

5-Hour Diagnostic Test for MRSA

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October 26, 2008 (Washington, DC) — Diagnostic technology that uses bacteriophages has the potential to quickly identify pathogens and their drug sensitivity to better guide therapy. Initial data on the new approach were presented in a poster here at the 48th Annual ICAAC/IDSA 46th Annual Meeting, a joint meeting of the American Society for Microbiology and the Infectious Diseases Society of America.

"The technology uses bacteriophages as a surrogate for identifying bacteria and determining whether they are susceptible or resistant to a given drug," Drew Smith, PhD, explained to *Medscape Infectious Diseases*. He is Director of Research and Development at MicroPhage, Inc, the company that is developing the diagnostic test.

The sample — initially blood, but the approach is amenable to a wide range of samples, including urine, saliva, nasal, and wound swabs — is combined with a mixture containing the phages and growth medium. The process takes about 5 minutes. The mixture is maintained at 35 °C for 5 hours.

A few drops of the "brew" are then added to a detector strip housed in a device similar to a home pregnancy test. The appearance or nonappearance of bars on the strip indicates the presence or absence of drug-resistant bacteria.

Initial testing with a representative panel of 120 clinical isolates of *Staphylococcus aureus* had a sensitivity of 93% and a specificity of 96%. Dr. Smith anticipates that the clinical specificity will be greater than 99% by the time the test is ready for market. That is equal to or better than existing diagnostic tests for the pathogens.

Polymerase chain reaction (PCR) tests "tell you what drugs the physician can't use to treat the patient; this is a susceptibility test, so it tells physicians what drug they can use." He said the test has greater clinical utility, requires no trained staff, is more rapid, and costs less (~\$20) than PCR tests. "We are trying to move the tests out closer to the patient."

"The nice thing about bacteriophages is that they grow everywhere — urine, blood, and pus don't inhibit them the way they do enzymatic reactions like PCR. Saliva is known to be a big inhibitor of PCR," said Dr. Smith.

Expanded testing is underway at Johns Hopkins University, the University of Maryland, and Northwestern University. Approval trials are likely to begin next spring, and a product will likely be on the market as early as early 2010.

The diagnostic tool "is looking at how the bacteriophage behaves, particularly in response to an antibiotic. It takes a couple of hours for the biology to happen," Dr. Smith said. He anticipates that, in subsequent generations of the test, time will be reduced by up to half, but no further.

The company has begun work with other pathogens and anticipates developing subsequent generations of the diagnostic tool that will be able to identify multiple pathogens on a single platform. That will be particularly important for treating wounds.

David Classen, MD, professor at the University of Utah School of Medicine, in Salt Lake City, welcomed the prospect of a quicker, easier test, but he does not believe it will change clinical practice. He told *Medscape Infectious Diseases* that physicians treat empirically. "In my practice, I culture and treat and use the results from the culture to guide further therapy."

Dr. Classen said the test might have greater utility in conducting surveillance if screening on entry becomes more common at healthcare facilities, or if it could be applied to colonization with methicillin-resistant *S aureus* (MRSA). He recommended the recently issued Healthcare-Associated Infections Prevention Compendium, which he was involved in developing, as a good resource for questions on infection control.

Dr. Smith is an employee of MicroPhage Inc, which is developing the diagnostic. Dr. Classen has disclosed no relevant financial relationships.

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