An evaluation of the Amplidiag bacterial gastroenteric assay

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KEY WORDS: Bacterial GE, Amplidiag

AIM

To examine the performance of the Amplidiag Bacterial GE assay, a multiplex real-time PCR assay, for the detection of bacterial pathogens causing gastroenteritis. This was compared by parallel testing of stool samples alongside our current laboratory platform, BD MAX Enteric Bacterial assay. Additionally, to analyse the advantages and disadvantages of the Amplidiag platform.

INTRODUCTION

Amplidiag is a family of diagnostic tests for mid to high-volume screening of gastrointestinal pathogens. The Amplidiag is composed of the Amplidiag easy which serves to extract nucleic acid from the stool sample and also a second component, the CFX which serves as a real time PCR amplification tool for the extracted nucleic acid. The Amplidiag had a maximum capacity of 30 samples when testing for bacterial gastroenteritis pathogens if only one CFX is in use.

The BD Max is a fully-integrated, automated platform that performs nucleic acid extraction and real-time PCR providing results for up to 24 samples on one individual run.

The bacterial pathogens that both the BD MAX and Amplidiag platforms are able to detect are Salmonella species, Campylobacter species, Shigella species/EIEC (Enteroinvasive E. coli) and EHEC (Enterohemorrhagic E. coli). The Amplidiag also detects EPEC (Enteropathogenic E. coli), ETEC (Enterotoxigenic E. coli), Yersinia and Yersinia entercolitica.

Bacterial target | Amplidiag | BD MAX  
--- | --- | ---  
Salmonella spp. | √ | √  
Campylobacter spp. | √ | √  
Shigella spp./EIEC (Enteroinvasive E. coli) | √ | √  
EHEC (Enterohemorrhagic E. coli) | √ | √  
EPEC (Enteropathogenic E. coli) | √ | √  
EPEC (Enterotoxigenic E. coli) | √ | √  
Yersinia species | √ | √  

Figure 1 – Bacterial targets for BD MAX and Amplidiag

RESULTS

The Amplidiag platform detected 5 Salmonellas species, 15 EAECs, 7 Shigella species, 26 Campylobacter species, 6 ETECs and 33 EPECs. It did not detect any Yersinia species or EHECs.

A comparison between the number of positives on the BD Max and Amplidiag

![Figure 3 – Comparison between the bacterial pathogens detected on the BD Max and Amplidiag](https://www.example.com/figure3)

<table>
<thead>
<tr>
<th>Bacterial Target</th>
<th>Number of positive cultures</th>
<th>Number of BD MAX/Amplidiag positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Shigella</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>EHEC (enterohemorrhagic E. coli)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 4 – Number of positive cultures from the Salmonella, Shigella and EHEC positives

DISCUSSION

The evaluation demonstrated good overall performance for the Amplidiag GE assay compared to BD Max. Salmonella species and Shigella species showed 100% concordance for both platforms. For Campylobacter species, two were not detected by Amplidiag. Repeat testing of these samples on both platforms produced a negative result. Yersinia species was not detected. EPEC, ETEC and EAEC were detected by Amplidiag which resulted in the platform detecting more positives than the BD Max overall. EHEC results were negative on both platforms. Both assays were comparable for the bacterial targets they were each designed to detect.

Good comparative culture results were recorded for Salmonella species. Two samples did not grow on culture. These were QCMD samples not suitable for molecular testing were isolated on culture. This could possibly be due to low level molecular detection or degradation of Shigella in the stool sample.

If any future testing were to occur, then putting some known EHEC positives alongside our current laboratory platform, BD MAX Enteric Bacterial assay.

METHOD

Over a period of two weeks, 330 stool samples were tested for bacterial pathogens on both the BD MAX platform and Amplidiag platform. The Amplidiag bacterial GE assay consisted of extracting nucleic acid from stool samples and then amplifying the extracted nucleic acid. The extraction process was performed by the Amplidiag Easy. A separate instrument (CFX) amplified the target nucleic acid. Software attached to the CFX was used to detect the amount of nucleic acid present for each pathogen once the amplification process was finished. A growth curve of each targeted pathogen was then produced. From this graph any positives were confirmed.

REFERENCES

- https://moleculardiagnostics.bd.com/bd-max-system/
- https://mobidiag.com/products/amplidiag/

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