

FDA Clears New Diagnostic Test to Distinguish MRSA and MSSA

MRSA Diagnostic Cleared

The KeyPath MRSA/MSSA Blood Culture Test for *Staphylococcus aureus* strains was cleared by the FDA.

Katherine DeYoung, PhD

May 12, 2011 – MicroPhage, Inc., of Longmont, Colorado, has received US Food and Drug Administration (FDA) 510(k) clearance for its KeyPath MRSA/MSSA Blood Culture Test, according to an FDA news release.

The test is the first to rapidly distinguish between methicillin resistant *Staphylococcus aureus* (MRSA) and methicillin susceptible *Staphylococcus aureus* (MSSA).

The FDA decision is based on results of a clinical study conducted at 4 major U.S. medical centers, including Duke University Medical Center, UMDNJ-Robert Wood Johnson Medical School, Northwestern University and Denver Health. Of 1,116 blood samples evaluated, MRSA was detected with 98.9% accuracy (178/180) and MSSA with 99.4% accuracy (153/154) in those samples identified to contain *Staphylococcus aureus* (*S. aureus*).

A 2010 study by the Centers for Disease Control and Prevention (CDC) showed that invasive hospital-acquired MRSA infections declined 28% from 2005-2008. In people with recent exposure to healthcare settings, invasive MRSA infections diagnosed before hospital admission declined 17% over the same period.

The CDC also notes a rapid increase in rates of community-acquired MRSA over the past decade and states that the risk of developing community MRSA does not seem to be following the same downward trend as healthcare-associated infections.

The KeyPath MRSA/MSSA Blood Culture Test uses proprietary bacteriophage amplification technology, developed by MicroPhage, Inc., to distinguish between resistant and sensitive bacteria. As described on the manufacturer's website, bacteria isolated from a patient blood sample are exposed to bacteriophage plus a target antibiotic. Susceptible bacteria will be killed by the antibiotic, but resistant bacteria will be infected by the bacteriophage, producing a detectable protein signal within about 5 hours after bacterial growth is confirmed in the patient's blood culture. Currently available methods of MRSA testing take up to several days.

"Clearing this test gives health care professionals a test that can confirm *S. aureus* and then identify whether the bacteria is MRSA or MSSA," stated Alberto Gutierrez, PhD, 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," Gutierrez concluded.