(ID ESGLI15-55)

STATENS SERUM INSTITUT

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

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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.

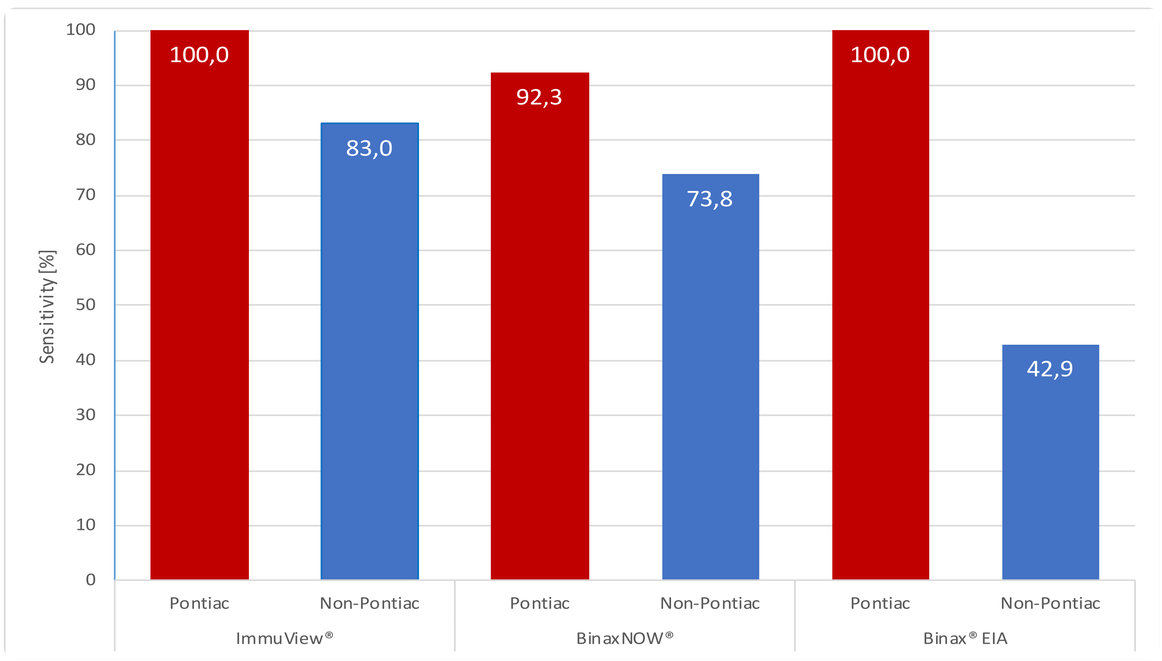

Figure 1: Sensitivity of the ImmuView®, BinaxNOW® Legionella Urinary Antigen Card, and Binax® EIA determined upon investigation of 55 urine samples from L. pneumophila serogroup 1 culture confirmed LD cases.

	Legionella pneumophila		
	ImmuView®	BinaxNOW®	Binax® EIA
Positive	7*	7*	7*
Negative	77	77	77

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.*

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.