Evaluation of Coris BioConcept’s KPC K-SeT Assay for Rapid Accurate Distinction of KPC Carbapenem-Producing Organisms (CPO) from other CPO Genotypes and from Non-CPO

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ABSTRACT

Background: Emerging CPO threatens global public health. Microbiology laboratories face challenges in distinguishing CPO from epidemiologically less-significant non-CPO. Timely confirmation and distinction between genotypes is critical for timely implementation of infection control interventions. Coris BioConcept’s K-SeT assay aims to provide an easy-to-use, rapid immunochromatographic method for detecting KPC carbapenemases with high sensitivity and specificity.

Methods: Prior to the study, all genotypes were confirmed using MALDI-TOF. Sensitivity and specificity were assessed using blinded non-CPO isolates from clinical specimens, or when surveillance specimens produce isolates on selective screening algorithms. Isolates were tested in triplicate on K-SeT (C) and K-SeT (T) controls. Conclusive results were analyzed using sensitivity, specificity, PPV, and NPV. All assays were performed individually by at least two operators on at least two occasions, blinded to organisms species and genotypes.

Results: All K-SeT results were in agreement with MALDI-TOF results. One K-SeT false-negative was recorded for a known CPO isolate.

Conclusion: The Coris BioConcept’s K-SeT assay provided highly accurate results for detecting KPC-type CPO. It is simple, rapid, and low-complexity, making it suitable for laboratories not equipped with PCR capabilities. The assay is easy to use and highly sensitive and specific for detecting KPC-type CPO.

INTRODUCTION

Rapid准确 detection of CPO is integral to preventing transmission of organisms that may lead to high-mortality patient outcomes. In areas of low-prevalence, clinical laboratories mostly use culture-based methods for CPO detection given cultures’ lower cost and the limited ability of commercial PCR’s to detect all genotypes in global circulation. CPO are typically suspected when routine susceptibilities indicate non-susceptibility to >1 carbapenems in isolates from clinical specimens, or when surveillance specimens produce isolates on selective screening algorithms. Many laboratories, however, do not have the resources or protocol in place to use culture-based methods for CPO detection. This study evaluated Coris BioConcept’s low-complexity K-SeT assay for its ability to distinguish KPC-type CPO from other CPO isolates.

Rapid accurate detection of CPO is integral to preventing transmission of organisms that may lead to high-mortality patient outcomes. In areas of low-prevalence, clinical laboratories mostly use culture-based methods for CPO detection. Although PCR remains an important tool for selective use in high-risk cases to enable immediate direct-from-swab detection of common CPO tested 134 (44.7)/0 (0) McDiff test isolates (No. (%) test isolates). Isolates were tested in triplicate on K-SeT (C) and K-SeT (T) controls.

METHODS

Rapid and accurate detection of CPO is critical to preventing transmission of organisms that may lead to high-mortality patient outcomes. In areas of low-prevalence, clinical laboratories mostly use culture-based methods for CPO detection. Although PCR remains an important tool for selective use in high-risk cases to enable immediate direct-from-swab detection of common CPO tested 134 (44.7)/0 (0) McDiff test isolates (No. (%) test isolates). Isolates were tested in triplicate on K-SeT (C) and K-SeT (T) controls.

RESULTS

Table 1. Characteristics of 60 Gram-negative bacteria used to evaluate Class A CPO detection using Coris BioConcept's KPC K-SeT assay

<table>
<thead>
<tr>
<th>Genotype</th>
<th>No. (%) of KPC-positive isolates</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>142 (100)</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1. Summary of K-SeT results obtained from all CPO and non-CPO isolates tested for KPC detection

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</tbody>
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Table 2. Evaluation of Coris BioConcept’s KPC K-SeT Immuno-chromatographic assay for detecting KPC CPO

<table>
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<tr>
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<th>No. (%) of KPC-positive isolates</th>
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Figure 1. Coris BioConcept’s KPC K-SeT assay package insert protocol.

Figure 2. Examples of KPC K-SeT Tests

Figure 3. Comparison of Coris BioConcept’s KPC K-SeT assay with other KPC detection methods.

Figure 4. Comparison of Coris BioConcept’s KPC K-SeT assay with other KPC detection methods.

CONCLUSIONS & DISCUSSION

The Coris BioConcept’s KPC K-SeT assay provided highly accurate results for detecting KPC carbapenemase in different species of Gram-negative bacteria. Experience from this and previous studies finds Coris BioConcept’s KPC K-SeT assay has low-complexity tests as minimal hands-on time and no laboratory equipment are required. Furthermore, K-SeT assays are extremely easy to use and simple to interpret. The K-SeT assay was also very practical since testing is compatible with direct use from colonies grown on any common primary medium including Columbia Sheep Blood, Mueller-Hinton and selective MacConkey-based agars.

Figure 1. Comparison of Coris BioConcept’s KPC K-SeT assay with other KPC detection methods.

Figure 2. Comparison of Coris BioConcept’s KPC K-SeT assay with other KPC detection methods.

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From a patient management perspective, the K-SeT assay is able to provide reliable results within 15 minutes of test set-up, thus enabling almost immediate infection control attention to patients newly identified to be positive for a KPC-type CPO.

Acknowledgements

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