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MicroPhage Results on Rapid *S. aureus*/MRSA Blood Culture Test Published

LONGMONT, CO: May 21, 2009 –The performance of a new diagnostic test platform that rapidly identifies *Staphylococcus aureus* (*S. aureus*, “staph”) bacteremia and determines antibiotic resistance or susceptibility in as little as 5 hours was presented at the 109th General Meeting of the American Society of Microbiology in Philadelphia, PA this week.

The poster summarized the performance of the test prototype in a multisite clinical trial in late 2008 in three separate clinical microbiology laboratories. In 711 evaluable clinical samples, the test demonstrated perfect specificity for *S. aureus*, with no cross reactivity against non-target organisms, and high sensitivity, detecting 9 out of every 10 *S. aureus* present. Specificity in determining methicillin-resistant *S. aureus* (MRSA) was also found to be high, at 99%, while methicillin-sensitive *S. aureus* (MSSA) specificity exceeded 99%.

“Current methods rapidly identify *Staphylococcus* to the species level but are not capable of determining resistance,” said lead author Julie D. Kingery, MD, of Johns Hopkins University School of Medicine, “Complex molecular assays can do this, however they are frequently expensive, require special expertise, and their utility as rapid tests is reduced because they may need to be batched. This assay allows tests to be set up in real time and is easy to use. Because no instrumentation is required, the assay is also inexpensive.”

MicroPhage’s prototype assay is designed to rapidly identify *Staphylococcus aureus* (staph) bacteria and determine methicillin resistance (MRSA) or susceptibility (MSSA) in suspected cases of bacteremia – bacteria in the blood. The research preceded FDA required clinical studies, which are scheduled to begin this summer. Clinical testing sites included Johns Hopkins University Hospital, Northshore University Healthcare (IL), and the University of Maryland Medical School. More information on the study is available on the National Institute of Health’s ClinicalTrials.gov website, study # NCT00814151.

The MicroPhage test platform requires no instrumentation and is composed of two small reaction tubes for incubating blood culture specimens. After five hours, the incubated samples are added to a dual dipstick-like detector, which looks much like a pair of home pregnancy tests. One part of the detector shows if the sample is infected with *S. aureus* bacteria and the other shows if it is susceptible or resistant to the antibiotic.

According to Drew Smith, Ph.D, Director, Research and Development at MicroPhage, test performance at the three sites exceeded all study goals for the prototype. “This test performed more like a market-ready test, producing excellent results with regard to specificity,” said Smith. “We are confident the final manufactured product will be robust and meet the demands of the clinical laboratory market and the scrutiny of the FDA, including increased test sensitivity. We have already made significant improvements to this test since the trial.” He added that the test will be released to US hospitals later this year for Investigational Use Only. US market clearance will follow early next year.

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About the MicroPhage Technology

MicroPhage has adapted bacteriophage-amplification, a natural biologic process, for identifying bacterial infections. Phages are harmless bacteria-specific viruses that multiply aggressively when exposed to target bacteria. In the detection process, reaction of the bacteriophage proteins on the test strip indicates the sample is positive for staph bacteria. For susceptibility analysis, the organism in the sample is challenged with an antibiotic. Because phages depend on host bacteria for amplification, any compound that kills or inhibits the microbe will stop phage amplification. Only strains resistant to the antibiotic allow this amplification and yield a positive signal on the second detector strip, indicating an MRSA infection. Further information about the technology is available at www.microphage.com/technology.

About Staph Infections

Staphylococci are frequently implicated in bloodstream infections (BSI) with high morbidity and mortality. In a multinational study, 36% of bloodstream isolates were staphylococci, 61% of which were *Staphylococcus aureus*. In a prospective cohort of patients with hospital-acquired BSIs in the United States, *S. aureus* was a primary cause, accounting for 20% of cases. The incidence of *S. aureus* bacteremia has increased significantly over the past decade, largely due to the increasing use of intravascular catheters and invasive devices. There has also been a significant rise in rates of methicillin-resistant *S. aureus* (MRSA). Almost 60% of *S. aureus* bacteremias in the United States are now caused by these resistant strains. Despite advances in medical therapy and diagnostic procedures, *S. aureus* bacteremia is often associated with serious complications with a mortality rate that exceeds 20%, especially if appropriate therapy is not administered rapidly. A rapid and reliable test for this diagnosis would allow clinicians to optimize diagnostic and therapeutic decisions. Antibiotic therapy could be adjusted early, leading to better health outcomes for patients with lower pharmacy and hospitalization costs.

Diekema DJ, Schmitz FJ, Pfaller MA, Bell J, Smayevsky J, Beach M, Jones RN, and the SENTRY Participants Group. Survey of infections due to *Staphylococcus* species: frequency of occurrence and antimicrobial susceptibility of isolates collected in the United States, Canada, Latin America, Europe, and the Western Pacific region for the SENTRY antimicrobial surveillance program, 1997–1999. *Clin Infect Dis* 2001;32:S114–S132

About MicroPhage, Inc.

Based in Longmont, Colorado and privately held, MicroPhage, Inc. is working to be a global leader in developing rapid diagnostics products for bacterial identification and antibiotic susceptibility/resistance testing. Using its proprietary bacteriophage-based amplification platform, the company has developed a patented process that is a product platform for rapid, easy-to-use, inexpensive diagnostic tests. Its first products, expected in late 2009, will set a new standard for clinicians in *S. aureus* identification and antibiotic susceptibility testing, and are designed to fit the demands of hospitals and laboratories of all sizes. For further information, go to www.microphage.com.

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