Opinion Paper

Peter B. Luppä*, Holger F. Rabenau, Norbert Gässler, Daniela Huzly, Matthias Nauck, Udo Reischl, Christoph Schoerner and Heinz Zeichhardt for the Participating Professional Societies

Rational clinical use of near-patient analytical systems for molecular detection of infectious agents

<https://doi.org/10.1515/labmed-2021-0035>

Received March 16, 2021; accepted March 22, 2021;

published online April 14, 2021

Abstract

Background: Tests for diagnosing infectious diseases (ID-POCT) play a special role among the available point-of-care testing (POCT) methods.

The original German manuscript can be found as PDF in the respective download areas of the websites of the DGKL, <https://www.dgkl.de>; DGHM, <https://www.dghm.org>; GFV, <https://www.g-f-v.org>; and BÄMI, <https://www.baemi.de>.

German Society for Clinical Chemistry and Laboratory Medicine (DGKL), POCT Section: Prof. Dr. med. Peter B. Luppä, Prof. Dr. rer. nat. Norbert Gässler, Prof. Dr. med. Matthias Nauck; German Society for Hygiene and Microbiology (DGHM): Prof. Dr. rer. nat. Udo Reischl, Dr. med. Christoph Schoerner; Society for Virology e.V. (GFV) and the German Association for the Control of Viral Diseases (DVG): Prof. Dr. rer. med. Holger F. Rabenau, Prof. Dr. rer. nat. Heinz Zeichhardt.

***Corresponding author: Prof. Dr. med. Peter B. Luppä**, Institut für Klinische Chemie und Pathobiochemie, Klinikum rechts der Isar der TU München, Ismaninger Str. 22, 81675 Munich, Germany, Fax: +49 89 4140 4875, E-mail: p.luppä@tum.de

Holger F. Rabenau, Institute of Medical Virology, Universitätsklinikum Frankfurt/Main, Frankfurt/Main, Germany

Norbert Gässler, Center for Laboratory Diagnostics, St. Bernward Hospital, Hildesheim, Germany

Daniela Huzly, Institute of Virology, Universitätsklinikum Freiburg, Freiburg, Germany

Matthias Nauck, Institute of Clinical Chemistry and Laboratory Medicine, Universitätsmedizin Greifswald, Greifswald, Germany

Udo Reischl, Institute of Clinical Microbiology and Hygiene, Universitätsklinikum Regensburg, Regensburg, Germany

Christoph Schoerner, Microbiology Institute – Clinical Microbiology, Immunology and Hygiene, Universitätsklinikum Erlangen, Erlangen, Germany

Heinz Zeichhardt, IQVD GmbH – Institut für Qualitätssicherung in der Virusdiagnostik, Berlin, Germany

Methods: A systematic literature search was performed in PubMed. Based on this literature review and our own experience, aspects associated with using molecular biological methods in the diagnostic amplification of pathogen DNA/RNA (nucleic acid testing = NAT) and/or signal amplification were discussed in an interdisciplinary manner. This resulted in the following recommendations for the near-patient use of NAT methods.

Results: Due to the current rise in the use of near-patient NAT testing (e.g., using disposable cartridges), recommendations are made for their implementation and appropriate clinical use in the hospital setting. Particular emphasis is placed on the analytical quality of the results. Furthermore, internal best-practice rules and selection criteria are proposed to ensure rapid diagnosis. Equally important are a medically valid interpretation of results and compliance with hygiene requirements. These recommendations emphasize that near-patient NAT should always be procured in conjunction with a (preferably) multidisciplinary institution responsible for POCT and knowledge of the test specifications and risks, as well as quality assurance need to be in place before they are carried out.

Conclusions: These recommendations are intended to improve patient safety and to avoid economically questionable expenditures.

Keywords: infectious agents; nucleic acid testing; POCT.

Introduction

The timeliness of the following recommendations is reflected by the events of the 2020 SARS-CoV-2 pandemic. Specific RNA amplification protocols for the detection of the novel SARS-CoV-2 coronavirus have been in place since January 2020, initially as laboratory developed tests (LDT) and now widely as CE-certified test systems. Compact, automated nucleic acid testing (NAT) systems have also been available since April 2020 for near-patient laboratory

testing. The reaction sequences take place as isothermal processes or in accordance with the PCR principle and include extraction, reverse transcription of the viral RNA, amplification and detection [1].

In response to these developments, the POCT Section of the German Society for Clinical Chemistry and Laboratory Medicine (DGKL), in collaboration with the German Society for Hygiene and Microbiology (DGHM), the Society for Virology (GfV), the German Association for the Control of Viral Diseases (VVK), and the Professional Association of Physicians of Microbiology, Virology and Infection Epidemiology (BÄMI e.V.), has developed the following recommendations for implementing near-patient analysis systems for the molecular detection of infectious agents in the clinical setting.

Definition of point-of-care testing

According to the guideline of the German Medical Association (Rili-BÄK) [2], point-of-care testing (POCT) is defined as medical laboratory testing that is performed directly on individual (not serial) samples without sample preparation (volume dosing is permitted). Another important criterion is the ability to derive further diagnostic or therapeutic measures from the test. Rili-BÄK stipulates simplified quality assurance for the utilization of unit-use reagents that are used for and consumed after one test.

Additional characteristics of POCT are listed in Table 1. Tests for identifying infectious agents (infectious disease POCT = ID-POCT) play a special role among the near-patient laboratory tests currently on the market. While most systems are based on the immunochromatographic detection of a specific microbial antigen (lateral flow immunoassay = LFIA), a variety of molecular biological methods have been available for some time that amplify the pathogen DNA/RNA. Recommendations for the appropriate implementation and use of these procedures will be made here for hospitals since

Table 1: Additional characteristics of point-of-care testing (POCT).

1. The analyses are performed directly at the patient's bedside or in close proximity to the patient.
2. Most users of the POCT devices do not have in-depth medical or technical training. They are also required to undergo training to use the devices as stipulated by the Medical Devices Act (MPG) and Rili-BÄK.
3. Even when not all of the criteria listed here are fulfilled, it is still considered point-of-care testing (POCT) so long as the typical character of such a test (especially with regard to the Rili-BÄK definition) is retained. A special chapter under B3 of the Rili-BÄK guideline from 2019 [2] applies when closed test systems (e.g., cartridge systems) are used for molecular genome detection of pathogen DNA/RNA (details under the section "Quality assurance").

these point-of-care NAT methods are primarily being used in this setting and because currently only a handful of regulations are in place for comprehensive quality management of NAT conducted at the point of care.

Clinical use of near-patient NAT methods

POCT – including the ID-POCT methods – is performed in almost all German hospitals. Over time, the Rili-BÄK guideline [2] has placed the responsibility for the quality assurance of near-patient testing on central laboratories. However, quality assurance needs to be further developed in light of the advancements, especially in molecular testing for infectious diseases.

Because medical laboratory testing is handled very differently by different hospitals, the authors have arrived at the following recommendations, which are listed in Table 2.

These recommendations were formulated jointly by the professional societies and aim to ensure that near-patient NAT testing is only procured in conjunction with the **multi-disciplinary unit responsible for POCT processes** with access to a functioning Laboratory Information System/Hospital Information System (LIS/HIS) network. In-depth knowledge of the test specifications and risks is required, and quality assurance should be in place. Another aim is to ensure that the risk-based quality assurance introduced by the current Rili-BÄK guideline is implemented comprehensively in the interest of patient safety.

The coordination unit defines the test specifications, monitors equipment maintenance and performance, and assures the quality of the analysis. It also monitors the workplace-related hygiene requirements and produces medically sound findings from reports sent via the LIS/HIS network. Additional equipment and test data are taken into account when producing the findings (e.g., Cp/Cq/Ct values, curve progression).

Treatment decisions can be made directly at the hospital after interpretation of the NAT results. In addition, hospital hygiene measures, such as isolation measures, can be derived immediately on the basis of the results. The coordination unit also fulfills the obligation to report in accordance with Section 7 of the German Protection Against Infection Act (obligation of laboratories to report). Another important task is the continuous training (in particular with regard to pre-analytical issues) and certification of the clinical staff involved in point-of-care laboratory analyses.

In Germany, the requirements of the Rili-BÄK guideline are binding for laboratory testing and have a legal character. In terms of certification, quality assurance

Table 2: Recommendations for the appropriate use of near-patient nucleic acid testing (NAT).

1. The quality assurance required by the Rili-BÄK is best ensured by means of a **multidisciplinary unit responsible for overseeing POCT** whose composition is determined by the hospital's own POCT commission. This POCT unit should be responsible for all decentralized POCT analyses including NAT procedures performed near to the patient.
2. Hospitals are very heterogeneous when it comes to in-house medical laboratories. The spectrum ranges from hospitals without in-house laboratories, to ones with laboratories in which medical laboratory tests including microbiological and virological analyses are carried out under one roof, and university hospitals that have a department for laboratory medicine as well as separate departments for medical microbiology and virology as part of their medical care. Therefore, in the case of POCT-NAT, the unit responsible for POCT should establish a competence team consisting of the management of the medical laboratory in association (or in personal union) with experts in the field of medical microbiology/virology (e.g., from an internal or external department of microbiology and/or virology).
3. In hospitals without their own medical laboratory, a POCT committee can also propose a suitable coordinator, possibly also an external coordinator, who is then appointed by hospital management to be responsible for this activity.
4. Another possible option for organizing quality assurance is a POCT-NAT support, for example in an emergency department, under the sole authority of a microbiology/virology laboratory. One prerequisite for this is the existence or establishment of a bidirectional LIS/HIS network.

of decentralized POCT systems falls under the provisions of DIN EN ISO 22870:2017-04. In contrast, DIN EN ISO 15189:2014 is applied to ID-POCT support, provided by the microbiology/virology lab under its sole responsibility.

In the past, LFIA showed a limited analytical sensitivity for detecting bacterial, viral, mycological, or parasitic antigens [3]. This led to the recent development of highly sensitive molecular genetic assays. POCT-NAT methods were also developed with the aim of speeding up diagnosis in comparison to traditional microbiological/virological analysis methods. This improves treatment options and enables a more rapid and targeted use of anti-infectives. Devices with PCR cartridges have been developed that allow rapid, contamination-free, single-test analysis performed by appropriately trained personnel. Ready-to-use cartridges pre-filled with reagents – some in blister packs – are used for this purpose. Here all PCR process steps (sample digestion with nucleic acid release, amplification and detection) are fully mechanized. A large selection of such NAT cartridge devices, including multiplex PCR systems, are available on the In-Vitro Diagnostics (IVD) market.

Unlike the above-mentioned immunological test systems, for the majority of NAT methods, the test samples (e.g., swabs

with liquid medium) must be placed or filled into a disposable cartridge either immediately or after mixing them with elution solution. This is then inserted into the NAT system which performs the sample preparation process. This **preanalytical step** is critical as errors can occur at this point. The type and quantity of the sample material used in the analysis must be selected according to the manufacturer's specifications. The swab and transport systems (e.g., swabs and liquid media) must also be compatible with the device being used. It should be noted that NAT pathogen detection only makes sense when the sample material is highly likely to contain the pathogen in detectable quantities and is validated accordingly. Special attention may need to be paid to ensuring that samples are taken correctly from the right location (e.g., deep nasopharyngeal swab) to avoid deficient samples that could lead to false analytical results. In this case, the personnel taking the sample and the personnel using POCT-NAT must undergo intensive training in order to ensure that a preanalytical control of the sample material, which is otherwise carried out in the microbiology/virology lab, is also performed as part of routine point-of-care testing.

Some newer systems enable several pathogens to be detected at once in a single assay run (so-called multiplex PCR). Such an approach provides rapid and sensitive pathogen detection when there are symptoms that can be assigned to several pathogens. The panels of various devices for “syndromic testing” allow for the detection of a wide range of pathogens. These approaches should only be used if there is a strong clinical indication. In addition to the costs, the multiplex approach often requires a higher level of interpretation when evaluating results and knowledge is needed of the detection limits for the pathogen composition.

The assurance of high-quality results is important for POCT-NAT methods that use closed (e.g., cartridge) systems. In Germany, this has been incorporated in the latest version of the Rili-BÄK guideline published in 2019 [2]. More specifically, and as explicitly defined in this guideline, these cartridges already contain all the necessary reagents and no further reagents or patient material are required and/or can penetrate the closed cartridge once the patient material has been manually or automatically added. This significantly minimizes the risk of contamination. It is also not possible to open the system, preventing the release of nucleic acid amplicates.

Implementing near-patient NAT testing in a hospital setting

There are undeniable advantages of using POCT in hospitals. These include the elimination of long transport times

for samples and a rapid availability of the results which could have immediate treatment implications for the patient. Studies have shown [4] that POCT reduces the length of patient stays in emergency rooms. However, this time savings is not always accompanied by medically verifiable benefits [5]. An ill-considered and hasty introduction of such tests, especially NAT, can lead to diagnostic uncertainties and the inability to conduct follow-up tests using the same sample material. Nevertheless, there is an increasing demand for the clinical use of such analytical systems in the hospital sector. For example, NAT testing for influenza A, B and Respiratory Syncytial Virus (RSV) is already being performed in some large emergency rooms. In addition to obtaining fast results, it has resulted in a reduction in “bed blocking” which has proven beneficial. Thus, the near-patient use of NAT to detect the influenza virus can also be cost-effective [6]. The same applies to the NAT-based detection of SARS-CoV-2 RNA.

Quality assurance – new Rili-BÄK requirements for NAT testing using closed test systems (e.g., disposable cartridges)

The latest version of the Rili-BÄK guideline from December 2019 [2] has defined in Chapter 2.1.2.3. the measures for implementing quality assurance for closed, fully mechanized molecular genetic test systems (e.g., cartridge systems) to detect pathogen-specific DNA/RNA. In addition, internal quality assurance for molecular biological procedures is listed in Tables B 3-1 and B 3-1a. Point 5 of this chapter is particularly relevant for near-patient NAT, an excerpt of which is presented below:

Quotation: (5) For closed test systems (e.g., cartridge systems) for the qualitative or quantitative detection of pathogen-specific nucleic acid, there is no need for additional control samples for each test procedure if sufficient procedural controls are in place to ensure reagent functionality, including extraction, purification, amplification and inhibition.

In the absence of a manufacturer’s specification or if no positive and/or no negative control sample is deemed necessary by the manufacturer, the laboratory must substantiate the frequency of positive and/or negative control samples by means of specifications adapted to the respective procedure (risk-based quality assurance). The frequency and results of these control sample measurements must be documented.

Internal standards for best practice

When implementing near-patient NAT testing in hospitals, various preparatory measures must be made on site by the

clinical departments involved (e.g., emergency department) in close cooperation with the team of microbiology/virology experts in the unit responsible for POCT (often also referred to as the POCT coordination unit, see also “Clinical use”). Primary aspects include the selection of a suitable system, training of the primary clinical staff in the correct indications, preanalytical steps and the conducting of the testing, a suitable IT connection to the LIS, a clinical validation of the results, correct interpretation of the results, a comprehensive cost/benefit analysis and adequate therapy consultation. In addition, quality assurance measures (internal and external quality controls) should be in place alongside algorithms for mandatory reporting in accordance with the German Protection Against Infection Act (IfSG) and/or internal reporting to those responsible for hospital hygiene. Particular attention should be paid to the correct use of point-of-care NAT. When indications are too broadly defined, the tests are often used incorrectly, resulting in unnecessary costs. On the other hand, well defined indications improve process flows, which can lead to corresponding cost savings.

Selection criteria

The NAT systems should be selected based on the conditions of the respective clinical setting. This assessment must be carried out by persons with microbiology/virology expertise together with the unit responsible for the POCT processes (see section “Clinical use”). In addition to the analytical aspects, requirements for the preanalytical process must also be considered. Table 3 lists potential selection criteria that should be taken into account and reviewed prior to performing point-of-care NAT (modified from van der Eijk et al. [7]).

The test method needs to be evaluated based on the conditions present in the respective facility. It is important to take into account the patient population in the facility (proportion of patients primarily receiving emergency care, proportion of pediatric or geriatric patients, ratio of surgical to non-surgical cases, proportion of intensive care patients, etc.). The specificity, sensitivity as well as the positive and negative predictive values of the assay must be evaluated in detail as information has been published on false-positive and false-negative results of some commercially available POCT systems for various forms of pathogen detection [8, 9].

Preanalytical requirements

As with any other laboratory procedure, including microbiological procedures, conducting proper preanalytics plays

Table 3: Selection criteria for using near-patient nucleic acid testing (NAT).

NAT technology: extent to which the technology
<ul style="list-style-type: none">– is medically useful,– must undergo an in-house evaluation with regard to sample taking, specificity, sensitivity, reproducibility, cost per test etc.,– is suitable for the working environment within a given hospital setting,– can be integrated into the existing IT and data security infrastructure.
Implementation: checking whether
<ul style="list-style-type: none">– the test is approved for use by (inter)national regulatory bodies and complies with current laws and regulations,– the new service can be integrated into existing workflows,– the requirements regarding a multidisciplinary body responsible for overseeing POCT are met by the hospital,– the risks associated with implementation (e.g., use by untrained personnel) can be mitigated.
Use and alternatives: checking and/or estimating
<ul style="list-style-type: none">– the degree of acceptance by users for this type of diagnostic testing,– the number of POCT users who will perform this analysis,– alternatives to the new NAT service.
Operation: clarification and/or taking into account
<ul style="list-style-type: none">– the possibility to link the NAT to existing POCT middleware and LIS/HIS,– the simplicity/low susceptibility to error when using the new NAT technology,– training for physicians, nurses, technicians, etc. and scheduling of regular performance reviews,– the ready availability of consumables needed for testing,– whether simple maintenance and repairs can be made by the medical staff should the NAT system experience technical issues,– structural and contractual situation within the facility (including authority to issue instructions to staff when performing the test),– responsibilities related to ensuring/adhering to maintenance procedures and the reordering of the required test kits.
Strategy: clarifying how the new NAT service contributes to
<ul style="list-style-type: none">– the quality of the results,– the efficiency of the diagnosis/treatment process,– the efficiency of the nursing process.

a decisive role in diagnostic testing. Four important aspects of this are explained in Table 4.

Table 4: Preanalytical aspects of near-patient nucleic acid testing (NAT).

<ul style="list-style-type: none">– Correct swabbing/samples collection is crucial for the test. This means that the type and quantity of sample material used in the analysis is selected in accordance with specifications and that the sample is used immediately, i.e., without sample preparation. This is the case for most NAT systems that have an integrated sample preparation process; here the manufacturer’s specifications must be strictly followed.– From practical experience, it only makes sense to use NAT-supported direct pathogen detection when the swabs/samples are highly likely to contain detectable quantities of the infectious agent.– During the preanalytical process, special attention must also be paid to ensuring the swab and transport system is suitable for the respective NAT device (e.g., nylon flocked swabs with Amies medium). The manufacturer’s specifications on the use of a swab system must be strictly followed.– The compliance with the personal protection must be taken into account particularly when there is a clinical suspicion of highly infectious or highly contagious pathogens. Cross-contamination must also be avoided when openly handling sample material outside the microbiology/virology laboratory (see also section on “Hygiene requirements”).

Interpreting results

The issuance and interpretation of the results should be clear and unambiguous, i.e., without the need for further interpretation, e.g., “pathogen detected/not detected” or “mutation present/not present”. Depending on the selected POCT approach, once the POCT-NAT results have been transferred to the LIS, they are verified for the final written report using microbiology/virology expertise and, if necessary, interpreted further. This ensures that immediate decisions can be made at the point of care based on the results. The findings are prepared by a competent party and, if necessary, reported to the health authorities in line with the IfSG. These aspects are covered in detail in the document “MM03: Molecular Diagnostic Methods for Infectious Diseases” published by the Clinical & Laboratory Standards Institute (CLSI) [10] (Table 5).

Hygiene requirements

Hygiene aspects must also be taken into account. As part of a risk assessment conducted in accordance with Section 4 of the Ordinance on Biological Substances (BioStoffV) and Section 3 of the German Labor Protection Act (ArbStättV), users of POCT-NAT must take suitable protective measures in line with

Table 5: Issuance and interpretation of results as per the Clinical & Laboratory Standards Institute (CLSI) document [10].

Reporting results	NAT results should be primarily communicated to the clinician as “positive”, “negative”, “ambiguous”, or “uninterpretable” – with further interpretation as needed.
Critical results	Critical results should be defined for tests that significantly influence treatment decisions. The attending physician is to be informed immediately. Users of point-of-care NAT should understand the significance of critical results for the test formats they perform themselves.
Notification of clinically significant test limitations	This should only be briefly stated in the report to avoid distracting from the primary finding. Examples include cross-reactions, systematic errors caused by genome changes in the pathogen, and the presence of interfering substances. In some cases, these limitations are already stated in the test manufacturer’s package insert. The use of laboratory developed tests and the use of NAT methods for other types of sample material or for previously undefined purposes (intended use) is only permitted as an exception.

the current hygiene plan before working with the potentially infectious (swab) materials and, if necessary, develop operating instructions. Particular attention must be paid to hand hygiene, personal protective equipment, disinfection of surfaces and waste treatment. The relevant regulations (e.g., TRBA 100 and 250, and the specifications of the Committee on Biological Agents [ABAS]) must be observed [11, 12].

Surfaces on which NAT is performed may be contaminated with pathogens or, even after proper disinfection/decontamination, with their nucleic acids. Therefore, in

order to control infection and to avoid cross-contamination, the basic rules listed in Table 6 must be observed.

When performing near-patient NAT to detect pathogens, aerosols can be generated during various steps, e.g., when opening sealed lids on sample containers, mixing samples, and when pipetting and emptying syringes and sample containers. Therefore, depending on the NAT method, a microbiological safety workbench is required. If this is not possible due to space limitations, personal protective equipment (PPE) in accordance with TRBA 100 must be worn when pipetting the sample into the test cartridge (e.g., safety goggles, protective gown, mouth/nose protection/FFP mask) depending on the pathogen to be detected. The PPE must be disposed of properly afterwards. Further precautions must be taken where necessary (e.g., when testing for SARS-CoV-2 [12]). The area around the testing device must be decontaminated regularly with a suitable surface disinfectant.

Table 6: Hygiene requirements – basic rules.

- Spatial separation of workspaces with exposure to infectious material from those without any exposure.
- Regular cleaning and/or disinfection of the work surfaces with suitable disinfectants (if possible after each test and as a rule directly after any visible contamination).
- Eating, drinking, smoking and storing food at the POCT-NAT workstation is not permitted.
- When handling infectious material, touching the face and work equipment (telephone, computer keyboards, writing utensils, etc.) should be avoided. Regular hand disinfection is mandatory.

Further consequences

Further clinical and molecular biological consequences are summarized in Table 7.

Table 7: Clinical management and further tasks of the unit responsible for point-of-care testing (POCT).

Clinical management of the NAT results is supported by intensive collaboration between the clinician and the unit responsible for POCT.	
1.	When pathogens are identified, the positive results should be checked and/or verified using other microbiological methods (if available).
2.	The clinical interpretation of complex test results, such as multiplex PCR results, is the responsibility of the clinician and a microbiology/virology expert and must be reassessed by them on a case-by-case basis.
3.	The treatment options, as stipulated by the NAT results, are to be discussed with the attending physician, if possible.
4.	Likewise, any resulting hospital hygiene measures (e.g., isolation, special disinfection measures) are to be organized by the clinician in conjunction with the hospital hygienist.
Additional tasks as part of POCT molecular genetic testing:	
1.	The unit responsible for POCT arranges for external EQA measurements to be conducted at the hospital and sends the results to one of the EQA organizations approved by the German Medical Association (BÄK). The unit also monitors the outcome of the external quality assurance and initiates the necessary corrective measures when there are deviations in the results.
2.	The unit ensures that all data from point-of-care NAT testing are stored in the LIS/HIS to enable further statistical and epidemiological analysis.
3.	In addition, the competence team provides the following consultation services to the attending physician: <ul style="list-style-type: none"> a. notifying the public health authority of the detection of a pathogen in the case of pathogens that must be reported as per the Protection Against Infection Act (IfSG), b. providing information on the epidemiological situation of a pathogen, c. collaborating with the antibiotic stewardship team.

Examples of successful realization of POCT-NAT include the implementation of rapid influenza or SARS-CoV-2 NAT in the emergency rooms of university hospitals in Germany. Here, collaboration with microbiology/virology departments has resulted in the quality control of testing through the networking of POCT devices, fast support in the event of technical problems, and, in selected cases, confirmatory and comparative testing at the virology laboratories [13].

Research funding: None declared.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Competing interests: **Professor Luppa** has received consulting fees from the company Lumira DX, UK. He has been paid a speaking fee by the companies Werfen and Nova Biomedical. He has received re-search support (indirectly to the employer) from GNA Biosolutions, Martinsried. **Professor Rabenau** declares no conflict of interest. **Dr. Huzly** declares no conflict of interest. **Professor Nauck** declares no conflict of interest. **Dr. Schoerner** declares no conflict of interest. **Professor Zeichhardt** is the owner and CEO of IQVD GmbH – Institut für Qualitätssicherung in der Virusdiagnostik, Berlin, as well as a shareholder and CEO of GBD – Gesellschaft für Biotechnologische Diagnostik mbH, Berlin; with no influence on this article.

Informed consent: Not applicable.

Ethical approval: Not applicable.

References

1. Kohmer N, Rabenau HF, Ciesek S. SARS-CoV-2: Der richtige Nachweis. *Dtsch Arztebl* 2020;117:A-866/B-729.
2. Bundesärztekammer. Neufassung der Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen – Rili-BÄK. *Dtsch Arztebl* 2019;116:A-2422/B-1990/C-1930.
3. Kozel TR, Burnham-Marusch AR. Point-of-care testing for infectious diseases: past, present, and future. *J Clin Microbiol* 2017;55:2313–20.
4. Jang JY, Shin SD, Lee EJ, Park CB, Song KJ, Singer AJ. Use of a comprehensive metabolic panel point-of-care test to reduce length of stay in the emergency department: a randomized controlled trial. *Ann Emerg Med* 2013;61:145–51.
5. St John A, Price CP. Economic evidence and point-of-care testing. *Clin Biochem Rev* 2013;34:61.
6. You JHS, Tam L-p, Lee NLS. Cost-effectiveness of molecular point-of-care testing for influenza viruses in elderly patients at ambulatory care setting. *PloS One* 2017;12:e0182091.
7. van der Eijk AA, Tintu AN, Hays JP. Pre-implementation guidelines for infectious disease point-of-care testing in medical institutions. *Future Microbiol* 2017;12:51–8.
8. Hahn A, Podbielski A, Meyer T, Zautner AE, Loderstädt U, Schwarz NG, et al. On detection thresholds – a review on diagnostic approaches in the infectious disease laboratory and the interpretation of their results. *Acta Trop* 2020;205:105377. [Epub 30 Jan 2020].
9. Hansen GT. Point-of-care testing in microbiology: a mechanism for improving patient outcomes. *Clin Chem* 2019;304782.
10. Day SP, Jackson CL, Nolte FS, Tezak-Fragale Z. Molecular diagnostic methods for infectious diseases, 3rd ed. CLSI report MM03. Wayne, PA, USA: Clinical and Laboratory Standards Institute (CLSI); 2015.
11. Kramer A, Gruner E. Bedeutung der Hygiene beim POCT. Kapitel 29. In: Luppa PB, Junker R, editors. *POCT – Patientennahe Labordiagnostik*, 3. Auflage. Berlin: Springer Verlag; 2017.
12. ABAS. (Stand: Beschluss 6/2020 02.12.2020) Empfehlungen zu Arbeitsschutzmaßnahmen bei der Point-Of-Care-SARS-CoV-2 Diagnostik. https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Coronavirus/pdf/Point-Of-Care-SARS-CoV-2%20Diagnostik.pdf?__blob=publicationFile&v=2.
13. Huzly D, Panning M. Implementation of a rapid influenza PCR algorithm at the emergency department of a large university hospital. In: Poster presentation Annual Meeting of the European Society of Clinical Virology, Stresa, Italy. Amsterdam: Elsevier; 2017.