

Near-patient PCR rapid test for whooping cough for Vivalytic by Bosch now available

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World's first fully automated PCR test for detection of

B. pertussis, *B. parapertussis*, *B. holmesii*

- The Vivalytic test is the world's first PCR test for near-patient testing to specifically detect all three whooping cough pathogens: *B. pertussis*, *B. parapertussis*, *B. holmesii*
- Pathogen differentiation is crucial for targeted antibiotic treatment in the early, still unspecific stage of the disease and for controlling the spread of infection
- Pertussis infection rates 2024 at highest level in recent years with high hospitalization rate in newborns and the elderly

Waiblingen – Bosch Healthcare Solutions (BHCS) has introduced a new PCR test Vivalytic Bordetella, expanding the Vivalytic analysis platform's capabilities to include whooping cough. This test can specifically detect the three major whooping cough pathogens *Bordetella pertussis*, *B. parapertussis*, and

B. holmesii in under an hour. BHCS is expanding its test portfolio for "respiratory diseases" to include "pertussis" diagnosis, just in time for the upcoming cold and flu season. The triple test, unique in its composition of pathogens, allows for rapid diagnosis in local healthcare facilities. Previously, such pathogens were only detectable in larger test panels. "Vivalytic Bordetella is our response to the rising number of pertussis cases in Germany. Pertussis poses a significant risk, particularly to infants, the elderly, and individuals with pre-existing health conditions, necessitating rapid diagnosis," says Marc Meier, president of Bosch Healthcare Solutions. Whereas PCR testing in a central laboratory requires one day and culture detection takes three to seven days¹, Vivalytic Bordetella provides results in under an hour. The new test is available for immediate order through distribution partners such as Randox Laboratories and R-Biopharm.

Rapid diagnosis is crucial for prompt treatment

Pertussis typically starts with mild cold-like symptoms, including a slight cough, sneezing, a runny nose, and possibly a moderate fever.² The characteristic staccato cough then develops, sometimes accompanied by wheezing, thick mucus, and vomiting.² Over 90% of patients under three months old and about 10% of those over 65 years old require hospitalization. Pertussis is especially hazardous for infants, for whom it can be life-threatening.³ "Prompt treatment is crucial for Bordetella infections, as the course and severity of the cough can only be mitigated if antibiotic therapy begins early. Moreover, initiating antibiotic treatment promptly and specifically can halt the disease's transmission by breaking the infection chain," says Dr. Stefan Zimmermann of Heidelberg University Hospital. Moreover, two-thirds of pertussis cases occur in adolescents and adults. In these individuals, the infection may not present with the characteristic coughing fits.² These factors underscore the importance of rapid near-patient testing. The Vivalytic Bordetella test is an excellent option for this.

Rising case numbers make the case for rapid testing

In Germany, pertussis case numbers have increased for the second consecutive year in 2024. By the end of July, the Robert Koch Institute (RKI) had been notified of over 11,000 cases.⁴ Germany, along with Poland and Austria, reports some of the highest case numbers.⁵ The surge is attributed to diminished immunity from coronavirus protection measures and a reduced vaccination rate against pertussis. The trend is therefore expected to persist. Whooping cough is extremely contagious. Triggers such as cold air, exertion, or cigarette smoke can induce a dry, tickly cough even months after the coughing fits have subsided. Prompt antibiotic treatment can reduce the duration of the illness.²

Comprehensive testing for all pertussis pathogens

Typically, *B. pertussis* triggers the infection, releasing a toxin that harms the respiratory tract's mucous membrane. In recent years, *B. parapertussis* has been responsible for around ten percent of all infections, which tend to be milder as this pathogen does not produce a toxin.² Since late 2022, the RKI has noted a surge in *B. parapertussis* infections, now accounting for over 50 percent of cases, with increased virulence.⁶ This rise may be attributable to a catch-up effect post-COVID-19 pandemic, more frequent testing, and the absence of an effective vaccine.⁷ *B. holmesii*, the third pathogen tested, is less

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virulent than *B. pertussis*² and typically causes milder, shorter-lasting pertussis-like symptoms.

Vivalytic Analyser enables rapid diagnosis in a remote testing environment

The Vivalytic Analyser allows for quick and easy testing for *B. pertussis*,

B. paraptussis and *B. holmesii* directly in the medical practice. 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 and the use of a deactivating sample medium significantly lower 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 the new Vivalytic Bordatella test.

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

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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.

The Bosch Group is a leading global supplier of technology and services. It employs roughly 429,000 associates worldwide (as of December 31, 2023). The company generated sales

of 91.6 billion euros in 2023. Its operations are divided into four business sectors: Mobility, Industrial Technology, Consumer Goods, and Energy and Building Technology. With its business activities, the company aims to use technology to help shape universal trends such as automation, electrification, digitalization, connectivity, and an orientation to sustainability.

In this context, Bosch's broad diversification across regions and industries strengthens its innovativeness and robustness. Bosch uses its proven expertise in sensor technology, software, and services to offer customers cross-domain solutions from a single source.

It also applies its expertise in connectivity and artificial intelligence in order to develop and manufacture user-friendly, sustainable products. With technology that is "Invented for life," Bosch wants to help improve quality of life and conserve natural resources. The Bosch Group comprises Robert Bosch GmbH and its roughly 470 subsidiary and regional companies in over 60 countries. Including sales and service partners, Bosch's global manufacturing, engineering, and sales network covers nearly every country in the world. Bosch's innovative strength is key to the company's further development. At 136 locations across the globe, Bosch employs some 90,000 associates in research and development, of which nearly 48,000 are software engineers.

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

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