

## Notification of new assay - MRSA SA SSTI by PCR

Bellin Lab began offering a real-time PCR assay for the detection on *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) from skin and soft tissue infection (SSTI) swabs on September 1, 2010. The assay is indicated for use in conjunction with other lab tests such as culture, and clinical data as an aid in the detection of MRSA and SA from skin and soft tissue infections. Real-time PCR provides the advantages of a greatly decreased time for answers and increased sensitivity. It is not intended to monitor treatment of infections because the test can detect DNA from non-viable organisms. Culture should be used in these cases.

*Order as* “MRSA SA SSTI by PCR”. Specify the source. **If a culture and sensitivity are also wanted, they must be ordered separately.**

*Specimen requirements:* Collect two sets of dual culture swabs (red topped BBL culture swab) from the infected area. Label and transport to Lab. If delivery is delayed, refrigerate the specimen.

Analytic time once the specimen arrives in lab is approximately one hour. Testing will be performed 24 hours a day. Results will be reported as:  
(Test name: MRSA SA SKIN OR TISSUE PCR)

STAPH AUREUS DNA      “DETECTED”      or      “NOT DETECTED”

MRSA DNA      “DETECTED”      or      “NOT DETECTED”

*Performance characteristics:*

Among subjects with no antibiotic use within the 3 weeks prior to sample collection, the Xpert MRSA/SA SSTI Assay identified 93.8% of the specimens positive for MRSA and 97.3% of the specimens negative for MRSA relative to the reference culture method, and 95.7% of the specimens positive for SA and 89.5% of the specimens negative for SA relative to the reference culture method.

*Interfering substances:*

1. StaphA + Septic (5% w/v), Hydrocortisone (5% w/v), and antibacterial hand sanitizer (5% w/v).
2. Samples containing Mercurochrome.
3. The MRSA/SA Assay can detect MRSA and/or SA DNA from non-viable organisms. The probability of this occurring increases for patients on antibiotics. In the pivotal clinical study the false positive rate (relative to culture) of detecting SA in patents using antibiotics, within 3 weeks prior to Xpert MRSA/SA testing, was 13.8%. The false positive rate (relative to culture) of detecting MRSA in patients using antibiotics, within 3 weeks prior to Xpert MRSA/SA testing, was 9.5%.
4. In a mixed culture containing MRSA/SA and other organisms (e.g. Gram negative bacilli, yeast), results can be false negative or variable depending on the concentration of MRSA/SA present,

## Notification of new assay – Blood Culture SA/MRSA PCR

Effective September 30, 2010 Bellin Lab has begun performing real-time PCR for the detection of Staph aureus (SA) and methicillin-resistant Staph aureus (MRSA) DNA directly from a patient's positive blood cultures. Current culture-based lab methods require an additional 18-48 hours for determination of Staph aureus or MRSA. Our new PCR assay will provide the result within one hour. The assay will be performed 24 hours a day.

The test will be done as reflex testing on one blood culture per patient that shows gram positive cocci in clusters (indicating Staphylococcus). Additional charges will apply. Please refer to your patient report.

Results will be reported as:

STAPH AUREUS DNA : *DETECTED* or *NOT DETECTED*

MRSA DNA: *DETECTED* or *NOT DETECTED* or *INDETERMINATE*  
*SUSCEPTIBILITY*  
*PENDING*

All positive blood culture reports are considered and automatic call-back result.

The addition of PCR testing will result in an additional patient charge.

Please call Bellin Lab Customer Service at 433-3650 or Bellin Microbiology department at 433-3725 for more information.