ineffective at best. However, it causes unnecessary expenditure on medicines and leads to a dramatic problem. Bacteria develop resistance to antibiotics. If this occurs, the range of effective drugs becomes smaller and expensive. In the worst case, no effective antibiotic is available even if the pathogen is known exactly. One of the main reasons for the increase in such resistance is the inappropriate use of antibiotics. The World Health Organization (WHO) considers the increasing occurrence of antibiotic resistance worldwide to be one of the greatest threats to human health. A

„Laborchemische Point-of-Care-Untersuchungen sind entscheidend für die gezielte Behandlung fieberhafter Infektionen. Die Unterscheidung zwischen viralen und bakteriellen Infektionen beeinflusst die Entscheidung zur Antibiotikagabe erheblich. Insbesondere bei Kindern sollten Antibiotika gezielt und sparsam eingesetzt werden, um Nebenwirkungen zu vermeiden, Resistenzen zu minimieren und Lieferengpässe zu reduzieren."

Dr. Frederik Lörsch, Kinder- und Jugendmedizin mit Schwerpunkt Neonatologie, Mannheim

11 You, J. H., Tam, L. P., & Lee, N. L. (2017). Cost-effectiveness of molecular point-of-care testing for influenza viruses in elderly patients at ambulatory care setting. PLoS One, 12(7), e0182091.

12 Garvey, M. I., Wilkinson, M. A., Bradley, C. W., Biggs, M., Reddy-Kolanu, V., Osman, H., ... & Holden, E. (2019). Impact of a PCR point of care test for influenza A/B on an acute medical unit in a large UK teaching hospital: results of an observational, pre and post intervention study. Antimicrobial Resistance & Infection Control, 8, 1-8.

13 Lingervelder, D., Koffijberg, H., Kusters, R., & IJzerman, M. J. (2021). Health economic evidence of point-of-care testing: a systematic review. PharmacoEconomics-Open, 5, 157-173.

14 Khalid, T. Y., Duncan, L. J., Thornton, H. V., Lasseter, G., Muir, P., Toney, Z. A., & Hay, A. D. (2021). Novel multi-virus rapid respiratory microbiological point-of-care testing in primary care: a mixed-methods feasibility evaluation. Family Practice, 38(5), 598-605.

15 Benirschke, R. C., McElvania, E., Thomson Jr, R. B., Kaul, K. L., & Das, S. (2019). Clinical impact of rapid point-of-care PCR influenza testing in an urgent care setting: a single-center study. Journal of clinical microbiology, 57(3), 10-1128.

16 de Lusignan, S., Dorward, J., Correa, A., Jones, N., Akinyemi, O., Amirthalingam, G., ... & Hobbs, F. R. (2020). Risk factors for SARS-CoV-2 among patients in the Oxford Royal College of General Practitioners Research and Surveillance Centre primary care network: a cross-sectional study. The Lancet Infectious Diseases, 20(9), 1034-1042.

17 Dale, A. P., Ebell, M., McKay, B., Handel, A., Forehand, R., & Dobbin, K. (2019). Impact of a rapid point of care test for influenza on guideline consistent care and antibiotic use. The Journal of the American Board of Family Medicine, 32(2), 226-233.

recently published study[18] assumes that more than 39 million people could die worldwide by 2050 as a result of resistance.

The increased and targeted use of diagnostics can contribute to the responsible use of antibiotics by doctors and demonstrably reduce prescriptions. The greatest leverage to be achieved lies in the differentiation between bacterial and non-bacterial infections in the sense of rapid exclusion diagnostics using POCT. The importance of testing is also reflected in the German government's antibiotics strategy (DART 2030). It emphasizes the importance of rapid, comprehensive microbiological diagnostics.

"The spread of STIs is a major problem and the numbers are rising worldwide. If we want to have a chance of reducing infections, a diagnosis and treatment decision must be made when a patient is still on site. Not only infections, but also serious secondary diseases can be avoided."

Prof. Dr. Norbert H. Brockmeyer,
President of the German STI Society

Sexually transmitted diseases: more protection, less risk

According to WHO estimates, sexually transmitted infections (STIs) cause one million infections worldwide every day[19]. They often show no symptoms and can cause serious illnesses such as inflammation of the abdomen, testicles or epididymis, infertility or tumors caused by papilloma viruses[20]. POCT increases the chances of timely and successful treatment and ultimately reduces the risk of further infections[21]. Rapid PCR tests can detect several pathogens at the same time, enabling targeted antibiotic therapy and improving the treatment of patients with infections[22]. In addition, POCT leads to a significant reduction in the overtreatment of women without infections[23].

Special case pandemic

The COVID-19 pandemic in the early 2020s showed that viral infections can develop into a global challenge. Detection methods for the SARS-CoV-2 coronavirus were developed at full speed by the diagnostics industry and made available worldwide by the millions. In the course of the pandemic, sequencing technologies and tests to differentiate between dif-

18 Naghavi, M., Vollset, S. E., Ikuta, K. S., Swetschinski, L. R., Gray, A. P., Wool, E. E., ... & Dekker, D. M. (2024). Global burden of bacterial antimicrobial resistance 1990-2021: a systematic analysis with forecasts to 2050. The Lancet, 404(10459), 1199-1226.

19 Sexually transmitted infections (STIs) who.int [accessed 15.1.2025]

20 Sexually transmitted diseases symptoms | Deutsche Aidshilfe [accessed 15.1.2025]

21 Guy, R. J., Natoli, L., Ward, J., Causer, L., Hengel, B., Whiley, D., ... & Kaldor, J. M. (2013). A randomized trial of point-of-care tests for chlamydia and gonorrhoea infections in remote Aboriginal communities: Test, Treat ANd GO-the "TTANGO" trial protocol. BMC infectious diseases, 13, 1-9.

22 May, L., Ware, C. E., Jordan, J. A., Zocchi, M., Zatorski, C., Ajabnoor, Y., & Pines, J. M. (2016). A randomized controlled trial comparing the treatment of patients tested for chlamydia and gonorrhea after a rapid polymerase chain reaction test versus standard of care testing. Sexually Transmitted Diseases, 43(5), 290-295.

23 Gaydos C. A., Ako M. C., Lewis M., Hsieh Y. H., Rothman R. E., Dugas A. F. (2019). Use of a rapid diagnostic for Chlamydia trachomatis and Neisseria gonorrhoeae for women in the emergency department can improve clinical management: report of a randomized clinical trial. Ann. Emerg. Med. 74 (1), 36-44.

ferent virus variants (mutations) as well as point-of-care tests in the form of rapid antigen tests and nucleic acid-based direct detection (PCR tests) were developed. The various test applications by the medical laboratory, by trained staff in healthcare facilities and by the medical layperson were part of the national testing strategy. They made an effective contribution to containing the pandemic. Together with the self-tests, the patient-oriented immediate diagnostics also helped to relieve laboratory capacities.

View of Europe

Other countries in Europe are also struggling with challenges in their healthcare systems and are using POCT to tackle them.

— In the UK, low-threshold services to prevent sexually transmitted diseases are funded by the NHS. Using a POCT instead of centralized testing resulted in cost savings of around GBP 124.[24]

— Countries such as Norway, the Netherlands, Switzerland and Denmark are pioneers in the use of CRP as a near-patient immediate diagnostic test. They are considered reference countries in the fight against antibiotic resistance, as CRP-POCT has been shown to reduce antibiotic prescribing in patients with symptoms of lower respiratory tract infections without compromising patient safety or satisfaction.[25]

— In Switzerland, there are around 7000 medical practices that carry out many primary care analyses as part of on-site analysis and have received a special tariff for this.[26] The costs are reimbursed by the Swiss healthcare system. The costs for laboratory services are published in the analysis list of the Federal Office of Public Health (FOPH) and apply to all insured persons throughout Switzerland.

24 Whitlock, G. G., Gibbons, D. C., Longford, N., Harvey, M. J., McOwan, A., & Adams, E. J. (2018). Rapid testing and treatment for sexually transmitted infections improve patient care and yield public health benefits. International journal of STD & AIDS, 29(5), 474-482.

25 Llor, C., Plate, A., Bjerrum, L., Gentile, I., Melbye, H., Staiano, A., ... & Hopstaken, R. (2024). C-reactive protein point-of-care testing in primary care-broader implementation needed to combat an-timicrobial resistance. Frontiers in Public Health, 12, 1397096

26 Requirements for POCT in Switzerland - healthcare-in-europe.com [accessed 15.1.2025]

IV. POCT and quality of healthcare

As illustrated by examples, patient-oriented immediate diagnostics are used in many areas of healthcare in a beneficial way. Nevertheless, this form of laboratory diagnostics is sometimes met with reservations regarding the quality of testing. These are usually based on the technical performance of these tests. However, concerns can be relativized in several respects.

Diagnostics stands and falls with quality assurance and analytical quality. Appropriate evidence is therefore crucial for the acceptance and use of POCT

Point of care testing is subject to the regulations of the "Guideline of the German Medical Association for the Quality Assurance of Laboratory Medical Examinations" (Rili-BÄK) and is therefore quality-assured. In particular, the special part B1, 2.1.5 RiLiBÄK is relevant. Essential components of quality assurance are internal precision and accuracy control. Internal quality assurance regulations apply to POCT with unit-use reagents. Measuring systems often include an integrated check of the device function, which prevents incorrectly issued measurement results. In certain constellations, an individual control sample measurement must also be carried out at least once a week. The results must be documented. In addition, participation in round robin tests is recommended.

The key criteria for test quality are the sensitivity and specificity of the in vitro diagnostic. In simple terms, these describe the probability with which a diseased person is actually recognized as such (true positive) or a non-diseased person is recognized as such (true negative). A test performance with 100 % sensitivity and 100 % specificity is never statistically feasible. Furthermore, a statement that a test with a sensitivity of, for example, 99.49% is superior to a test with a sensitivity of 99.45% is a partial observation that does not necessarily have clinical relevance.

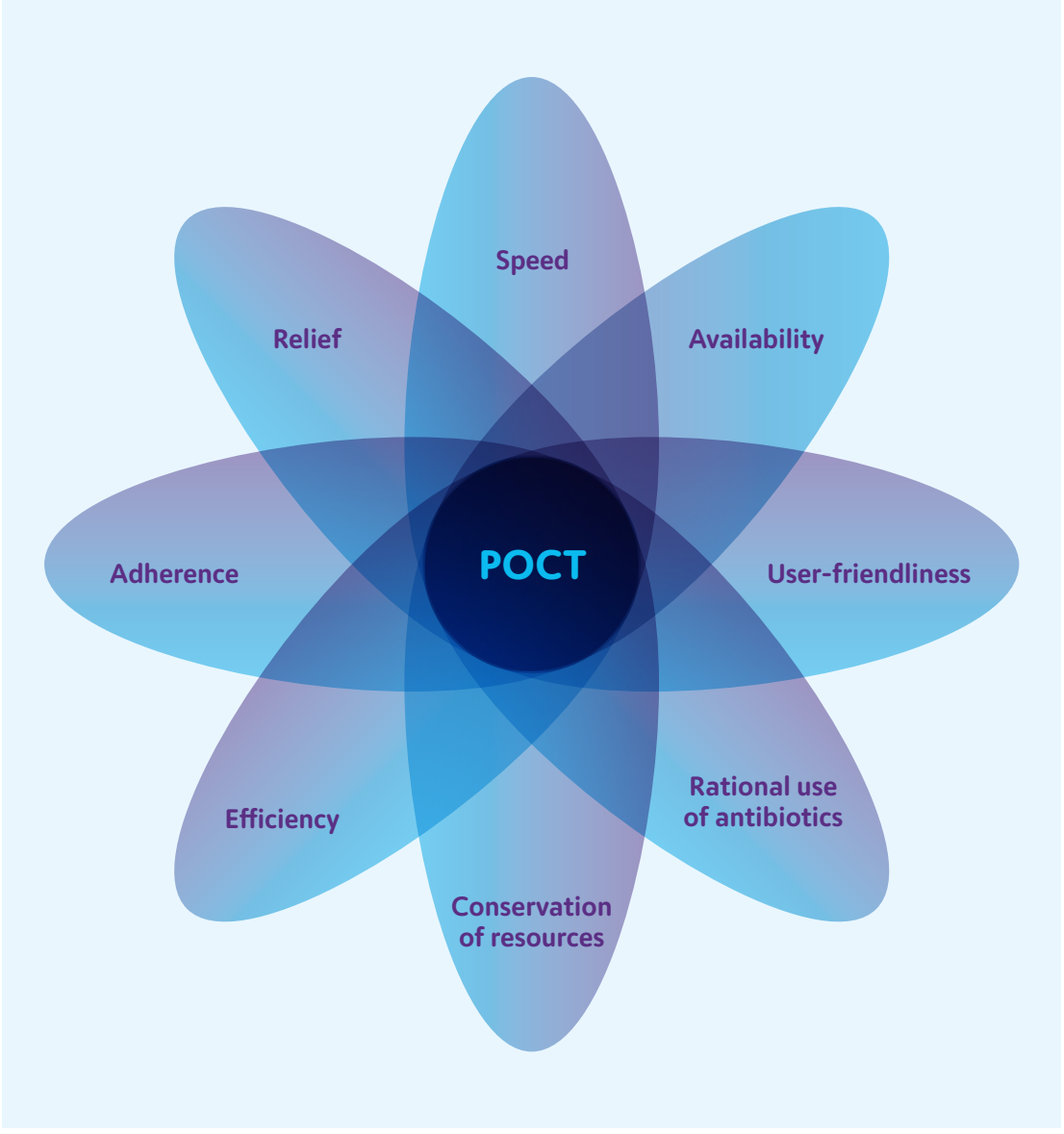
Narrowing the focus to purely technical quality falls short of the mark. This is because the smaller number of work steps and transfer points required makes POC diagnostics less susceptible to quality-relevant errors[27]. Another decisive factor is which diagnostic values are used to derive therapeutic consequences and when. For example, it is important to have a reliable HbA1c value promptly as part of the monitoring of diabetes in the doctor-patient consultation. It is important to note that healthcare does not improve simply because a minimally more precise measured value is generated. The decisive factor is the integration of the diagnostic information into the care processes. In many cases, rapid availability with assured quality is a more important aspect in order to leverage efficiency potential.

There are other quality criteria, such as the error tolerances for a measurement. These specifications are not to be understood as static, but are subject to adjustments. For example, the specifications for error tolerances when measuring the HbA1c value (a measured variable for long-term blood glucose) have been tightened in recent years by corresponding changes to the guidelines of the German Medical Association for the quality assurance of laboratory medical examinations.

27 Position paper of the DGKL and the DIVI on the requirements for laboratory medicine in intensive care and emergency medicine [accessed 15.1.2025].

The accuracy of test results from near-patient immediate diagnostics is quite comparable with the results of laboratory analyses. This is also shown by the report of the European Network for Health Technology Assessment (EUnetHTA) on the use of CRP tests as near-patient immediate diagnostics for the appropriate use of antibiotics in primary care for acute respiratory infections. The report shows that "patient safety and quality are ensured".[28]

V. What advantages does POCT offer?



Graphic: VDGH

Point-of-care testing has already established itself in various areas of healthcare. The technical possibilities of POCT have steadily improved and expanded in recent years and are reflected in ever more compact device sizes, improvements in usability and, in particular, in the speed and accuracy of the analysis. The main benefits of POCT are summarized below.

28 EUnetHTA Report - C-reactive protein (CRP): Measurement in acute respiratory infections in primary care

Speed/time saving

The outstanding feature of the POCT is that the test result is available within minutes. This means that a reliable diagnosis can be made and the consequences of treatment can be determined immediately and without unnecessary loss of time. This is essential for patients with acute life-threatening or organ-threatening conditions. However, the time factor also plays an important role in the diagnosis/exclusion diagnosis and monitoring of disease progression and therapy control and adjustment for other clinical pictures.

"POCT laboratory systems are supportive and save resources, as the patient can be discharged home or to the nearest suitable target hospital on the same day with a fast, reliable and further diagnosis and does not have to return to their own practice or medical center the next day or two for a laboratory consultation and the resulting delay in initiating treatment."

Boris Chr. Buck, general practitioner from Gröbenzell

Availability

The POCT can be carried out in the immediate vicinity of the patient and does not require the availability of a central laboratory or a laboratory doctor's practice. The easy availability and technical autonomy of POCT is indispensable in certain situations (emergency services, emergency room). However, it is also advantageous where the provision of laboratory capacities is more difficult (rural areas). The significance of POCT is even more different in countries and areas that do not have the healthcare infrastructure we are familiar with. There, rapid tests and a mobile laboratory are often the only diagnostic care available and are therefore indispensable.

Easy to handle

By using ready-to-use reagents and performing the test in a closed system, handling the POCT is simple and safe. A medical qualification is not required to operate the devices. The elimination of various work steps (sample preparation, pipetting, sample transportation, transmission of results) means that testing is faster. In addition, the number of interfaces required is reduced - and with it potential sources of error.

Saving

As point-of-care testing can be carried out by healthcare professionals, a larger number of professionals can be involved. Doctors' time does not have to be used or can be reallocated, which reduces the overall burden on medical work. The elimination of sample transportation, but also the fact that POCT avoids the patient having to return to the doctor's surgery, contribute in principle to the careful use of environmental resources (e.g. reduced CO2- emissions). However, this is offset by legal requirements that require more effort for certain POC tests (disposable packaging).

Reduction in unnecessary visits to the doctor/referrals/hospital admissions

POCT makes it possible to combine a medical consultation with the availability of a laboratory result during a doctor's visit. This reduces unnecessary visits to the doctor. Patients and practitioners benefit equally. Early diagnosis can also lead to a reduction in hospital admissions and the length of stay there, as well as a reduction in referrals to specialists. This effect is particularly well documented for the impact of rapid infection diagnostics.

Rational antibiotic therapy and infection control

Immediate patient-oriented diagnostics, which are used in the case of infections, are of particular importance for our healthcare system. Rapid exclusion diagnostics (bacterial or viral pathogens) not only benefits the affected patient. It also supports the rational use of antibiotics by general practitioners and in hospitals. The rational use of antibiotics is in turn the key to avoiding feared antibiotic resistance. And finally, POCT makes a significant contribution to taking appropriate measures (e.g. isolation) through the rapid detection of an infection, thereby containing the spread of pathogens and protecting the population.

Adherence

Adherence is understood as the adherence to jointly agreed treatment goals by the patient and the practitioner. This understanding has largely replaced the concept of compliance (adherence to therapy; unilateral adherence to therapy guidelines by the patient). Treatment decisions made in partnership lead to increased adherence. Trust in the doctor's treatment decision grows. If the POCT result at the GP visit shows that there is a viral infection, the decision not to use antibiotics is fact-based and immediately comprehensible. If the HbA1c value is not within the target range, the diabetologist discusses with the patient the appropriate and immediate behavioral adjustments.

Patient satisfaction

It is not only therapy decisions made in partnership that increase patient satisfaction. The rapid availability of laboratory results is perceived positively as a service orientation of the medical practice. Avoiding a return visit to the practice "just" to discuss a laboratory result saves the patient time and money. This is particularly beneficial for working people, single parents and people at a higher age. If POCT eliminates the need for a specialist referral or hospital admission, this also contributes to patient satisfaction.

VI. The system perspective: POCT's contribution to solutions

The specific challenges of our healthcare system and the advantages (benefits) of patient-oriented immediate diagnostics have been outlined in the previous sections of this paper.

More urgent than ever is the need for a counter-image to the progressive overburdening of the healthcare system and a cost-containment policy that merely addresses the symptoms. A coherent counter-image includes the following central perspectives

— the focus on efficient supply processes and

— the critical review of rigid supply structures.

Efficient supply processes

In view of the increasing shortage of specialists in the medical and nursing fields, an ageing population with a growing need for healthcare services and limited financial resources, the question of efficiency will determine the scope and intensity of healthcare provision more than ever before. Without process innovations, it will not be possible to maintain needs-based healthcare.

With the benefits described above, POCT can make a significant contribution to healthcare in the future. In addition to special analyses, high-throughput analyses and routine diagnostics, which for reasons of efficiency should ideally be performed in a central laboratory or laboratory practice, immediate diagnostics close to the patient in specific constellations has the potential to make more efficient use of time, personnel and financial resources.

— In inpatient treatment, POCT enables rapid diagnosis and, based on this, targeted treatment with improved patient management (emergency room, intensive care, ward) and close monitoring of the success of treatment. In this sense, POCT is also used as step-by-step diagnostics, which can rule out diseases with the help of diagnostic decision rules/scores and make further examinations unnecessary. This can avoid unnecessary hospital admissions, shorten waiting times in individual areas and achieve shorter inpatient stays overall

— Time" as a resource for the attending physician will also become increasingly important in the outpatient sector. This is where POCT makes a significant difference, as it reduces patient re-presentations and simplifies practice management

— In technical terms, existing POCT applications are undergoing continuous further development, which minimizes or barely reveals any differences in the quality of results compared to large laboratories. In addition, new analysis options are being developed on POCT systems, e.g. the detection of circulating tumor DNA or the nucleic acid-based detection of a large number of pathogens of respiratory and gastrointestinal diseases including resistance markers in one act (multiplex PCR). Overall, a broad spectrum of quality-assured POCT is already available today

— The integration of patient-oriented immediate diagnostics into corresponding information systems, e.. in hospitals, works. This requirement is also becoming increasingly important in view of scarce resources.

Digitalization as a game changer

In conjunction with the possibilities of digitalization, developments in the field of POCT are progressing continuously. New technologies and innovative approaches are opening up further potential to improve the efficiency and quality of medical care. The exponential growth of healthcare data combined with advanced digital technologies is driving new care models that could not only increase efficiency, but also enable a more flexible and sustainable healthcare system. Devices are becoming increasingly handy, faster and in some cases can analyze several parameters simultaneously. The operation of POCT devices is intuitive and simple, for example through the use of closed cassette systems. Digital and networked POCT solutions make it possible to record diagnostic data directly at the point of patient care and process it immediately. Today, values can already be displayed via interfaces in the practice or hospital software, in the electronic patient file or on the patient's own smartphone. This immediate availability supports rapid decision-making, reduces the burden on staff and reduces the risk of transmission errors. Platforms that not only integrate diagnostic tests but also communicate with health apps can also optimize workflows, improve patient care and reduce the workload on staff.

"Laboratory services are increasingly being withdrawn from hospitals and centralized. The longer transport routes significantly increase the return times for results. To ensure the rapid availability of emergency parameters with high quality standards for patient care, tests on POCT devices are indispensable. If these devices are connected to POCT software that handles a lot of the legally required documentation and archiving and monitors the RiliBÄK in Germany, the burden on hospital staff is significantly reduced."

Jürgen Handl, Point-of-Care Manager
KH-IT Synlab Holding Deutschland

Digitization in the point-of-care area is of crucial importance as it enables efficient, standardized and transparent patient care. The networking of POC devices via a central middleware offers decisive advantages in terms of compliance, auditability, user management and accreditation. At the same time, this networking contributes to cost savings by avoiding the need to connect each device individually to a laboratory information system.

Finally, the integration of artificial intelligence or machine learning can also make a significant contribution to analyzing complex data in the context of patient-oriented immediate diagnostics and delivering precise results.

In the future, the integration of different diagnostic approaches will play an increasingly important role. While (central) laboratory diagnostics will remain indispensable, e.g. in high-throughput diagnostics, POCT can offer valuable advantages in suitable situations through the rapid availability of test results directly at the point of care. The combination of these two approaches allows both to develop their respective strengths. Many large laboratory practices already have POCT devices as a matter of course to analyze a sample quickly and perhaps outside the process line if necessary or to test their own employees. In parallel and in addition to this, it is important to utilize the growing possibilities of POCT.

Supply structures

In addition to the need for process optimization and the resulting efficiency gains, structural changes are also part of the healthcare of the future. All major health policy legislative projects, whether planned or already implemented, revolve around this challenge. The starting points are both intrasectoral (e.g. hospital reform) and cross-sectoral (e.g. reform of emergency care).

"POCT is an additional important device for the care of critically ill patients, and not just in rural areas."

Dr. Frank Mieck, Medical Director of the Dahme-Spreewald District Rescue Service

Analogous to the principle of outpatient before inpatient, the following should apply to in vitro diagnostics: "On-site at the patient instead of centrally remote from the patient". This applies in particular if the prompt result brings diagnostic and therapeutic advantages, but also if the above-mentioned efficiency gains are generated.

If the principle of point-of-care testing is taken to its logical conclusion, it means moving towards mobile diagnostics. Ideally, and taking into account what is technically possible, the diagnostics come to the patient and not the patient to the diagnostics. Mobility and low-threshold availability are key elements in overcoming rigid sector boundaries.

- **Care in rural areas:** In view of an ageing population and the increasing shortage of healthcare professionals, comprehensive healthcare provision in rural areas is a challenge. Patients have to travel ever greater distances to see a doctor. Telemedical care for these patients often fails due to the availability of the diagnostics required for medical decision-making. The Fraunhofer Center for Digital Diagnostics (ZDD) project "Neighborhood Diagnostics", which several Fraunhofer Institutes are currently working on, is addressing this challenge. Various application-oriented projects of the center aim to enable cost-efficient healthcare in the area by means of a digital ecosystem consisting of wearables and smart medical devices, as well as trustworthy POCTs. Comprehensive integration of digital health applications and diagnostics can a decisive contribution to overcoming challenges, particularly in rural areas and in healthcare in general.
- **Age and care:** At the end of 2023, around 5.7 million people in Germany were in need of care. The number of people in need of care is growing even faster than can be expected due to the ageing of society[29]. It is obvious that diagnostic care for these people is becoming increasingly important. In nursing homes, where a fifth of those in need of care live, POCT can significantly relieve the burden on medical care in the home when carried out by nursing staff. For the vast majority of people in need of care who are cared for at home by family members and/or outpatient care services, POCT and digital care applications (DiPA), which integrate diagnostic data, enable considerable progress, e.g. in monitoring fluid balance.

29 Press release from the Federal Statistical Office dated 18.12.2024 5.7 million people in need of care at the end of 2023 - Federal Statistical Office [accessed 15.1.2025]

The "Stay@Home - Treat@Home" project funded by the Innovation Fund of the Federal Joint Committee is also cross-sectoral in nature.[30] Studies show that in up to 30 percent of cases, treatment in the emergency room or hospital would not be necessary if health changes in the person in need of care diagnosed at an early stage and graduated measures were initiated on site.

Another federally funded project is the "Digital Residency Practice" in the Translational Region for Digitized Healthcare (TDG). The TDG is located in the border region between the federal states of Saxony-Anhalt, Saxony and Thuringia. It is testing how the region can be provided with adequate medical care as efficiently as possible. In the digital resident practices set up in nursing homes, specially trained nursing staff accompany patients while they are in digital contact with doctors.

"Neighborhood Diagnostics" creates a digital ecosystem of wearables and smart medical devices to provide diagnostics in a decentralized manner. The integration of reliable POCT ("ProVorOrt" project) improves care and reduces distances for patients in rural areas, enabling more efficient healthcare close to home."

Dr. Ullrich Stein, Main Coordinator & Head of Office, Fraunhofer Center for Digital Diagnostics ZDD

— **Digital health applications:** Since 2020, SHI-insured persons have been entitled to benefits for digital health applications (DiGA) in accordance with Section 33a SGB V. DiGAs are also known colloquially as "health apps on prescription". They can help insured persons to identify, monitor and treat illnesses or compensate for impairments. Digital health applications that integrate relevant diagnostic data into medical software can catalyze and effectively support the function of immediate diagnostics close to the patient. Especially for people with a chronic illness, DiGAs offer support between visits to the doctor's office; the possibility of transmitting DiGA data to the doctor's office with the patient's consent makes it easier for the attending physician to keep an eye on the course of the illness.

— **Mobile stroke units:** Specialized hospital units, so-called stroke units, are available for the acute care of stroke victims. Even the best stroke units can achieve little if the stroke patient arrives too late. Against this background, mobile stroke units are being tested in Germany and the USA, which travel to the patient, analyze therapeutically relevant blood values with a mini-laboratory and, if necessary, initiate thrombolysis on site (80 percent of all strokes are caused by a thrombus blocking a cerebral artery). Studies show that the proportion of patients who suffer no or minimal consequential damage is significantly increased by the advance treatment.[31]

30 STAY@HOME-TREAT@HOME - Establishment of a telemedically supported transsectoral cooperation network from neighborhood assistance to emergency care for outpatient care recipients - G-BA Innovation Fund [accessed 15.1.2025]

31 Von Lutterotti N Treatment under blue light, Frankfurter Allgemeine Zeitung from 31.12.2024, p. N1

VII. Opportunities and limitations: Improving framework conditions for the use of POCT

POCT has established itself in various areas of healthcare and is being used successfully there. In addition, immediate diagnostics close to the patient offers further potential for meeting future challenges. This potential is being dynamically expanded by advances in medical technology. Academic and industrial research in the field of in-vitro diagnostics represent this progress.

However, the possible applications of POCT are limited by the existing framework conditions of our healthcare system. Some of the most recent decisions taken in healthcare legislation and joint self-administration appear counterproductive with regard to the further development of patient-oriented immediate diagnostics. Other health policy reform projects that were intended to promote the availability of and low-threshold access to in-vitro diagnostics have fallen by the wayside following the premature end of the coalition government.

The following questions, among others, are relevant in order to utilize the benefits of patient-oriented immediate diagnostics even more effectively:

- Which legal measures are suitable for promoting the use of POCT?
- Which professional groups are allowed to provide and bill POCT?
- How can the value of patient-oriented immediate diagnostics be adequately reflected in the remuneration structures of SHI-accredited physicians and inpatient care?
- How can low-threshold diagnostic contact points be established without weakening the medical perspective and decision-making authority?
- Where does the digitalization of the healthcare system need to be accelerated in a targeted manner, and where do adjustments need to be made?
- What concrete steps need to be taken to empower healthcare providers to effectively lead the fight against antibiotic resistance?

As the voice of diagnostics manufacturers, the VDGH would like to use this initial assessment as a basis for further contributions to the discussion and concrete proposals for improving the framework conditions. It invites all those involved in the healthcare system to participate and enter into a fruitful dialog for the benefit of patients.

Imprint

Publisher

VDGH · Verband der Diagnostica-Industrie e. V.
(Association of the Diagnostics Industry)
Dr. Martin Walger, responsible

Neustädtische Kirchstraße 8
10117 Berlin

Phone +49 30 2005 99 -40

vdgh@vdgh.de
www.vdgh.de

Design

FGS Kommunikation, Berlin

Translation

Readers are requested to note that this is a translation for information purposes only. The original German text is legally binding.

Berlin, April 2025

www.vdgh.de/poct-whitepaper

VDGH