

C-161 Detection of *S. aureus* Skin and Soft Tissue Infections by Use of Bacteriophage Amplification Technology

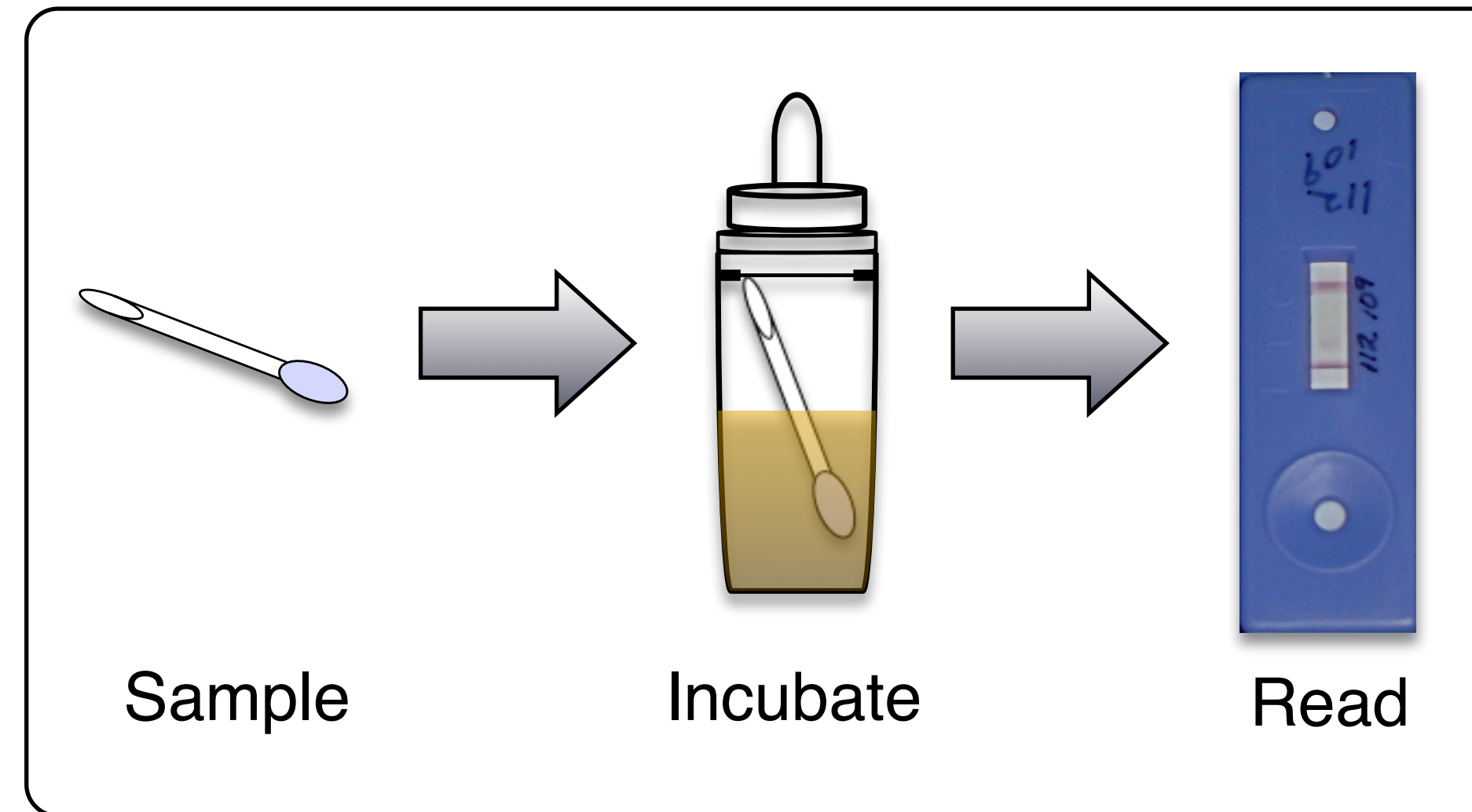
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Background: Accurate, rapid and simple methods for detection of *S. aureus* wound infections are a key unfilled need in clinical microbiology. Tests based on MicroPhage's Bacteriophage Amplification Technology have been developed for identification and susceptibility testing of *S. aureus* bacteremia, and for screening of nasal swabs. We tested the performance of the MicroPhage *S. aureus* Screening Test in detecting *S. aureus* from wound swabs. The Test performed well, detecting 7 of 8 *S. aureus*-positive wound swabs taken from a variety of body sites. There was no evidence of interference from sample matrix.

Methods: 33 excess specimen wound swabs, with all patient information deleted, were obtained from St. Mary Corwin Hospital (Pueblo, CO). The tests were run in 1.0 ml of culture broth and a cocktail of *S. aureus*-specific bacteriophage. Swab buds were placed in the test broth, and a sample of each reaction was taken for colony counts and classical microbiology. The reactions were incubated at 35° for 16 hours. Phage amplification was detected by plaque assay, and by lateral-flow immunoassay (LFI).

Microbiology: Samples were plated on Tryptic Soy and ChromAgar *S. aureus* plates. All samples testing positive on the ChromAgar or MicroPhage tests were further characterized by gram staining, tube coagulase, and API Staph tests.



The MicroPhage test: A sample swab is collected and placed in a test bottle containing bacteriophage and 1 ml culture broth. The mixture is incubated, allowing the bacteriophage to amplify if the target species is present. Amplification is detected by anti-phage antibodies on a lateral-flow immunoassay device

Results: Four samples had been identified by the hospital lab as *S. aureus*-positive, and all of these were positive by the MicroPhage test. Our microbiology testing revealed 4 additional positive samples, and 3 of these were detected by the MicroPhage test. The one false-negative sample contained very low bacterial input (90 cfu). Overall, 7/8 positives were detected by the MicroPhage test, compared to 4/8 by the hospital's standard method.

Three false-positives were reported. All of these samples were predominantly gram-negative, and had very high levels of bacterial recovery, 5×10^5 - 6×10^6 cfu/swab. One false-positive showed no phage amplification, suggesting that the immunoassay was the source of the test cross-reaction.

Whether the phage-positive false-positives are the result of amplification on gram-negative hosts, or of amplification on low levels of *S. aureus* present has not been resolved.

ID results	Reference		Total
	SA	not SA	
Micro Phage	SA	7	10
	not SA	1	23
Total		8	33

Conclusions: These initial results suggest that development of a MicroPhage *S. aureus* SSTI Test is highly feasible. The *S. aureus* Nasal Swab Screening Test was used with no modification or adaptation, and was able to detect 7/8 *S. aureus*-positive swabs. There was no evidence of matrix interference, as positive results were obtained from two samples that contained significant visible levels of blood and pus.

Hands-on time for the test was less than 5 minutes. The phage reaction was run overnight for convenience; the optimal incubation time has not been determined, and is likely to be much shorter, closer to the incubation time for our *S. aureus* bacteremia test, 5 hours.