Evaluation of a *Mycoplasma genitalium* TMA assay for diagnostic use

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Aim

To determine the performance and usability of the Aptima *Mycoplasma genitalium* assay with the aim of introducing a NAAT assay for diagnostic testing.

Introduction

*Mycoplasma genitalium* is a significant cause of sexually transmitted infections in men and women, associated with non-gonococcal urethritis, pelvic inflammatory disease and pre-term birth. Infections are often asymptomatic or have similar symptoms to other STIs. Multi-drug resistance has been observed for *M. genitalium* and few antibiotic treatments options remain. Routine testing is not widely performed due to the limited availability of suitable assays, as well as the time and cost associated with reference laboratory testing.

The Aptima *M. genitalium* Assay is a CE-marked transcription mediated amplification (TMA) assay targeting the 16S ribosomal RNA. It is run on Hologic Panther analysers allowing automated high throughput testing. Our laboratory has Panther systems in place for Aptima assays detecting *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis*. Addition of the *M. genitalium* assay would enable simultaneous testing for several pathogens on a single sample, enabling prompt diagnosis and initiation of appropriate treatment. The simultaneous testing and prompt results are achievable due to the Hologic Panther system being a true random access platform with bidirectional interface. These two features are key in the Panther system creating a simple and easy-to-use sample process and workflow for the laboratory.

Results

Of the 165 samples tested 30(18%) were positive, in line with expectations for the patient groups tested. A higher positive rate (33%) was seen in rectal swabs which reflects the demographic of patients tested and is consistent with published data showing a higher prevalence in MSM². Table 1 below shows the summary of results:

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>No. Tested</th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 in 1</td>
<td>37</td>
<td>33 (89%)</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>Rectal Swab</td>
<td>24</td>
<td>16* (67%)</td>
<td>8 (33%)</td>
</tr>
<tr>
<td>Urethral Swab</td>
<td>1</td>
<td>1 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>Vaginal Swab</td>
<td>31</td>
<td>29** (94%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Urine</td>
<td>71</td>
<td>56 (79%)</td>
<td>15 (21%)</td>
</tr>
<tr>
<td>Unknown Sample</td>
<td>1</td>
<td>0</td>
<td>1 (100%)</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>165</strong></td>
<td><strong>135 (82%)</strong></td>
<td><strong>30 (18%)</strong></td>
</tr>
</tbody>
</table>

* 1 sample – original was insufficient, sample diluted in 1ml of Aptima buffer
** 4 samples – originals were insufficient, samples diluted in 1ml of Aptima buffer

In total, 9 positive samples were tested at STBRU Colindale by real-time PCR for the MgpA gene. It was not possible to confirm all of the positive results due to financial constraints, therefore only the positive samples with the highest and the lowest values for each sample type were sent for confirmation.

The results showed 5 samples confirmed as positive, 3 gave negative results and 1 was inhibitory in the PCR. The Aptima assay targets the ribosomal RNA (rRNA) with each bacterial cell containing multiple copies, whereas the STBRU PCR targets a section of the MgpA gene which is only present as a single copy. The rRNA target gives the Aptima assay greater sensitivity, which could explain the negative results from the reference lab².

Discussion

Overall the Aptima *M. genitalium* Assay performed well, showing good sensitivity and it fits easily with current workflow. The results were straightforward to interpret, and as there were no invalid results, repeat testing was not required. The introduction of the Aptima *M. genitalium* assay as part of the diagnostic Virology test repertoire is made simpler due to the random access workflow of the Panther system. Therefore, Viapath can provide a more comprehensive and cost efficient STI testing service, which will help to administer targeted treatment regimes to affected individuals their sexual partners, and could potentially slow the increase in anti-microbial resistance.

References


Acknowledgements:

Kits provided free of charge by Hologic