The Staph ID/R Blood Culture Panel: An FDA Cleared Rapid Detection Method for *Staphylococcus* and the mecA Gene Direct from Positive Blood Culture

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**Abstract**

*Staphylococcus* (Staph) bacteria are one of the most common causes of healthcare-associated bloodstream infections. The Staph ID/R Blood Culture Panel is a DNA multiplex assay that directly detects *S. aureus*, *S. lugdunensis*, either Staph-species, and the mecA gene for methicillin-resistant *S. aureus* within 2 hours from a positive blood culture. The Staph ID/R Blood Culture Panel demonstrates a limit of detection (LoD) well below typical blood culture bacteria load and a broad reactivity profile across multiple Staph species.

The assay is unique in its ability to distinguish Coagulase-negative *Staphylococcus* (CoNS), which may not require treatment with antibiotics, from pathogenic *Staphylococcus* In addition the Staph ID/R Blood Culture Panel displays high specificity, is broadly reactive within the genus, and is compatible across multiple blood culture bottle types and manufacturers. Fast and accurate diagnosis of Staph bloodstream infections leads to decreased hospital length of stay, lower treatment costs by rapidly identifying appropriate antimicrobial therapy and assists healthcare organizations with antimicrobial stewardship programs.

**Background and Methods**

- **For all Staphylococcus testing (i.e., LoD, reactivity, media compatibility):**
  - BACTEC Blood culture bottles were inoculated with approximately 10-100 CFU, incubated to allow positivity in a BACTEC 9500 Blood Culture System and Gram stained to confirm the presence of Gram Positive Cocci or Cocci Clusters (GPC or GPCG).
  - GPC were enumerated by plating serial dilutions on tryptic soy agar, diluted to target levels with negative blood culture media if necessary, and enumerated to confirm target levels were obtained.
  - For media compatibility, non-BACTEC media bottles were incubated 16-20 hours, shaking at 37°C. Samples were Gram stained to confirm presence of GPC, and enumerated by plating serial dilutions on tryptic soy agar plates. *Staphylococcus* species ± mecA, including *S. aureus*, *S. lugdunensis*, *S. epidermidis*, were triplicated from three (3) independent blood culture bottles (9 tests per strain and bottle type).
  - For all non-Staphylococcus testing (i.e., specificity):
    - Non-Staphylococcus GPC, Gram Negative, and Yeast were incubated 8 hours past alarm positivity to achieve high titer (≥10⁵ CFU/mL) and enumerated to confirm target levels by plating serial dilutions as above.
    - Genomic DNA for Mycoplasma and Mycobacterium were inoculated into negative blood culture media at a concentration ≥10⁶ genomic copies/mL.

**Limit of Detection (LoD)**

<table>
<thead>
<tr>
<th>Species</th>
<th>BACTEC™</th>
<th>Plus Aerobic/F</th>
<th>Plus Anaerobic/F</th>
<th>Pods Plus™</th>
<th>Lytic/10 Anaerobic/F</th>
<th>Standard/10 Aerobic/F</th>
<th>Standard/10 Anaerobic/F</th>
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</thead>
<tbody>
<tr>
<td><em>S. aureus</em></td>
<td>25923</td>
<td>3.5 - 8.2 x 10⁵</td>
<td>3.9 - 6.2 x 10⁵</td>
<td>3.6 - 5.8 x 10⁵</td>
<td>2.7 - 4.7 x 10⁵</td>
<td>2.6 - 4.7 x 10⁵</td>
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</tbody>
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**Staph ID/R Blood Culture Panel Highly Reproducible**

- **Species, Bacteria Load (Low or High), Sample input (CFU/mL):**
  - *S. aureus* or *S. lugdunensis*: 25923, 6538, 11632, 23964, 51560, 62480, 49850, 27630

**Conclusions**

The Staph ID/R Blood Culture Panel can determine the presence of *Staphylococcus* (either *S. aureus* or *S. lugdunensis* species, or *Staphylococcus* genus) as well as whether it harbors the mecA within 2 hours (2) hours of testing a GPCG positive blood culture. The Staph ID/R Blood Culture Panel demonstrates a limit of detection (LoD) well below typical blood culture bacteria load. The test is broadly reactive across the *Staphylococcus* genus with no loss in sensitivity for any individual species and is highly specific. Additionally, the Staph ID/R Blood Culture Panel is compatible across multiple blood culture bottle types and manufacturers and demonstrates excellent reproducibility.