Evaluation of the RenDx Fungiplex® Surface-Enhanced Raman Scattering PCR Assay for the Detection of Aspergillus spp in Sputum

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Introduction

- Incidence of invasive pulmonary aspergillosis is increasing in the immunocompromised population and is difficult to diagnose definitively.
- Prompt diagnosis and initiation of treatment may improve patient outcomes, however culture of respiratory samples for Aspergillus spp. is substantially less sensitive than either antigen detection or PCR.
- PCR is heavily underrepresented in clinical laboratories due to lack of standardisation and commercially available assays.
- The RenDx Fungiplex, a semi-automated PCR surface-enhanced Raman scattering (SERS) assay for the detection of Aspergillus and Candida spp., has recently been launched.
- SERS is an analytical spectroscopic technique that offers greater sensitivity and multiplexing potential over conventional fluorescence (Figure 1).

Methods

- Eighty sputum samples were collected prospectively from patients with proven or probable chronic pulmonary aspergillosis and analysed for the presence of Aspergillus and Candida spp. using the RenDx Fungiplex assay [Renishaw Diagnostics Limited, Glasgow, UK].

Results

- Of the 80 samples tested, a total of 24 (30%) were found to be fungal culture positive compared to 59 (73%) which were found to be positive using the RenDx Fungiplex assay. Results can be found in Table 1.
- Samples were treated and extracted as two aliquots using Myconostica [Microgen Bioproducts, Camberley, UK]. MycXtra DNA extraction kits which were then pooled prior to testing.
- Samples were initially analysed following the process shown in Figure 2.
- Results were compared to primary culture performed as per Public Health England SMIB57: Investigation of bronchoalveolar lavage, sputum and associated specimens.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Culture Positive</th>
<th>RenDx Fungiplex Positive</th>
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<tbody>
<tr>
<td>Aspergillus spp.</td>
<td>14/80 (17.5%)</td>
<td>39/80 (49%)</td>
</tr>
<tr>
<td>Candida spp.</td>
<td>10/80 (12.5%)</td>
<td>20/80 (25%)</td>
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Table 1: Fungiplex and culture positivity for tested samples

Conclusion

- Active treatment of patients may be accountable for the low number of culture positive samples when compared to Fungiplex. Of the Fungiplex Aspergillus positive samples, 20/39 (51%) were on active treatment with a further 10/21 (47%) of Fungiplex negative samples being derived from patients on active treatment. 13/20 (65%) Fungiplex Candida positive samples were on active treatment.
- The currently observed results suggest RenDx Fungiplex may have superior sensitivity to culture especially for those patients undergoing active treatment. Whilst its use as a standalone test for sputum samples remains unclear, it may be beneficial when used alongside other relevant diagnostics.