PCR rapid test for 3 important gastroenteritis pathogens for Vivalytic by Bosch now available / World’s first fully automated PCR test for detection of C. difficile, norovirus, and rotavirus at the sampling point

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- The Vivalytic test is the first test to specifically detect 3 of the most important gastroenteristis pathogens: *Clostridioides difficile*, norovirus, and rotavirus.

- *Clostridioides difficile* infection rates are on the rise in Germany, with cases becoming more severe and increasingly affecting younger patients.

- Pathogen differentiation is crucial to initiate the appropriate treatment, avoid complications, and control the spread of the infection.

Bosch Healthcare Solutions has introduced a new PCR test for *C. difficile*, norovirus, and rotavirus, expanding the Vivalytic analysis platform’s capabilities to include gastroenteritis. This innovative test can simultaneously and automatically detect these 3 major diarrhea pathogens in under an hour right on site. Unlike previous tests that either included these pathogens in a larger panel or tested for each individually, this triple test is the first of its kind. The new Vivalytic test is available through distribution partners such as Randox Laboratories and R-Biopharm. “We developed this test so that medical practices and clinics can identify the cause of gastroenteritis more quickly and respond appropriately: with the right treatment and measures to prevent further spread and infection," explains Marc Meier, president of Bosch Healthcare Solutions. Due to transportation and limited test availability, the complete detection of *C. difficile* can take up to several days.

Rapid diagnosis is crucial for correct treatment

Gastroenteritis is one of the most common reasons for visiting a doctor’s practice or clinic, especially among children and older adults. “Rapid and accurate diagnosis of the pathogen is crucial to initiate the right treatment, prevent potential complications, and bring the infection under control,” says Dr. Stefan Zimmermann, Senior Physician at the Center for Infectious Diseases at Heidelberg University Hospital. The bacterium *Clostridioides (formerly Clostridium) difficile* is the main cause of nosocomial diarrheal diseases, which are associated with a relatively high mortality rate. To prevent life-threatening outcomes, an infection must be diagnosed quickly and treated effectively, emphasizes Zimmermann. According to the Robert Koch Institute (RKI), however, *C. difficile* is still under-tested.1

In addition, other pathogens can also cause diarrhea, making a more comprehensive diagnosis, such as the Vivalytic test for norovirus, rotavirus, and *C. diff.* sensible. The Vivalytic Analyser from

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Bosch Healthcare Solutions supports rapid sample processing, which is particularly important for *C. difficile*, as the toxin may no longer be detectable at room temperature within two hours. Rapid sample processing is therefore recommended by the RKI.2

Risk factors and effects of *Clostridioides difficile* infections

Clostridioides difficile (C. difficile) infections cause gastrointestinal complications, especially during and after antibiotic therapy, and are particularly prevalent in older, multimorbid individuals. Risk factors include advanced age, underlying gastrointestinal diseases, prolonged hospital stays, and immunosuppression. The incidence of *C. difficile* infections has risen in recent decades due to demographic aging, increased comorbidity, and multimedication. In addition, more virulent *C. difficile* strains lead to more severe courses of disease. Recently, an increase in community-acquired *C. difficile* infections has been observed in young, healthy patients without recognizable risk factors. Mortality averages one to two percent, but it is significantly higher in older patients with comorbidities and in intensive care units. This makes meaningful, rapid testing *for C. difficile* all the more important, and with the new Vivalytic PCR test from Bosch Healthcare Solutions now quickly possible.

Rotavirus and norovirus, especially in children and the elderly

Preventing outbreaks of viral gastroenteritis, such as those caused by rotavirus and norovirus, in hospitals is crucial. Differentiating these viruses from other pathogens such as *C. difficile* is essential for effective management. Noroviruses are responsible for the majority of non-bacterial gastroenteritis cases, affecting approximately 30 percent of children and up to 50 percent of adults.[3] Children under five and adults over 70 are particularly vulnerable. Rotaviruses are highly infectious, with as few as 10 to 100 virus particles capable of causing an infection. They are the most common cause of viral intestinal infections in children aged six months to two years.4 Just 10 virus particles can be enough to infect a child. The incidence of rotavirus infections increases again in people over 60 years of age. According to RKI reporting data, 35 percent of reported rotavirus infections in this age group require hospital treatment.

Vivalytic Analyser enables rapid diagnosis at the point of care

The Vivalytic Analyser allows for quick and easy testing for *C. difficile*, norovirus, and rotavirus directly at the point of care. The system is user-friendly and requires only a brief training session for medical staff. The collected sample is placed into a test cartridge, which already contains all necessary reagents. The cartridge is then inserted into the Vivalytic Analyser for automatic processing. The test result is shown on the display. The fully automated process significantly lowers the risk of infection for the user. The Vivalytic Analyser thus facilitates rapid and precise diagnostics in PCR quality, bypassing the frequently lengthy process through a central laboratory. Bosch Healthcare Solutions recently obtained CE certification for 3 versions of its new gastroenteritis test: Vivalytic C. difficile, Vivalytic norovirus and the triple test Vivalytic norovirus, rotavirus, C. diff.

This is a press release for journalists. Under no circumstances does it replace a consultation or recommendation by a medical practitioner.

Sources

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4. RKI Ratgeber Rotaviren https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Rotaviren.html, retrieved on 07/15/2024

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Distribution partners for Vivalytic: https://www.bosch-vivalytic.com/en/distribution/

Bosch Healthcare Solutions GmbH is a wholly owned subsidiary of Robert Bosch GmbH. The subsidiary was established in 2015 with the aim of developing products and services that improve people's health and quality of life. Nearly 300 associates (state 2024) are employed at the company's headquarters in Waiblingen, Germany. The subsidiary's solutions draw on the Bosch Group's core competencies: sensors to collect data, software to evaluate that data, and services based on this data analysis.

Additional information is available online at www.bosch-healthcare.com, www.vivatmo.com, www.bosch-vivalytic.com.

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The company was set up in Stuttgart in 1886 by Robert Bosch (1861–1942) as "Workshop for Precision Mechanics and Electrical Engineering." The special ownership structure of Robert Bosch GmbH guarantees the entrepreneurial freedom of the Bosch Group, making it possible for the company to plan over the long term and to undertake significant upfront investments in the safeguarding of its future. Ninety-four percent of the share capital of Robert Bosch GmbH is held by Robert Bosch Stiftung GmbH, a charitable foundation. The remaining shares are held by Robert Bosch GmbH and by a corporation owned by the Bosch family. The majority of voting rights are held by Robert Bosch Industrietreuhand KG. It is entrusted with the task of safeguarding the company's long-term existence and in particular its financial independence – in line with the mission handed down in the will of the company's founder, Robert Bosch.

Additional information is available online at www.bosch.com, www.iot.bosch.com, www.bosch-press.com.

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