IMMUVIEW® S. PNEUMONIAE AND L. PNEUMOPHILA URINARY ANTIGEN TEST

For *in vitro* diagnostic use

Application
The ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is intended for diagnosis of *Streptococcus pneumoniae* and *Legionella pneumophila* infections by detection of urinary antigens for either or both *S. pneumoniae* and *L. pneumophila* serogroup 1. The principle of the test is immunochromatography also called lateral flow.

Description
ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is a rapid lateral flow test for qualitative detection of *S. pneumoniae* and *L. pneumophila* serogroup 1 antigens in human urine samples.

The test is effective in presumptive diagnosis of pneumococcal pneumonia caused by *S. pneumoniae* or *Legionella pneumonia* (Legionnaires’ Disease) caused by *L. pneumophila* serogroup 1, in conjunction with culture and other methods.

Correct and early treatment is vital for the prognosis of both diseases and therefore quick methods to confirm both diseases in the initial phase are very important in order to initiate the proper antibiotic treatment as soon as possible.
Principle
ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is a rapid lateral flow test for detection of *S. pneumoniae* and *L. pneumophila* using the same test.

Limitations
ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is not yet validated on Cerebral Spinal Fluid (CSF).

Materials Provided

- 1 tube with 22 test strips
- 0.5 mL combined positive control for *S. pneumoniae* and *L. pneumophila*
- 0.5 mL negative control
- 2.5 mL running buffer
- 1 tweezer
- 22 transfer pipettes
- 22 test tubes
- 1 cardboard test tube holder

Quick guide on inside of box and in package insert

Materials Required but not Provided
Timer or stopwatch. Sterile standard urine collection containers/transport tubes.

Sample Collection
Collect urine sample in sterile standard container. If the sample is run within 24 hours it can be stored at room temperature. Alternatively, the sample can be store at 2-8°C for 1 week or frozen for 2 weeks. Make sure that samples always reach room temperature before testing.
Procedure
The positive and negative controls should follow the same procedure as if it was a urine sample. The positive control should be visible at the control test line and the *S. pneumoniae* and *L. pneumophila* test line. The negative control should only be visible at the control line.

1. Bring the patient urine sample to room temperature. Whirl thoroughly prior to testing.
2. Apply a test tube in the cardboard holder.
3. Fill the transfer pipette with urine and add 3 drops of sample to the test tube (hold the pipette vertically).
4. Add 2 drops of running buffer to the test tube (hold the buffer bottle vertically).
5. Whirl the test tube gently.
6. Grab a hold of one test strip from the container at the “SSI P&L”-section using the tweezer.
7. Insert the test strip into the test tube.
8. Wait 15 minutes.
9. Lift the test strip out of the test tube and read the result after 15 minutes.
10. DO NOT READ the test strip after 15 minutes as the results may be inaccurate.
11. Discard the test strip after interpretation of the result.
Quick guide

Sample addition

Running Buffer Addition

Add test

15 minutes

Results

1  Legionella and Pneumococcus positive
2  Legionella positive
3  Pneumococcus positive
4  Negative
5  No control - test invalid
6  No control - test invalid
Interpretation of results
The Control test line in the top will appear purple/grey, but can also be more blue or red depending on whether the sample is positive for either \textit{S. pneumoniae} or \textit{L. pneumophila} serogroup 1.

A \textbf{positive sample for both \textit{Legionella} and \textit{Pneumococcus}} will show a pink/red line in the bottom half of the test for Pneumococcus positive followed by a blue line in the middle for \textit{L. pneumophila} serogroup 1 positive, and at the top of the test a purple/grey Control line will appear (see test number 1).

A \textbf{positive sample for \textit{Legionella}} will show a blue line for \textit{L. pneumophila} serogroup 1 positive, and at the top of the test a purple/grey Control line will appear (see test number 2).

A \textbf{positive sample for \textit{Pneumococcus}} will show a pink/red line for Pneumococcus positive, and at the top of the test a purple/grey Control line will appear (see test number 3).

A \textbf{negative sample} will show a single purple/grey Control line in the top of the test (see test number 4).

If no Control line is observed the test is \textbf{invalid} and the sample should be retested (see test number 5 and 6).
Clinical Sensitivity and Specificity
The clinical sensitivity of the *S. pneumoniae* test line was obtained by testing retrospective urine samples from patients with a blood culture positive sample for *S. pneumoniae*.

The clinical sensitivity of the *L. pneumophila* test line was obtained by testing retrospective urine samples from patients with a confirmed Legionnaires’ Disease.

The clinical specificity of the *S. pneumoniae* and *L. pneumophila* test lines was obtained by testing urine samples from patients with urinary tract infections and blood culture negative samples. Furthermore, no cross-reaction between *S. pneumoniae* and *L. pneumophila* serogroup 1 urine samples was detected.

*S. pneumoniae*

<table>
<thead>
<tr>
<th></th>
<th>ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test</th>
<th>Commercial Rapid Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (n=64)</td>
<td>80%</td>
<td>78%</td>
</tr>
<tr>
<td>Specificity (n=76)</td>
<td>99%</td>
<td></td>
</tr>
</tbody>
</table>

Commercial rapid test

<table>
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<th>Sensitivity (n=64)</th>
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</table>
### L. pnemophila

<table>
<thead>
<tr>
<th></th>
<th>ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test</th>
<th>Commercial Rapid Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (n=125)</td>
<td>83%</td>
<td>66%</td>
</tr>
<tr>
<td>Specificity (n=76)</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

### S. pneumoniae and L. pnemophila combined

<table>
<thead>
<tr>
<th></th>
<th>ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test</th>
<th>Combination of two Commercial Rapid tests for S. pneumoniae and L. pneumophila</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (n=189)</td>
<td>82%</td>
<td>69%</td>
</tr>
<tr>
<td>Specificity (n=76)</td>
<td>99%</td>
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</tr>
</tbody>
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**Analytical Sensitivity and Specificity**

To determine the analytical sensitivity and specificity of the ImmuView® S. pneumoniae and L. pneumophila Urinary Antigen Test, a panel of the 92 S. pneumoniae serotypes, the 8 subgroups of L. pneumophila serogroup 1, 16 L. pneumophila
non-serogroup 1, 4 *Legionella* species, and a panel of 116 potential cross-reactants were tested. No cross-reactions were detected.

The panel of 116 potential cross-reactants was spiked in negative urine at a concentration of $10^7$ CFU/mL.

<table>
<thead>
<tr>
<th>Acinetobacter (4)</th>
<th>Lacto. catenaforme</th>
<th>S. mutans</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus subtilis</em></td>
<td>Lacto. rhamnosus</td>
<td>S. parasanquis</td>
</tr>
<tr>
<td><em>Bordetella pertussis</em></td>
<td>Listeria monocytogenes</td>
<td>S. sanquis</td>
</tr>
<tr>
<td><em>Branhamella catarrhalis</em></td>
<td>M. morganii</td>
<td>S. saprophyticus</td>
</tr>
<tr>
<td><em>Candida albicans</em> (4)</td>
<td>Moraxella osloensis</td>
<td>S. thomson</td>
</tr>
<tr>
<td><em>C. aquaticum</em> (2)</td>
<td>N. cineria</td>
<td>S. typhimurium</td>
</tr>
<tr>
<td><em>Corynebacterium sp.</em></td>
<td>N. gonorrhoeae (3)</td>
<td>Serratia marcescens</td>
</tr>
<tr>
<td><em>E. cloacea</em> (4)</td>
<td>N. lactamica</td>
<td>Staph. aureus (6)</td>
</tr>
<tr>
<td><em>E. coli</em> (10)</td>
<td>N. meningitidis</td>
<td>Staph. epidermidis (5)</td>
</tr>
<tr>
<td><em>E. faecalis</em> (5)</td>
<td>N. polysak</td>
<td>Staph. saprophyticus</td>
</tr>
<tr>
<td><em>E. faecium</em></td>
<td>P. mirabilis (2)</td>
<td>S. maltophilia</td>
</tr>
<tr>
<td><em>Enterococcus durans</em></td>
<td>P. vulgaris (2)</td>
<td>Streptococcus group A (2)</td>
</tr>
<tr>
<td><em>G. vaginalis</em></td>
<td>Pseudomonas (2)</td>
<td>Streptococcus group B (10)</td>
</tr>
<tr>
<td><em>H. influenzae</em> (11)</td>
<td>Ps. aeruginosa (4)</td>
<td>Streptococcus group C</td>
</tr>
<tr>
<td><em>H. parainfluenzae</em></td>
<td>Ps. stutzeri</td>
<td>Streptococcus group F</td>
</tr>
<tr>
<td><em>K. oxytoxa</em> (2)</td>
<td>S. breedeney</td>
<td>Streptococcus group G</td>
</tr>
<tr>
<td><em>K. pneumoniae</em> (3)</td>
<td>S. epidermidis</td>
<td>Streptococcus group L</td>
</tr>
<tr>
<td>Lactobacillus</td>
<td>S. glostrup</td>
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</tr>
</tbody>
</table>
The analytical test performance is:
Sensitivity (n = 100) 100 %
Specificity (n = 116) 100 %

Storage and Shelf Life
Store at room temperature. Expiry date is printed on the package.

Quality Certificate
SSI Diagnostica’s development, production and sales of in vitro diagnostics are quality assured and certified in accordance with ISO 9001 and ISO 13485.

Information and Ordering
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