FDA authorizes marketing of Roche MRSA diagnostic test

Dec. 27, 2019—The FDA authorized marketing of the Cobas VivoDx MRSA (Roche) diagnostic test based on bacterial viability and novel technology to detect methicillin-resistant *Staphylococcus aureus* bacterial colonization.

The Cobas VivoDx MRSA test uses a new bacteriophage technology based on bioluminescence to detect MRSA from nasal swab samples in as few as five hours compared with 24 to 48 hours for conventional culture. The FDA reviewed data from performance studies in which the Cobas VivoDx MRSA test correctly identified MRSA in approximately 90 percent of samples where MRSA was present and correctly identified no MRSA in 98.6 percent of samples that did not have MRSA present. The test is intended to aid in the prevention and control of MRSA infections in health care 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.