

**STREPTOCOCCUS PNEUMONIAE URINARY ANTIGEN TEST**

<b>Test Notes</b>	<i>Streptococcus mitis</i> is an expected cross-reactant as it shares the antigen against which this assay is directed. <i>Streptococcus mitis</i> is associated with endocarditis, not pneumonia, and is not likely to appear with any frequency in the population intended to be tested with the test kit used by this laboratory
<b>Test Method</b>	Immunoassay
<b>Alternative Test Name(s)</b>	Not applicable
<b>Specimen Container</b>	Sterile screw capped container or boric acid tube
<b>Preferred Specimen</b>	1st morning urine specimen 3 – 5 mL (Midstream Clean Catch, Indwelling Catheter, Straight In and Out Catheter, Kidney, Pediatric Bag or Suprapubic Aspirate Urine)
<b>Minimum Volume</b>	1 milliliter (1 mL)
<b>Instructions</b>	Inform the laboratory of the patient's recent antimicrobial therapy history and/or suspected pathogens.
<b>Transport Temperature</b>	Immediately upon collection; if delayed, refrigerate the specimen (2 – 8 degrees Celsius)
<b>Stability</b>	<ul style="list-style-type: none"> <li>• Room Temperature (20 – 25 degrees Celsius): &lt; 24 hours;</li> <li>• Refrigerated (2 – 8 degrees Celsius): &gt;24 hours to &lt; 14 days;</li> <li>• Frozen (- 10 to -20 degrees Celsius): &gt; 14 days</li> </ul>

<b>Rejection Criteria</b>	<ul style="list-style-type: none"> <li>• Unlabeled or mislabeled specimens</li> <li>• Non-sterile or leaking containers</li> <li>• Inadequate specimen quantity</li> <li>• Specimens collected with swabs or specimens unsafe to handle (sharps)</li> <li>• Specimens containing additives or fixatives other than boric acid</li> </ul>						
<b>Test Performed</b>	Sun – Sat; All Shifts						
<b>Report Available</b>	Within 1 hour of specimen processing						
<b>Interfering Substances</b>	Extremely bloody specimens may interfere with the interpretation of the test results.						
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• A negative BinaxNOW Streptococcus pneumoniae result does not exclude infection with S. pneumoniae. Therefore, the results of this test as well as culture results, serology or other antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.</li> <li>• Do not perform testing within 5 days of the administration of the Streptococcus pneumoniae vaccine.</li> <li>• The accuracy of this assay in urine from young children has not been proven.</li> </ul>						
<b>Reference Range</b>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Normal Value</td> <td style="width: 50%;">Negative</td> </tr> <tr> <td colspan="2"><hr/></td> </tr> <tr> <td>Critical Value</td> <td>Any detection of Streptococcus pneumoniae antigens</td> </tr> </table>	Normal Value	Negative	<hr/>		Critical Value	Any detection of Streptococcus pneumoniae antigens
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<b>Performance Characteristics of the Test</b>	Retrospective and prospective studies using both outpatient and hospitalized patient urine samples yielded a sensitivity of 86% – 90% and a specificity of 71% - 94%.
<b>References</b>	Product Insert – Abbott Binax NOW Streptococcus pneumoniae Urinary Antigen Card, IN710050 Rev.12; January 15, 2020