Xpert® MRSA/SA SSTI

Detect MRSA & SA Skin and Soft Tissue Infections In Less Than One Hour
MRSA is the most common identifiable cause of skin and soft-tissue infection among patients presenting to emergency departments. When antimicrobial therapy is indicated for the treatment of skin and soft-tissue infections, clinicians should consider obtaining cultures and modifying empirical therapy to provide MRSA coverage.”

Moran, et al.
New England Journal of Medicine, August 2006

THE NEED

SSTIs are a major health concern:

- The most common cause of skin and soft tissue infections is *Staph aureus*; MRSA represents over 50% of these infections in parts of the U.S.\(^1\)
- Current laboratory methods can take up to 72 hours to determine if a SSTI is SA or MRSA
- Empiric treatment, found to be incorrect in 57% of patients according to one study, is employed due to lack of a rapid identification method\(^2\)

THE SOLUTION

The only rapid and comprehensive SSTI test available:

- Xpert\(^{®}\) MRSA/SA SSTI is a rapid, on-demand test for detecting MRSA and SA from skin and soft tissue swabs in less than one hour
- Xpert MRSA/SA SSTI is the most comprehensive *Staph aureus* test available:
  - Includes targets for *Staph aureus*, MRSA, and mecA
  - Identifies presumptive positive “empty cassette” strains for correct classification as SA sensitive
  - Unparalleled automation with the GeneXpert\(^{®}\) System provides reduced hands-on time and improved laboratory efficiency

Important healthcare benefits of rapid detection:

- Helps ensure the right therapy sooner for improved patient management
- Enables a targeted antimicrobial therapy approach for better antimicrobial stewardship
- Allows for immediate identification of patient infection for improved isolation and infection control measures
PERFORMANCE
Performance characteristics of Xpert® MRSA/SA SSTI were determined in a multi-site prospective investigation study at three institutions by comparing the Xpert MRSA/SA SSTI test on the GeneXpert® System to enriched culture, the most sensitive culture method.

Summary of Results

<table>
<thead>
<tr>
<th>Type</th>
<th>Positive Percent Agreement</th>
<th>Negative Percent Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA</td>
<td>93.8%</td>
<td>97.3%</td>
</tr>
<tr>
<td>SA</td>
<td>95.7%</td>
<td>89.5%</td>
</tr>
</tbody>
</table>

MRSA/SA Performance in Subjects with No Antibiotic Use (within 3 weeks of sample collection) vs. Reference Culture

<table>
<thead>
<tr>
<th>Xpert</th>
<th>CULTURE</th>
<th>MRSA+</th>
<th>SA+/MRSA-</th>
<th>Neg/No Growth</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA+</td>
<td>137&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2</td>
<td>6</td>
<td></td>
<td>145</td>
</tr>
<tr>
<td>SA+/MRSA-</td>
<td>3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>79</td>
<td>16</td>
<td></td>
<td>98</td>
</tr>
<tr>
<td>SA-</td>
<td>6</td>
<td>4</td>
<td>188</td>
<td></td>
<td>198</td>
</tr>
<tr>
<td>Total</td>
<td>146</td>
<td>85</td>
<td>210</td>
<td></td>
<td>441</td>
</tr>
</tbody>
</table>

<sup>a</sup>1 of the 137 were mixed infections of MRSA and SA.
<sup>b</sup>2 of the 3 were mixed infections of MRSA and SA.

COMPREHENSIVE
Capable of detecting strains with all SCCmec types found in both healthcare-acquired and community-acquired MRSA.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Type</th>
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</thead>
<tbody>
<tr>
<td>Swabs collected for routine care of SSTIs</td>
<td></td>
</tr>
<tr>
<td>SCCmec</td>
<td>I, II, III, IVa, V, VI</td>
</tr>
</tbody>
</table>
ORDERING INFORMATION

Xpert® MRSA/SA SSTI (10 test) ............................... Catalog No. GXMRSA/SA-SSTI-10

References:
1. CDC Press release 09/08/2008 entitled “CDC Steps Up Efforts to Fight Drug-Resistant Germ”.

For In Vitro Diagnostic Use.