Gram positive bacteria *Streptococcus pneumoniae* is one of the most important pathogen that affects mainly children and elderly and can cause life-threatening diseases. *Streptococcus pneumoniae* infection leads to many clinical manifestations including meningitis, septicemia, bacteremia, pneumonia, acute otitis media and sinusitis. It has caused great morbidity and mortality worldwide, especially in children. Pneumococcal infection annually has caused approximately 14.5 million cases of invasive pneumococcal disease (IPD) and 0.7-1 million deaths in children under five years old, mostly in developing and underdeveloped countries.

The CerTest *Streptococcus pneumoniae* card test allows for early diagnosis of *Streptococcus pneumoniae* infection through detection of a specific soluble antigen present in the urine of patients with *Streptococcus pneumoniae* infection. *Streptococcus pneumoniae* cell wall polysaccharide antigen has been detected in urine as early as three days after the onset of symptoms.

**CerTest Streptococcus pneumoniae one step card test** offers a simple and highly sensitive assay to make a presumptive diagnosis of pneumococcal infection caused by *Streptococcus pneumoniae* in infected humans from urine samples.
**Streptococccus pneumoniae detection kit**

**Test procedure**

1. **Step 1**
   - Using a separate testing tube or vial for each sample, add 3 drops of urine sample or liquid urine control.

2. **Step 2**
   - Add 1 drop of Reagent A into the testing tube or vial and mix.

3. **Step 3**
   - Remove CerTest Streptococcus pneumoniae card from its sealed bag just before using it.

4. **Step 4**
   - Use a separate pipette and device for each sample or control. Dispense 3 drops from the testing tube in the circular pathway marked with the letter S.

5. **Step 5**
   - Wait for colored bands to appear. Read the results at 15 minutes. Do not read the test result later than 15 minutes.

**Interpretation of the results**

- **C** for Control
- **T** for Test

<table>
<thead>
<tr>
<th>Streptococcus pneumoniae</th>
<th>Streptococcus pneumoniae</th>
<th>Invalid</th>
<th>Invalid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Positive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**External Positive and Negative Controls are included in the kit**

The use of positive and negative controls is recommended to assure functionality of reagents and proper performance of assay procedure.

**Clinical Sensitivity and Specificity**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>CerTest Streptococcus pneumoniae IC Test vs Alere BinaxNow® Streptococcus pneumoniae Antigen Card</td>
<td>89.2% (74.6-97.0%)</td>
<td>98.6% (92.7-100%)</td>
</tr>
</tbody>
</table>