

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 rapid test on the market that can identify infection with *Legionella* and Pneumococci in a single test.

Results (continued)

Table 1. 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.

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

ImmuView® <i>Legionella</i> UAT	<i>L. pneumophila</i> serogroups† control antigen
Positive	1 (All monoclonal subtypes) 2, 3, 4, 5, 6, 7, 11, 12, 13, 14, 15
Negative	8, 9, 10,

† The serogroup antigens were boilates of known serogroups

Table 3. Specificity range of *L. pneumophila* serogroups detected by ImmuView *Legionella* UAT

Product name	Overall Sensitivity (%)	Sensitivity (%) †	Specificity (%)
SSI, Diagnostica ImmuView® <i>Legionella</i> UAT	84	90	100

The sensitivity was calculated from previously diagnostically definitive cases that were either/or urinary antigen, >four fold rise in titre to *L. pneumophila* Sg 1 or culture positive.

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

Table 4. Sensitivity of pneumococcal antigen detection with the 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

Method – SSI Diagnostica ImmuView® UAT

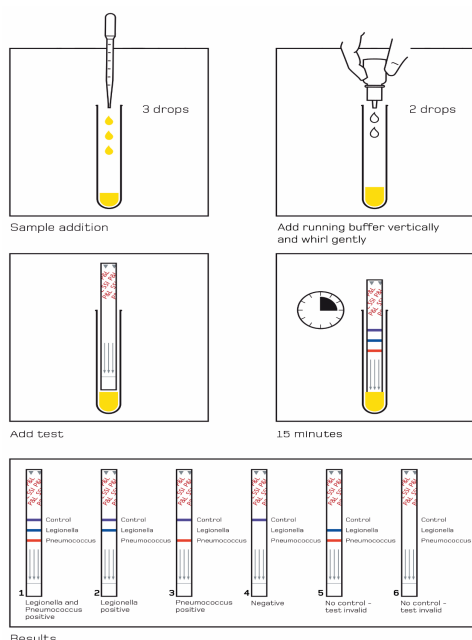


Figure 1. Schematic of the SSI Diagnostica ImmuView® Pneumococcal and *Legionella* UAT

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 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 integrity 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 the sensitivity of the assay increased to 90% (Table 2). In total, 554 urines were tested and no false positives were detected giving a specificity of 100% for the *Legionella* component of the assay (Table 2). The range of *L. pneumophila* serogroups detected are shown in Table 3.

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 4). The ImmuView was found to be more sensitive for the detection of pneumococcal antigen. 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.

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.