

BinaxNOW® *S. pneumoniae* Test

NOW Urine/CSF *S. pneumoniae* rapid tests -
a new gold standard



Rapid enough to guide therapy immediately

- Dependable accuracy without the disadvantages of other test methods
 - No waiting for results
 - No results negatively affected by previous antibiotic use

Easy to use

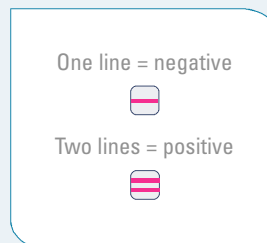
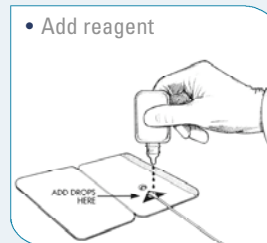
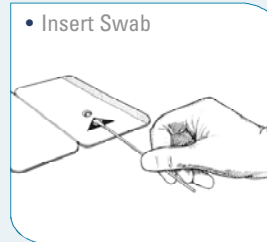
- Simple, time-saving procedure
- Self-contained, swab-based device - no tubes or pipettes
- Insert urine- or CSF-saturated swab into test card, add reagent, read in 15 minutes

Easy to interpret

- Objective, qualitative results
- No subjective assessment required
- Both built-in and external positive and negative controls ensure test viability

BinaxNOW® *S. pneumoniae*

Testing made simple



Ordering Information:

- 710-012 BinaxNOW® *S. pneumoniae* Urinary Antigen Test (12 test kit)
- 710-000 BinaxNOW® *S. pneumoniae* Urinary Antigen Test (22 test kit)
- 710-010 BinaxNOW® *S. pneumoniae* Control Swabs (5 each positive and negative swabs)

Other BinaxNOW Tests:

- BinaxNOW® Influenza A & B
- BinaxNOW® Legionella
- BinaxNOW® RSV
- BinaxNOW® Strep A
- BinaxNOW® Malaria
- BinaxNOW® Filariasis (not available in US or EU)

References:

1. Plouffe JS, Moore R, Davis R, et al. Serotypes of *Streptococcus pneumoniae* blood culture isolates from adults in Franklin County, Ohio. *J Clin Microbiol* 1994;32:1606-1607.
2. Ruiz-Gonzalez A, Falguera M, Noguea A, et al. Is *Streptococcus pneumoniae* the leading cause of pneumonia of unknown etiology? A microbiologic study of lung aspirates in consecutive patients with community-acquired pneumonia. *Am J Med* 1999;106:385-390.
3. Schrag SJ, Beall B, Dowell S. Resistant pneumococcal infections. WHO, 2001.
4. Mandell LA, Bartlett JG, Dowell SF, et al. Update of practice guidelines for the management of community-acquired pneumonia in immunocompetent adults. *CID* 2003;37 (1 December), 1405-1433.
5. Holmberg H, Krook A, Sjogren A. Determination of antibodies to pneumococcal C polysaccharide in patients with community-acquired pneumonia. *J Clin Microbiol* 1985;22:808-814.
6. Johnston, Jr, R. Pathogenesis of pneumococcal pneumonia. *Rev Infect Dis* 1991;13(Suppl6):S509-S517.
7. Robbins JB, Austrian R, Lee CJ, et al. Considerations for formulating the second-generation pneumococcal capsular polysaccharide vaccine with emphasis on the cross-reactive types within groups. *J Infect Dis* 1983;148:1136-1159.

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BinaxNOW®

S. pneumoniae

A race against time to identify
S. pneumoniae

Rapid detection of
pneumococcal pneumonia and
pneumococcal meningitis

When the result is critical...

...so is the test

www.binax.com



Pneumococcal pneumoniae...

...common and deadly



- *S. pneumoniae* is the leading cause of community-acquired bacterial pneumonia^{1,2}
- *S. pneumoniae* causes 1 million deaths worldwide in children under 5 years of age and is a leading cause of death in the elderly³
- *S. pneumoniae* is a common cause of secondary or co-infection in patients with influenza⁴
- *S. pneumoniae* is associated with significantly higher mortality rates (30%) than viral causes of acute respiratory infections^{1,5}



S. pneumoniae can also cause meningitis and sepsis⁶⁻⁸

- Unlike viral meningitis, bacterial meningitis is deadly
- Permanent brain damage can result in patients who survive
- Can occur as complication of other pneumococcal infections or arise spontaneously without any preceding illness
- Meningitis can progress from mild illness to coma within hours, making rapid diagnosis and treatment critical
- Guidelines call for immediate, aggressive empiric antibiotic therapy until pneumococcal meningitis can be ruled out
- Rapid test results identifying bacterial etiology are essential to appropriate antibiotic therapy

BinaxNOW® *S. pneumoniae* Test

A rapid assay for detection of Streptococcus pneumoniae antigen in the urine of patients with pneumonia



Quickly identify pneumonia caused by *S. pneumoniae*

Rapid

- Facilitates compliance with new guidelines for antibiotic administration within 4 hours of admission
 - The only test rapid enough to provide information at this critical decision point
 - The only test rapid enough to impact antibiotic choice
 - Results seen in 15 minutes
- Enables timely, targeted treatment with pathogen-specific antibiotic only when necessary
 - Avoids use of costly broad-spectrum antibiotics in large population that doesn't need them

Accurate

- Highly specific for *S. pneumoniae*
- Much more sensitive than blood and sputum cultures
 - Half of pneumococcal pneumonia patients cannot produce a quality sputum sample
 - Only 5% of patients are bacteremic
 - One third of patients are already on antibiotics, which cloud the results
- Results not affected by previous antibiotic therapy
- In conjunction with Gram stain, is highly specific and highly sensitive for detection of pneumococcal pneumonia⁹

*Retrospective study data. Blood culture used as reference. †Numbers reflect percent of pneumococcal pneumonia patient population estimated to be bacteremic. NOTE: Sensitivity and specificity data on blood culture, sputum culture and sputum Gram stain taken from various published studies. The reliability of both sputum Gram stain and sputum culture is dependent on sample integrity and technician interpretation, as well as other factors. References available upon request.

Methodology	Component Detected	Sample Type	Sensitivity	Specificity	Turnaround Time
BinaxNOW® <i>S. pneumoniae</i>	Analyte	Urine	86%*	94%*	15 minutes
Blood Culture	Organism	Blood	10%-30%†	>95%	24-48 hours
Sputum Culture	Organism	Sputum	50%-60%	50%-85%	24-48 hours
Sputum Gram stain	Organism	Sputum	50%-88%	50%-80%	15 minutes

BinaxNOW® *S. pneumoniae* Test

A rapid assay for detection of Streptococcus pneumoniae antigen in the cerebrospinal fluid of patients with meningitis



Diagnose pneumococcal meningitis without delay

Rapid

- Can be performed in Emergency Department when spinal tap is done
- Results seen in 15 minutes
- Avoids delays associated with Gram stains and CSF culture

Accurate

- More sensitive than Gram stain
- Sensitivity of 97% and specificity of 99% when CSF culture used as reference
- Results not affected by previous antibiotic therapy
 - CSF culture takes 48 hours and is negatively affected by prior antibiotic therapy

A valuable part of the clinical pathway

- Can guide treatment decision right in Emergency Department
 - Enables timely, targeted treatment with pathogen-specific antibiotic
 - Negative result provides valuable rule-out
 - Avoids inappropriate use of highly aggressive antibiotic regimens

Important note regarding use in children: The accuracy of the BinaxNOW test in urine has not been proven in young children. However, performance data on CSF in young children is well established.