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Roche set to market MRSA bacteria diagnosis test

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The FDA granted marketing authorization of the cobas vivoDx MRSA test to Roche Molecular Systems Inc.

The U.S. Food and Drug Administration authorized marketing of a new diagnostic test based on bacterial viability and novel technology to detect Methicillin-resistant *Staphylococcus aureus* (MRSA) bacterial colonization, a widespread cause of hospital-acquired infections. The cobas vivoDx MRSA diagnostic test may allow health care professionals to evaluate patients for colonization with MRSA bacteria more quickly than traditional culture-based techniques when such testing is needed.

“Diagnostics that are able to provide accurate results more quickly can offer health care providers an advantage when trying to prevent and contain the spread of resistant bacteria,” said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health. “Today’s authorization adds a new tool in the fight to prevent and control MRSA in high-risk settings. The FDA remains committed to supporting efforts to address antimicrobial resistance in order to better protect patients against this ongoing public health challenge.”

MRSA is a type of bacteria that can lead to serious illness, and even death, if a patient develops an infection. According to the Centers for Disease Control and Prevention (CDC), approximately 5% of U.S. hospital patients carry the MRSA bacteria, although many of those that carry the bacteria do not develop infections. MRSA has been defined as a serious antimicrobial resistant threat by the CDC. It is resistant to many common antibiotics, which means that if infections develop they can be very challenging to treat and control. The use of active screening to detect MRSA colonization and enable implementation of infection control measures has played an important role in reducing the rates of MRSA infection. The CDC estimates that there were more than 323,000 MRSA cases in hospitalized patients in the U.S. and more than 10,000 deaths in 2017.

The cobas vivoDx MRSA test uses a new bacteriophage technology based on bioluminescence to detect MRSA from nasal swab samples in as little as 5 hours compared to 24-48 hours for conventional culture. Diagnostic tests that can more quickly and easily detect MRSA could benefit patient care and may help healthcare providers prevent the spread of MRSA. The FDA reviewed data from performance studies in which the cobas vivoDx MRSA test correctly identified MRSA in approximately 90% of samples where MRSA was present and correctly identified no MRSA in 98.6% of samples that did not have MRSA present. The cobas vivoDx MRSA test authorized today is intended to aid in the prevention and control of MRSA infections in healthcare settings and can be used to identify patients needing enhanced precautions for infection control such as isolation and additional decolonization efforts.

The FDA reviewed the cobas vivoDx MRSA test through the de novo premarket review pathway, a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this authorization, the FDA is establishing special controls for tests of this type, including requirements relating to labeling and design verification and validation to address certain risks, such as false positives. When met, the special controls, along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

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