

Use of the NOW *Streptococcus pneumoniae* urinary antigen test in cerebrospinal fluid for rapid diagnosis of pneumococcal meningitis.

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Abstract *Streptococcus pneumoniae* is one of the most common pathogens in bacterial meningitis. Rapid diagnosis is critical for effective treatment. The aim of this study was to assess the accuracy of the NOW *S. pneumoniae* Urinary Antigen Test, (Binax, Portland, ME, USA) originally developed for urine testing, in detecting the *S. pneumoniae* antigen in cerebrospinal fluid (CSF). The study included 519 patients with suspected meningitis. CSF, blood and urine samples were cultured according to standard methods. CSF viral culture was also performed. CSF and urine specimens were tested for pneumococcal antigen with the NOW *S. pneumoniae* test. *S. pneumoniae* was isolated from the CSF of 22 patients. The direct antigen test was positive in CSF in 21/22 patients (95.4% sensitivity), and in urine, in 12/21 (57.1% sensitivity). Direct CSF smear was positive in 15/22 (68% sensitivity). CSF samples that cultured negative for *S. pneumoniae* (n = 470) or positive for other bacteria (n = 27) were also negative on the NOW test (100% specificity). By contrast, urine samples of 63/470 of patients with negative CSF culture were positive on the NOW test, as were 5/27 urine samples of patients with CSF culture positive for other bacteria (p = 0.45). The NOW *S. pneumoniae* antigen test in CSF yields a rapid and very reliable diagnosis of pneumococcal meningitis, enabling prompt and adequate treatment. Its low sensitivity in urine indicates that this mode of testing is not useful for the diagnosis of pneumococcal meningitis. These data have been included in the FDA application for approval of the NOW test for use in the CSF for the diagnosis of pneumococcal meningitis.

Results and Discussion

Streptococcus pneumoniae is currently the leading cause of bacterial meningitis in children and adults. The estimated mortality of pneumococcal meningitis is approximately 20%, higher than for any other meningitis of bacterial etiology.

Rapid and accurate diagnosis of pneumococcal meningitis is critical for adequate initial empiric treatment. However the Gram stain will only detect about 75% of specimens which are eventually cultured. The sensitivity of the Gram stain is decreased further to 50% in patients who have been given antimicrobial therapy.

This has created an urgent need for a rapid and reliable laboratory method for the diagnosis of pneumococcal meningitis. The aim of the present study was to assess the accuracy of the BinaxNOW *Streptococcus pneumoniae* antigen test originally developed for urine testing (pneumococcal pneumonia), in detecting the *S. pneumoniae* antigen in the CSF, in a large group of patients with suspected meningitis. The test is simple to use and provides results within 15 minutes.

In this study *S. pneumoniae* was isolated from the CSF of 22 patients. The BinaxNOW *S. pneumoniae* antigen test was positive in 21/22 patients from CSF. In the patient who was not detected only 2 colonies of *S. pneumoniae* were detected on blood agar. By comparison the Gram stain was only positive in 15 patients (68.2% sensitivity).

The present study was conducted in a much larger sample base compared to previous studies and the results were more conclusive. We found that the BinaxNOW *S. pneumoniae* antigen test in the CSF provides a rapid and very reliable diagnosis of *S. pneumoniae* meningitis (95.4% sensitivity and 100% specificity), allowing prompt and adequate treatment.



When the result is critical...

...so is the test

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Manufacturer's note Urine cannot be tested for the diagnosis of pneumococcal meningitis