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FDA NEWS RELEASE

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FDA clears first test to quickly diagnose and distinguish MRSA and MSSA

The U.S. Food and Drug Administration today cleared the first test for Staphylococcus aureus (S.aureus) infections that is able to quickly identify whether the bacteria are methicillin resistant (MRSA) or methicillin susceptible (MSSA).

There are many different types of Staphylococci bacteria, which cause skin infections, pneumonia, food and blood infections (blood poisoning). While some S.aureus infections are treated easily with antibiotics, others are resistant (MRSA) to commonly prescribed antibiotics such as penicillin and amoxicillin.

The KeyPath MRSA/MSSA Blood Culture Test determines whether bacteria growing in a patient's positive blood culture sample are MRSA or MSSA within about five hours after any bacterial growth is first detected in the sample. Aside from blood culture equipment, the test does not require any specific instruments to get results, which makes it useful in any laboratory.

"Clearing this test gives health care professionals a test that can confirm S.aureus and then identify whether the bacteria is MRSA or MSSA," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics Device Evaluation and Safety in the FDA's Center for Devices and Radiological Health. "This not only saves time in diagnosing potentially life-threatening infections but also allows health care professionals to optimize treatment and start appropriate contact precautions to prevent the spread of the organism."

MRSA infections can occur anywhere; however, infections appearing in health care settings are usually more severe and potentially life-threatening given patients being treated in those facilities may have weakened immune systems and frequently undergo procedures such as surgery, which allows an easier spread of bacteria directly into the body.

The FDA based its clearance on a clinical study of 1,116 blood samples evaluated at four major U.S. hospital centers. Within the organisms determined to be S.aureus, the MRSA determination was 98.9% accurate (178/180) and the MSSA determination was 99.4% accurate (153/154).

The KeyPath MRSA/MSSA Blood Culture Test is manufactured by MicroPhage Inc. of Longmont, Colo.

For more information:

[FDA: Medical Devices](#)¹

[FDA: Device Approvals and Clearances](#)²

[CDC: MRSA Infections](#)³

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