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vivalytic

New care options through decentralized rapid PCR tests in hospitals

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Introduction

PCR testing systems produce rapid results at the point of care (POC), where they are needed most. They are reliable and enable targeted patient treatment. A full-fledged PCR lab the size of a small desktop PC, Vivalytic is the all-in-one solution for molecular diagnostics directly at the POC.

- ▶ The testing procedure is always consistently simple and intuitive.
- ▶ Vivalytic can be set up wherever tests need to be performed.
- ▶ Test results in laboratory quality are available directly where they are needed: on the ward or in the emergency room directly with the patient.
- ▶ Quality controls are integrated into each cartridge and are automatically monitored and documented.
- ▶ The devices are easily integrated into hospital or laboratory information systems.

This allows pathogens to be detected reliably and quickly using laboratory-quality PCR anywhere in the hospital on a hospital ward, in clinics, or the emergency room,

Vivalytic tests are available for respiratory, nosocomial, and urogenital infections. Vivalytic analyzes patient samples such as different swabs or urine. All that is required is the test cartridges and a device that automates the entire testing procedure.

The POC approach is gaining more and more traction in medical practice. One of the reasons is that rapid results can save avoidable costs. In suspected cases of pathogens such as MRSA, for example, patients can be isolated and antibiotic treatment prescribed even before the microbiological result is back from the lab, which usually takes a few days. The Vivalytic system delivers results in less than one hour, on the basis of which informed decisions can be made regarding isolation and therapy.



On the Vivalytic Analyser the detection of pathogens is displayed in form of an amplification curve.

The Vivalytic system ...

... is suitable for use in a central laboratory or in laboratory chains as well as decentralized for near-patient diagnostics at the POC.

Vivalytic provides reliable PCR results at all times – outside regular consulting times, on weekends, evenings, or at night, or even in the event of staff shortages.

For decentralized use, rapid diagnostics of infectious agents in emergency rooms or intensive care units is a useful application. POC testing capabilities are especially suited for hospitals that do not have their own laboratory. Data from the German Hospital Institute, for example, shows that the majority of hospitals with fewer than 600 beds outsource molecular diagnostics to external laboratories. The devices can be easily integrated into the hospital IT environment and centrally managed. (See details about Vivasuite on pages 7 & 8)

... is fast

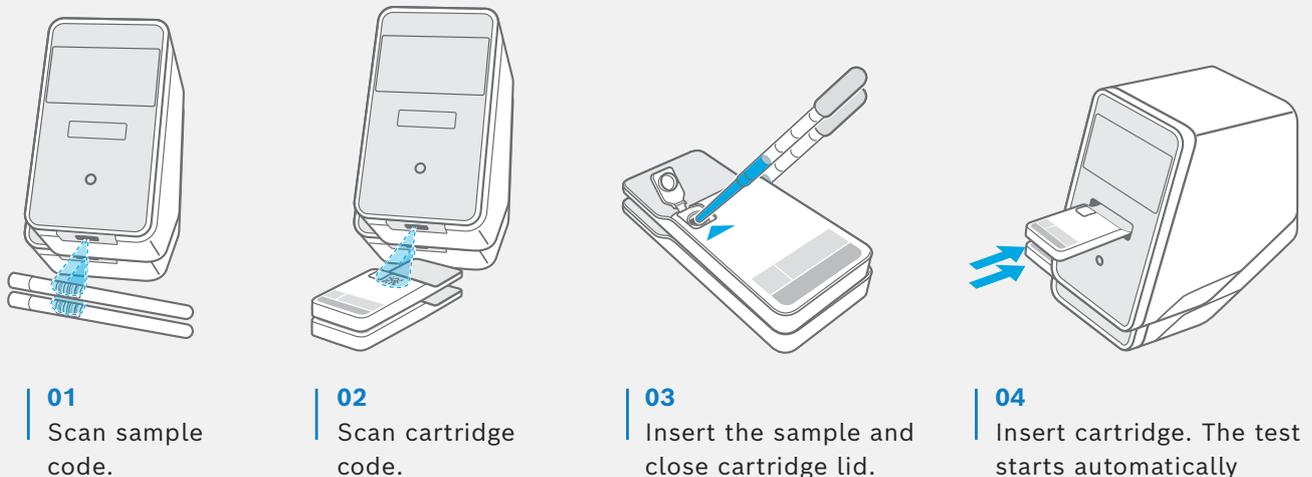
Depending on the test, Vivalytic delivers PCR results in less than half an hour. Preparation for the test takes less than one minute. Use directly at the POC saves transport costs and the time needed for sample transport of up to 48h. Thanks to the rapid result, cost-intensive isolation measures only need to be initiated in cases with confirmed infection.

One example: Due to the non-specific symptoms, differentiation of respiratory diseases is often only possible with targeted testing. With a test at the POC, the treating physician and the patient receive the result within a very short time and preventive and cost-intensive isolation can be avoided.

... is intuitive

The entire process is simple, very intuitive and always the same. Once the cartridge is inserted into the device, the entire analysis is completely automated. The result is automatically displayed on the screen.

No calibration, cooling, or additional sample preparation is required. Quality controls are integrated into each cartridge and are automatically monitored and documented, increasing acceptance and robustness for safe use 24/7.



... is safe

The sample is filled into the cartridge directly with a pipette and the cover is securely sealed. The cartridge is a closed system. Liquids remain inside the cartridge. This allows clinical staff to use the Vivalytic system reliably, regardless of how experienced they are with laboratory diagnostic processes.

... enables direct detection and screening

Whether for detecting a single target in a singleplex test or many parameters in a multiplex test – when it comes to infectious agents, Vivalytic can do both. Vivalytic identifies nosocomial pathogens such as MRSA. It thus supports hygiene management and isolation decisions. SARS-CoV-2, influenza A/B and RSV can be detected from a single swab. The same system can also be used to detect 10 different sexually transmitted infections (STIs) simultaneously from a single urine sample. In addition, Vivalytic can support safe antibiotic therapy by distinguishing between viral and bacterial infection during syndromic testing. In the future, resistance detection will make it possible to target the use of antibiotics. Depending on the field of application and the suspected infection, different approaches can be implemented, such as step-by-step diagnostics or syndromic testing for many different pathogens.



... is future-proof

Whether SARS-CoV-2 or MPOX* Bosch has managed to bring automated PCR tests for the Vivalytic platform to market maturity in just a few weeks in each case. For example, in May 2020 a test was available that could detect SARS-CoV-2, one of the first PCR tests available for the POC for detection of the novel coronavirus. Bosch's broad technology expertise and sustainable focus enable the company to build a robust product pipeline. The concept of the Vivalytic system as an open platform, similar to an app store, allows various specialized development partners to contribute to the expansion of the test portfolio.

*Research use only

... is reliable

Delivery reliability and short supply chains are becoming increasingly important. Vivalytic's supply chains are located within Europe and Germany. Vivalytic features Bosch technology for highest quality and cost awareness. The production and quality control for the Vivalytic components is located in Germany at the company's site near Stuttgart. Cooperation with specialized distribution partners translates to proximity and short distances when it comes to customer service.

... can be deployed flexibly

The Vivalytic platform takes up less space than a DIN A3 sheet of paper and, weighing around 13 kilograms, can also be transported by a single person. No additional hardware is needed to perform the tests, as the monitor and scanner are already integrated into the platform. The cartridges require no cooling and can be stored at room temperature. The system can therefore be quickly and flexibly relocated to the current point of need. Wirelessly connected based on Bosch's IoT expertise, the platform can remain connected to the IT infrastructure and the Vivasuite cloud after relocation even without cabling. The results are immediately available digitally.



Vivasuite – cloud-based device management for Vivalytic Analyser

Vivasuite is the digital ecosystem developed by Bosch for healthcare devices and thus also for the Vivalytic Analyser. Vivasuite makes it possible to manage multiple devices at different locations. This brings a number of benefits that facilitate the management of the devices.

Simple device management

On the Vivasuite user interface, the “Device Management” item provides an overview of the entire pool, but also of each individual device, allowing simple and efficient task management. The individual Vivalytic Analysers are listed with their serial number, which can also be searched for.

When a device is selected, all important technical information is available for viewing at a glance, such as:

- ▶ Location
- ▶ List of applications available on the device
- ▶ Test frequency
- ▶ Current software version with software history
- ▶ Time when it was last online
- ▶ Time of last connection to Vivasuite

This data can be exported via a device list and used in other systems for statistics.

Efficient workflow

Vivasuite also offers a number of features that simplify everyday routines in hospitals and laboratories and support efficient processes. New software updates can be installed in the individual Vivalytic Analysers via Vivasuite, ensuring they are always up to date. Administrators can select the exact time of installation and determine it individually for different devices. This is a great advantage during day-to-day clinic procedures, because devices in the emergency room must be fully functional at all times. By scheduling the installation of updates in advance, clinical staff can thus ensure that only one analyser is ever busy with the update while the others are available for use. Alternatively, on a ward where no testing is carried out at night, all devices can be updated simultaneously overnight so that they are fully operational again the next morning. All this can be monitored and set remotely via Vivasuite, without requiring any intervention directly on site.

Remote admin

The test portfolio can also be expanded with minimum effort via Vivasuite, as the necessary software for new tests can be made available on Vivalytic Analysers via updates. In the Vivasuite dashboard, administrators can remotely view and document the number and type of tests performed.

The device passwords can also be reset via Vivasuite. Lost passwords can be reset via the platform without the need for intervention directly on the device. This speeds up processes and saves time: staff on site gain valuable test time, device administration saves the trip to the device, and service personnel deployments as well as the administrative effort required to schedule appointments are reduced.

Continuous support

Technical raw data of the devices can be transmitted to Bosch's support experts, who can use the data to carry out detailed specific analyses and troubleshoot more quickly. This speeds up service processes so that the devices are up and running again in less time.



*Vivalytic analyser ready or Plugins from third-party providers via HL7-Interface

No access to personal data

Bosch takes strict separation of technical data and personal data very seriously. Vivasuite only stores technical data relating to the devices, allowing speedy problem rectification in the case of service events.

Vivalytic enables secure export of patient data

Test results generated with Vivalytic can be automatically transferred to patient records. The Vivalytic devices can be connected with the laboratory information system (LIS) or the hospital information system (HIS) using an HL7 interface. Suitable middleware was used to verify that data transfer can be realized in compliance with the Guideline of the German Medical Association for Quality Assurance of Medical Laboratory Tests (RiliBÄK).

Extensive, growing test portfolio

Vivalytic is a powerful, universal platform for molecular diagnostics at the POC. Vivalytic can test a wide range of samples such as swabs, blood, or urine for pathogens using PCR. Both targeted testing for individual pathogens in the context of stepwise diagnostics and the syndromic approach of simultaneous testing for many pathogens (multiplex panel) are possible. Bosch creates the technological foundation on the basis of which new tests are developed and brought to market maturity in cooperation with specialized reagent developers. The result is an already extensive test portfolio that is continuously being expanded and further developed.

Example: Test portfolio for respiratory pathogens

For hospitals, respiratory pathogens play a role in two ways. Firstly, during flu epidemics, which is reflected in the utilization rate of emergency rooms, and secondly, in the context of hospital-acquired infections. Here, pneumonia is among the most common nosocomial infections and is associated with high mortality.¹ Clinical symptoms can be very similar for different pathogens, making diagnosis difficult. However, the correct treatment and isolation strategy may differ depending on the pathogen concerned. An accurate diagnosis can only be made and targeted therapy subsequently initiated with precise detection of the pathogen using PCR.

With the extensive Vivalytic test portfolio for respiratory pathogens, it is possible to simultaneously test for SARS-CoV-2, influenza A/B and RSV, among others, from one swab sample. In addition, pooling solutions are available for SARS-CoV-2, allowing multiple individuals to be tested efficiently in one run. This can help interrupt transmission, for example as part of regular employee screening.

Example: Test portfolio for hospital infections

The Vivalytic MRSA/SA test can detect both the antibiotic-sensitive (SA) and methicillin-resistant (MRSA) forms of the *Staphylococcus aureus* bacterium. MRSA infections can lead to serious complications and deaths, as well as result in a great deal of work and expense for hospitals. According to data from a German university hospital, these additional costs can exceed 8,000 euros per case.² The Vivalytic MRSA/SA test provides a reliable result in less than one hour directly at the site of sample collection. The short processing time makes this test a good example of the time difference compared to conventional diagnostics using cultures, where results are only available after two to three days. On the one hand, this reduces waiting times for operations, and on the other, it provides a reliable basis for suitable antibiotic treatment decisions. This helps to ensure that expensive reserve antibiotics are only used in a targeted manner, thus avoiding further resistance. Last but not least, the decision for or against costly isolation measures no longer has to be made on the basis of an assumption, but can be backed up by a reliable PCR test result.

Gastrointestinal and urinary tract infections are further hospital-acquired infections of relevance in terms of prevalence. Here, Bosch is working specifically on the development of tests for the Vivalytic portfolio.

Infection with the bacterium *Clostridioides difficile* (*C. difficile*), for example, is frequently associated with diarrhea in hospitalized patients, and prevention of further spread relies on early detection of the pathogen.³ However, nosocomial infections can also occur in association with bladder catheters. Approximately 12-16% of inpatients in Germany receive such a bladder catheter during their stay in hospital.⁴ This is accompanied by an increased risk of urinary tract infections, which in the worst case can cause urosepsis. Early testing and safeguarding against an infection in connection with a hospital stay provides relief in a number of ways: the infected person benefits from targeted treatment and the hospital can take rapid action to treat infections, interrupt chains of infection, and minimize costs.

View the current Vivalytic test portfolio online:

References

- ¹ Löffert et al. Die Bedeutung der Labordiagnostik für die Krankenhausversorgung: Eine Studie im Auftrag der Deutschen Vereinten Gesellschaft für Klinische Chemie und Laboratoriumsmedizin (DGKL) und des Verbands der Diagnostica-Industrie (VDGH), 2014
- ² Dahlhoff et al. Epidemiologie, Diagnostik und Therapie erwachsener Patienten mit nosokomialer Pneumonie - Update 2017*: S3-Leitlinie der Deutschen Gesellschaft für Anästhesiologie und Intensivmedizin e.V., der Deutschen Gesellschaft für Infektiologie e.V., der Deutschen Gesellschaft für Hygiene und Mikrobiologie e.V., der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin e.V., der Paul-Ehrlich Gesellschaft für Chemotherapie e.V., der Deutschen Röntgengesellschaft und der Gesellschaft für Virologie, 2017
- ³ Hübner et al. Analysis of MRSA-attributed costs of hospitalized patients in Germany. Eur J Clin Microbiol Infect Dis. 2014 Oct;33(10):1817-22. doi: 10.1007/s10096-014-2131-x. Epub 2014 May 18. PMID: 24838677
- ⁴ RKI Ratgeber Clostridioides, https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Clostridium.html, retrieved April 12, 2024
- ⁵ Prävention und Kontrolle Katheter-assoziiertes Harnwegsinfektionen: Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2015 Jun;58(6):641-50. German. doi: 10.1007/s00103-015-2152-3. PMID: 25824136.

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