

STREPTOCOCCUS PNEUMONIAE URINARY ANTIGEN TEST

Test Notes	<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
Test Method	Immunoassay
Alternative Test Name(s)	Not applicable
Specimen Container	Sterile screw capped container or boric acid tube
Preferred Specimen	1st morning urine specimen 3 – 5 mL (Midstream Clean Catch, Indwelling Catheter, Straight In and Out Catheter, Kidney, Pediatric Bag or Suprapubic Aspirate Urine)
Minimum Volume	1 milliliter (1 mL)
Instructions	Inform the laboratory of the patient's recent antimicrobial therapy history and/or suspected pathogens.
Transport Temperature	Immediately upon collection; if delayed, refrigerate the specimen (2 – 8 degrees Celsius)
Stability	• Room Temperature (20 – 25 degrees Celsius): < 24 hours; • Refrigerated (2 – 8 degrees Celsius): >24 hours to < 14 days; • Frozen (- 10 to -20 degrees Celsius): > 14 days

Rejection Criteria	• Unlabeled or mislabeled specimens • Non-sterile or leaking containers • Inadequate specimen quantity • Specimens collected with swabs or specimens unsafe to handle (sharps) • Specimens containing additives or fixatives other than boric acid	
Test Performed	Sun – Sat; All Shifts	
Report Available	Within 1 hour of specimen processing	
Interfering Substances	Extremely bloody specimens may interfere with the interpretation of the test results.	
Limitations	• 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. • Do not perform testing within 5 days of the administration of the Streptococcus pneumoniae vaccine. • The accuracy of this assay in urine from young children has not been proven.	
Reference Range	Normal Value	Negative
	Critical Value	Any detection of Streptococcus pneumoniae antigens

Performance Characteristics of the Test	Retrospective and prospective studies using both outpatient and hospitalized patient urine samples yielded a sensitivity of 86% – 90% and a specificity of 71% - 94%.
References	Product Insert – Abbott Binax NOW Streptococcus pneumoniae Urinary Antigen Card, IN710050 Rev.12; January 15, 2020