EVALUATION OF A NEW LATERAL FLOW TEST FOR DETECTION OF STREPTOCOCCUS PNEUMONIAE AND LEGIONELLA PNEUMOPHILA URINARY ANTIGEN

Charlotte S. Jørgensen1 (CSV@ssi.dk), Sören A. Ulidum2, Jesper F. Sørensen3, Ian C. Skovsted4, Sanne Otto5, Pernille L. Elverdal5
1Department of Microbiological Diagnostics & Virology, Statens Serum Institut, Copenhagen, Denmark.
2Department of Medical Biology, Statens Serum Institut, Copenhagen, Denmark.
3Department of Production and Development, SSI Diagnostica, Herredsvejen 2, Hillerød, Denmark.

OBJECTIVES
The objective of the study was to evaluate the first commercial combined test for pneumococcus and Legionella urinary antigen detection, the ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test (SSI Diagnostica, Denmark). In this poster we focus on the Legionella data, but S. pneumoniae results are available upon request.

METHODS
The ImmuView® Urinary Antigen kit was compared to the Binax® EIA Legionella kit (Alere) and the BinaxNOW® Legionella Urinary Antigen Card (Alere), using urine samples sent to the routine laboratory at SSI for investigation of S. pneumoniae and L. pneumophila urinary antigen. All tests were performed according to the kit instructions. The study was performed using samples from both culture confirmed L. pneumophila serogroup 1 legionnaires’ disease (LD) cases (n=55) and from an ongoing prospective study with samples sent to the laboratory for S. pneumoniae and/or L. pneumophila urinary antigen analysis (n=84).

RESULTS
The investigation of the 55 urine samples from the culture confirmed LD cases showed an overall sensitivity of 87.3%, 78.2% and 54.5% for the ImmuView®, the BinaxNOW® Legionella Urinary Antigen Card, and the Binax® EIA, respectively.

For unknown reasons, the Binax® EIA showed a surprisingly low sensitivity in this study for the non-Pontiac (MAb 3/1 negative) cases compared to the ImmuView® and the BinaxNOW® kit. See Figure 1.

The ongoing prospective study has so far shown identical results for the three tests. See Table 1.

Of the 77 samples which were negative in all three Legionella tests, four samples were from patients positive for L. pneumophila by both PCR and culture. Three of the patients were however culture positive for L. pneumophila non-serogroup 1. All the prospective samples were tested both with and without boiling, and so far the heat-treatment has not influenced the obtained results. However, due to the low number of positive samples, this has to be further investigated.

CONCLUSION
• The ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test had a higher sensitivity for culture-confirmed Legionella cases than BinaxNOW® Legionella Urinary Antigen Card and in this study surprisingly also higher than the Binax® EIA, especially due to a higher sensitivity for the non-Pontiac cases.
• Boiling did not seem to have any influence on the results (but more results are needed).
• The ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test was identified as a fast and sensitive point of care test for identifying the infectious agent in a large group of patients with pneumonia.

ACKNOWLEDGEMENTS
A special thanks to Hanne Tove Andersen, Mona Skafte Rønkendorff and Maja Olsen for testing all the samples in the different assays.

![Figure 1: Sensitivity of the ImmuView®, BinaxNOW® Legionella Urinary Antigen Card, and Binax® EIA determined upon investigation of 55 urine samples from L. pneumophila serogroup 1 culture confirmed LD cases.](Image)

Table 1: Results from an ongoing prospective study with samples sent to the laboratory for S. pneumoniae and/or L. pneumophila urinary antigen analysis, showing identical positive/negative results in the ImmuView®, BinaxNOW® Legionella lateral flow kit, and Binax® EIA tests.

- One sample was weak positive in Binax® EIA, whereas ImmuView® found the sample positive in two lots and negative in one lot. This urine sample seems to contain a relative low level of antigen, which will only be detected in few cases.

<table>
<thead>
<tr>
<th>Legionella pneumophila</th>
<th>ImmuView®</th>
<th>BinaxNOW®</th>
<th>Binax® EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>100,0</td>
<td>7*</td>
<td>7*</td>
</tr>
<tr>
<td>Negative</td>
<td>77</td>
<td>77</td>
<td>77</td>
</tr>
</tbody>
</table>

Table 1: Results from an ongoing prospective study with samples sent to the laboratory for S. pneumoniae and/or L. pneumophila urinary antigen analysis, showing identical positive/negative results in the ImmuView®, BinaxNOW® Legionella lateral flow kit, and Binax® EIA tests.

*One sample was weak positive in Binax® EIA, whereas ImmuView® found the sample positive in two lots and negative in one lot. This urine sample seems to contain a relative low level of antigen, which will only be detected in few cases.*