PCR rapid test for Candida auris for Vivalytic by Bosch now available - World's first fully automated PCR test for detection of the multidrug-resistant fungus at the point of care

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- Vivalytic test detects *Candida auris* in under an hour at the point of care, making it the world's first test suitable for screenings.
- *Candida auris* infection rates are on the rise in Germany and can cause severe infections, for example of the bloodstream (sepsis).
- Hospitals can use the new screening test to detect colonization, allowing them to implement measures to contain outbreaks.

Waiblingen – Bosch Healthcare Solutions has developed a PCR test for detecting *Candida auris* (*C. auris*) on the Vivalytic platform. The test is a global innovation now available for order from distribution partners including Randox Laboratories Ltd. and R-Biopharm. This test enables the fully automated detection of the frequently multi-resistant fungus in less than an hour at the point of care. The rapid testing capability also makes it suitable for carrying out screenings when necessary. In contrast, traditional culture tests in centralized laboratories require one to three days, delaying diagnosis and the initiation of targeted treatment. "Considering the heightened risk of severe progression in individuals with pre-existing conditions, we have developed a new test that enables clinics to respond more swiftly," states Marc Meier, managing director of Bosch Healthcare Solutions. Patients with compromised immune systems, such as those in intensive care, individuals with serious underlying conditions such as diabetes, or those who are immunosuppressed due to cancer or HIV, as well as patients about to undergo invasive surgery, face a heightened risk of active infection with *C. auris*. The mortality rate for *C. auris* infections ranges from 30 to 72 percent.

"*Candida auris* can be transmitted from person to person through contact and contaminated surfaces. When this fungus presents, rapid detection is therefore paramount to enable implementation of effective control and prevention strategies," says Dr. med. Alexander Maximilian Aldejohann, deputy head of the Würzburg Laboratory at the National Reference Center for Invasive Fungal Infections (NRZMyk.) Since July 2023, Germany has implemented a limited statutory reporting requirement under the Infection Protection Act. Aldejohann is in favor of extending this reporting obligation: "The fungus has the capacity to rapidly develop resistance to many common antifungal agents coupled with the ability to survive for a relatively long time on surfaces. This high so-called tenacity also increases the risk of outbreaks that are difficult to contain."

Increasing spread of *Candida auris*

C. auris is spreading globally. In some states in the U.S., the annual incidence rate has been shown to increase by a factor of 2 to 3. The Robert Koch Institute (RKI) also drew attention to a rise in cases within Germany during the past year in the Epidemiological Bulletin at the beginning of May. The RKI points out that in specific areas screening could be beneficial. In the U.S., the annual case count has in the meantime reached the thousands. The Centers for Disease Control and Prevention (CDC) already consider the screening of patients, visitors, and staff for *C. auris* as a crucial strategy to curb its spread in healthcare settings. While the fungus is harmless for healthy individuals, it can lead to severe nosocomial infections, i.e. infections acquired in hospitals or other healthcare environments, in patients at high risk and, if the fungus enters the bloodstream, can trigger sepsis.

Easy handling, rapid detection

The Vivalytic Analyser enables effortless testing directly at the point of care: The sample is placed into the test cartridge, which already contains all necessary reagents. The cartridge is then inserted into the Vivalytic Analyser for automated processing. Healthcare professionals require only minimal training to use the system, and the fully automated process significantly lowers the risk of infection. The Vivalytic Analyser thus facilitates rapid and precise diagnostics in PCR quality, bypassing the frequently lengthy process through a central laboratory. Bosch Healthcare Solutions is expecting CE certification for the Vivalytic *C. auris* test soon.

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