

Introduction

Urinary antigen tests (UAT) are important as a front line test in the diagnosis of pneumonic illness as antigen is excreted by the kidneys in the acute phase of disease. Often these immuno-chromatographic tests (ICT) can be performed as point 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 on the market that can identify infection with Pneumococci and *Legionella* in a single test.

Results (continued)

Table 1. Comparison of SSI Diagnostica ImmuView UAT with the Alere Binax NOW ICT for the detection of Pneumococcal antigen in urine

Product name	Positive	Negative	Invalid	Total
SSI, Diagnostica ImmuView® Pneumococcus UAT	45†	503	7	554
Alere Binax® Pneumococcus NOW ICT	23	70	0	93*

† Eight of the 45 pneumococcal positives were also positive for *Legionella*.

* All samples positive in the ImmuView® Pneumococcal UAT were repeated in the Binax® NOW and 48 random negatives were tested by the Binax® NOW throughout the course of testing

Table 2. Sensitivity of pneumococcal antigen detection with the SSI Diagnostica ImmuView UAT and Alere Binax NOW ICT

Dilution of pneumococcal antigen (mg/ml)	SSI Diagnostica ImmuView® Pneumococcus UAT	Alere Binax® Pneumococcus NOW ICT
1 x 10 ⁻⁹	Positive	Positive
1 x 10 ⁻¹⁰	Positive	Negative
1 x 10 ⁻¹¹	Positive	Negative
1 x 10 ⁻¹²	Negative	Negative

Table 3. Comparison of the SSI Diagnostica ImmuView with the Trinity Biotech Bartels EIA for the detection of *Legionella* antigen in urine

Product name	Positive	Negative	Invalid	Total
Trinity Biotech Bartels® <i>Legionella</i> EIA	83 †	471	0	554
SSI Diagnostica ImmuView® <i>Legionella</i> UAT	70	479	5	554

† The 83 positives were from a range of culture, serology and EIA positives so all definitive of a case by ECDC guidelines. The five urines that gave an invalid result were all retrospective frozen samples. This may have affected the integrity of the sample and ultimately the test result.

Method – SSI Diagnostica ImmuView® UAT

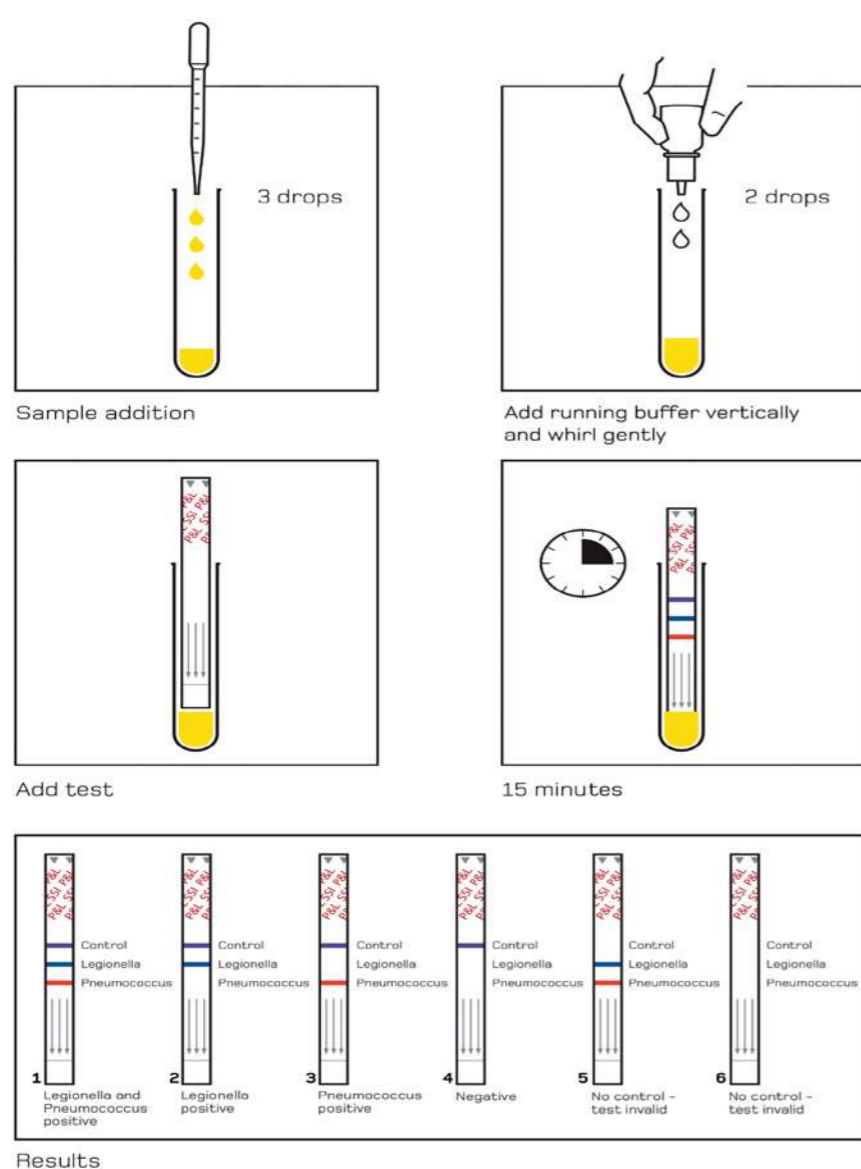


Figure 1. Schematic of the SSI Diagnostica ImmuView® Pneumococcal and *Legionella* UAT

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

Results

The SSI Diagnostica ImmuView *S. pneumoniae* and *L. pneumophila* urinary antigen test (UAT) was compared against the Binax NOW for the detection of pneumococcal antigen and two enzyme immunoassays (EIA) from Trinity Biotech and Binax for the detection of *Legionella* urinary antigen. In total, 554 urines were tested, 45 (8%) were positive for pneumococcal antigen but only 23 (4%) were confirmed in the pneumococcal Binax NOW test (Table 1). Eight of the 45 were also positive for *Legionella* antigen indicating the presence of a potential dual infection. A pneumococcal control antigen (10mg/ml) was diluted ten fold and tested in each UAT and the limit of detection of the ImmuView was 1 x 10⁻¹¹ mg/ml compared to 1 x 10⁻⁹ mg/ml for the Binax NOW (Table 2). The ImmuView was found to be more sensitive for the detection of pneumococcal antigen and this may account for the differences between the two assays on patient samples. Due to the anonymised nature of sample inclusion, no sensitivity or specificity data was available for the pneumococcal antigen component of the test. However, the ImmuView was more sensitive than the Binax NOW with the pneumococcal control antigen and further testing from known pneumococcal positive cases would inform sensitivity and specificity levels. Of the 83 previous *Legionella* positives, 70 were positive in the ImmuView UAT, 8 were negative and 5 gave an invalid result (Table 3).

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

Conclusions

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

- 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.