

Evaluation of the Sofia *S. pneumoniae* FIA and the Sofia *Legionella* FIA for detection of pneumococcal and *L. pneumophila* antigen in urine

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Conclusion

The Sofia *S. pneumoniae* FIA and the Sofia *Legionella* FIA performed similarly as other urine antigen tests on urine samples from infected patients with definite etiologies.

Background

Streptococcus pneumoniae and *Legionella pneumophila* may cause community-acquired pneumonia. We evaluated the novel Sofia *S. pneumoniae* Fluorescent Immunoassay (FIA) and the Sofia *Legionella* FIA (Quidel, San Diego, USA) for detection of pneumococcal cell-wall polysaccharide antigen and *L. pneumophila* serogroup 1 antigen in urine, respectively.

Methods

A total of 103 urine samples from adult patients (≥ 18 years) with bacteremia (pneumococcal, $n=47$; non-pneumococcal, $n=50$) or confirmed *Legionella* pneumonia (*L. pneumophila* sg 1, $n=5$; *L. bozemanii*, $n=1$) were included. The urine samples, had been collected along with blood culture bottles in the clinical routine work at three tertiary hospitals in Sweden (Örebro University Hospital, Karolinska University Hospital Huddinge and Skåne University Hospital Malmö) and were stored at -20°C until tested. All samples were tested with the Sofia *S. pneumoniae* FIA and the Sofia *Legionella* FIA in a randomized and blinded procedure. The samples were not concentrated or filtrated prior to testing. The test results were interpreted by an automatically reader (Sofia Analyzer) and invalid tests were retested. *L. pneumophila* etiology was determined by PCR on airway secretions and confirmed as serogroup 1 by Binax *L. pneumophila* serogroup 1 EIA on the urine samples.

The test results were compared with those from our previous study¹, in which we evaluated the BinaxNOW *S. pneumoniae* immunochromatographic test (ICT), the BinaxNOW *L. pneumophila* ICT and the ImmuView *S. pneumoniae* and *L. pneumophila* ICT (combined test) on the same urine samples.

Table 3. Invalid test results on urine samples from patients with positive blood cultures

Blood culture:	E. coli	E. coli	P. mirabilis	E. faecalis
Characteristics of urine samples	Glu, Ery, Leu	Ery, Leu, Viscous	Ery, Leu	Ery
Sofia <i>S. pne</i>	Inv/Inv	Inv/Inv	Inv/Pos	Inv/Inv
Sofia <i>L. pne</i>	Inv/Inv	Inv/Inv	Inv/Inv	Neg
BinaxNOW <i>S. pne</i>	Neg	Neg	Neg	Neg
BinaxNOW <i>L. pne</i>	Neg	Neg	Neg	Neg
ImmuView <i>S. pne</i>	Inv/Inv	Inv/Inv	Inv/Inv	Neg
ImmuView <i>L. pne</i>	Inv/Inv	Inv/Inv	Inv/Inv	Neg

Glu, glucose; Ery, erythrocytes; Leu, leucocytes; Inv, invalid; Pos, positive; Neg, negative.

Results

The Sofia *S. pneumoniae* FIA showed a sensitivity of 68.1% and specificity of 92.3% calculated on 99 valid test results (Table 1). The test showed a good inter-assay agreement with BinaxNOW *S. pneumoniae* ICT ($\kappa=0.78$) and ImmuView *S. pneumoniae* and *L. pneumophila* ICT ($\kappa=0.78$) for detection of pneumococcal antigen. Of four invalid tests, three showed invalid test results and one showed a positive test result when re-tested (Table 3).

Table 1. Detection of pneumococcal antigen in urine

	Sofia FIA % (n/N)	BinaxNOW ICT % (n/N)	ImmuView ICT % (n/N)
Sensitivity	68.1 (32/47)	61.7 (29/47)	61.7 (29/47)
Specificity	92.3 (48/52)	94.2 (49/52)	94.2 (49/52)

Table 2. Detection of Legionella antigen in urine

	Sofia FIA % (n/N)	BinaxNOW ICT % (n/N)	ImmuView ICT % (n/N)
Sensitivity	100 (5/5)	100 (5/5)	100 (5/5)
Specificity	97.9 (93/95)	100 (95/95)	100 (95/95)

The Sofia *Legionella* FIA was positive on all urine samples with *L. pneumophila* serogroup 1 etiology to pneumonia (100%) with a specificity of 97.9% calculated on 100 valid test results. The test showed a very good inter-assay agreement with BinaxNOW *L. pneumophila* ICT ($\kappa=1.00$) and ImmuView *S. pneumoniae* and *L. pneumophila* ICT ($\kappa=1.00$) for detection of *Legionella* antigen. Of three invalid tests, all three were invalid when re-tested (Table 3).

Discussion

The Sofia *S. pneumoniae* and the Sofia *Legionella* FIAs showed similar results as the other urine antigen tests after another year in -20°C . Long-time freezing of the samples may possibly affect the test results, however, the test results of the Sofia FIAs were not lower than for the other tests. The FIAs showed invalid results on samples with high levels of glucose, erythrocytes, leucocytes and high viscosity, similar to the ImmuView ICT in a previous study¹. It is recommended to re-test all urine samples with invalid test results and/or boil the samples for 10 minutes before re-testing.

¹ Athlin S, Iversen A, Özenci V. Comparison of the ImmuView and the BinaxNOW antigen tests in detection of *S. pneumoniae* and *L. pneumophila* in urine. Eur J Clin Microbiol Infect Dis. 2017.