

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

September 3, 2024
PI11883

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. paraptussis* 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. paraptussis* 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 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 Bordetella test.

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

Sources

- 1) <https://www.ecdc.europa.eu/en/publications-data/bordetella-pertussis-laboratory-diagnosis-and-molecular-surveillance>, retrieved on 07/24/2024
- 2) https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Pertussis.html#doc2374534bodyText7, retrieved on 07/24/2024
- 3) <https://www.impfen.de/impfungen/keuchhusten/#gefahr>, retrieved on 07/24/2024
- 4) <https://www.nali-impfen.de/monitoring-daten/krankheitsfaelle-in-deutschland/keuchhusten-pertussis/>, retrieved on 07/24/2024
- 5) <https://www.ecdc.europa.eu/en/publications-data/pertussis-annual-epidemiological-report-2021>, <https://www.ecdc.europa.eu/en/publications-data/pertussis-annual-epidemiological-report-2022>, retrieved on 07/24/2024
- 6) https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2023/33/Art_01.html retrieved on 07/24/2024
- 7) <https://www.aerzteblatt.de/archiv/234049/Robert-Koch-Institut-Zunahme-von-Keuchhusten-durch-B-parapertussis>, retrieved on 07/24/2024

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

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

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