



## MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test - BT Fact Sheet

### Product Overview

The MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test – BT is the first U.S. Food and Drug Administration-cleared test to simultaneously identify the presence of *Staphylococcus aureus* bacteria and determine if the isolate is methicillin resistant (MRSA) or methicillin susceptible (MSSA) directly from positive blood culture samples in 1 day.

The test is unique because it rapidly differentiates MSSA from MRSA, giving the clinician the opportunity to prescribe the optimum therapy to treat up to 2 days sooner than is possible with current test methods. As many as half of all patients with *S. aureus* infections are initially prescribed sub-optimal or inappropriate antibiotics, a practice that can negatively affect patient outcomes and increase costs to the healthcare system. Current tests can take between 2 and 5 days (3 days is most common) to identify a bacterial strain and determine its antibiotic susceptibility. During this time patients are generally treated with broad-spectrum antibiotics that may or may not be the ideal course of treatment for their particular infection.

The MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test – BT provides clinicians with two critical advantages:

- It enables them to optimize antibiotic therapy earlier in the course of disease, thus increasing potential to improve patient outcomes, reduce length of hospital stay and hospital costs
- Appropriate contact precautions can be initiated to prevent the spread of the organism within the clinical setting

Additionally, the MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test – BT does not require any specialized equipment or instrumentation, thus it can be readily integrated into hospitals of any size or financial means.

### **About *Staphylococcus aureus* (*S. aureus*)**

*S. aureus* is a strain of the *Staphylococci* bacteria, which is a leading cause of skin infections, pneumonia and blood infections (blood poisoning). While some *S. aureus* infections are treated easily with antibiotics, others are resistant to commonly prescribed antibiotics such as penicillin and amoxicillin.

*S. aureus* bloodstream infections have a fatality risk of 30 to 40 percent, allowing only a small window of time to administer antibiotic therapy to prevent a possible downward spiral into sepsis. Today's standard diagnostic methods, such as blood cultures and PCR-based tests, require 3 days, on average, to deliver results. During this time, prior to the results being available, patients are generally treated with broad-spectrum antibiotics that may or may not be the right ones for that particular infection. Earlier treatment with targeted antibiotics can result in improved patient outcomes, and reduced length of hospital stay and associated costs.

## **Hospital-Acquired Infections (HAI)**

HAIs exceed 1.7 million in the United States each year, resulting in more than 100,000 deaths.<sup>1</sup> This death rate exceeds that of breast cancer, prostate cancer and AIDS combined, and antibiotic resistance is considered a contributing factor in 75 percent or more of these deaths.<sup>2,3</sup>

While MRSA infections can occur anywhere, those that occur in hospital settings tend to be of higher severity due to patients' weakened immune systems and/or recent surgeries, which leave the body susceptible to infection.

## **Clinical Results**

The MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test – BT was evaluated in a clinical study of 1,116 blood samples evaluated at four major U.S. hospital centers, including Duke University Medical Center, UMDNJ-Robert Wood Johnson Medical School, Northwestern University Hospital System and Denver Health.

The test was 99.4 percent accurate (153/154) in determining MSSA and 98.9 percent accurate (178/180) for MRSA identification within the organisms identified as *S. aureus*.

## **Regulatory Status**

The U.S. Food and Drug Administration granted 510(k) clearance for the MicroPhage KeyPath™ MRSA/MSSA Blood Culture Test – BT in May 2011. The test obtained CE Mark in Europe in 2009.

## **About MicroPhage**

Based in Longmont, Colorado, privately-held MicroPhage, Inc. develops rapid, easy-to-use diagnostic products for bacterial identification and antibiotic susceptibility/resistance testing using its proprietary Bacteriophage Amplification Technology (BAT™) platform. The MicroPhage BAT™ platform does not require any instrumentation and is simple to operate, enabling time-critical microbiology testing in healthcare facilities of any size or financial means.

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<sup>1</sup> Klevens et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep (2007) vol. 122 (2) pp. 160-6

<sup>2</sup> Prostate cancer: 32,050 deaths in 2010, <http://www.seer.cancer.gov/statfacts/html/prost.html>. Breast cancer: 39,840 deaths in 2010, <http://www.seer.cancer.gov/statfacts/html/breast.html>. HIV/AIDS: 11,295 deaths in 2007, <http://www.cdc.gov/nchs/fastats/aids-hiv.htm>

<sup>3</sup> Klevens et al. The impact of antimicrobial-resistant, health care-associated infections on mortality in the United States. Clin Infect Dis (2008) vol. 47 (7) pp. 927-30