Evaluation of the rapid lateral flow ImmuView® urinary antigen test for the detection of *L. pneumophila* and *Streptococcus pneumoniae*

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Introduction

Urinary antigen tests (UAT) are important as a front line test in the diagnosis of pneumococcal illness as antigen is excreted by the kidneys in the acute phase of disease. Often these immune-chromatographic tests (ICT) can be performed as part of care to give a rapid diagnosis but most are performed in the laboratory setting.

In the past these rapid tests for bacterial antigens have been monovalent but the ImmuView® test by SSI Diagnostica, Denmark is the first rapid test on the market that can identify infection with *Legionella* and Pneumococci in a single test.

Method – SSI Diagnostica ImmuView® UAT

![Schematic of the SSI Diagnostica ImmuView® Pneumococcal and *Legionella* UAT](Image)

Figure 1. Schematic of the SSI Diagnostica ImmuView® Pneumococcal and *Legionella* UAT

Alere Binax® NOW and Trinity Biotech® Bartels EIA were performed as per manufacturer's instructions

Results

The SSI Diagnostica ImmuView *S. pneumoniae* and *L. pneumophila* urinary antigen test (UAT) was compared against two enzyme immunoassays (EIA) from Trinity Biotech and Binax for the detection of *Legionella* urinary antigen. Of 83 retrospective *Legionella* urinary antigen positives, 70 (84%) were also positive in the ImmuView UAT, 8 (10%) were negative and five (6%) were invalid (Table 1). Of the eight Bartels positive samples that were ImmuView negative, 5 had O.D values of <0.550 and the 3 others (with no information on OD readings) were from 2011(2) and 2013(1) therefore the sensitivity of the samples may have been affected by freeze thawing.

The overall sensitivity for the ImmuView *L. pneumophila* UAT was 84% but if the invalid samples were removed this increased to 90% (Table 2). The range of *L. pneumophila* serogroups detected by ImmuView was more sensitive than the Binax NOW with the pneumococcal control antigen. Of 83 retrospective frozen samples. This may have affected the integrity of the sample and ultimately the test result.

The sensitivity was calculated from previously diagnostically definitive cases that were either urinary antigen, >four fold rise in titre or culture positive. The specificity range of 84-90% with specificity of 100% for the detection by ImmuView EIA was 84% but if the invalid tests were removed this increase to 90%.

The assay also detects a number of clinically relevant *Legionella* serogroups† and *Streptococcus pneumoniae* serogroups‡ (6%) were invalid (Table 1). Of the eight Bartels positive samples that were ImmuView negative, 5 had O.D values of <0.550 and the 3 others (with no information on OD readings) were from 2011(2) and 2013(1) therefore the sensitivity of the samples may have been affected by freeze thawing.

The overall sensitivity for ImmuView UAT against *L. pneumophila* control antigens was 84% but if the invalid tests were removed this increased to 90%.

Conclusions

- SSI Diagnostica ImmuView® is the first UAT for the detection of *Legionella* and pneumococcal antigen in urine

- ImmuView® sensitivity for *Legionella* detection was between 84-90% with specificity of 100%

- The assay also detects a number of clinically relevant *L. pneumophila* serogroups

- ImmuView® is more sensitive than Binax® NOW for the detection of purified pneumococcal antigen

- The duality of the ImmuView® makes it a unique addition to the market and could provide clinicians with additional information regarding treatment and ultimately patient outcome.

Table 1. Comparison of the SSI Diagnostica ImmuView with the Trinity Biotech Bartels EIA for the detection of *Legionella* antigen in urine

<table>
<thead>
<tr>
<th>Product name/serogroup (EIA)</th>
<th>Positive</th>
<th>Negative</th>
<th>Invalid</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trinity Biotech Bartels® <em>Legionella</em> EIA</td>
<td>83 †</td>
<td>471</td>
<td>0</td>
<td>554</td>
</tr>
<tr>
<td>SSI Diagnostica ImmuView® <em>Legionella</em> UAT</td>
<td>70</td>
<td>479</td>
<td>5</td>
<td>554</td>
</tr>
</tbody>
</table>

† The serogroup antigens were isolates of known serogroups

Table 2. Specificity of the ImmuView *Legionella* UAT against *L. pneumophila* control antigens

<table>
<thead>
<tr>
<th>Product name</th>
<th>Overall Sensitivity (%)</th>
<th>Sensitivity (%) †</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSI, Diagnostica ImmuView® <em>Legionella</em> UAT</td>
<td>84</td>
<td>90</td>
<td>100</td>
</tr>
</tbody>
</table>

† The overall sensitivity was 84% but if the invalid tests were removed this increase to 90%

Table 3. Sensitivity of pneumococcal antigen detection with the ImmuView UAT and Alere Binax ICT

<table>
<thead>
<tr>
<th>Dilution of pneumococcal antigen (mg/ml)</th>
<th>SSI Diagnostica ImmuView® Pneumococcus UAT</th>
<th>Alere Binax® Pneumococcus NOW ICT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x 10^-9</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>1 x 10^-10</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>1 x 10^-11</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>1 x 10^-12</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Table 4. Specificity of pneumococcal antigens detected by ImmuView® UAT

- The sensitivity was calculated from previously diagnostically definitive cases that were either urinary antigen, >four fold rise in titre or culture positive.
- † The serogroup antigens were isolates of known serogroups.
- ‡ The overall sensitivity was 84% but if the invalid tests were removed this increase to 90%.

Thank you to SSI Diagnostica, Denmark and Oxford Biosystems for providing kits free of charge for this evaluation.