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Overview

Useful For
Rapid diagnosis of pneumococcal meningitis

Method Name
Immunochromatographic Membrane Assay

NY State Available
Yes

Specimen

Specimen Type
CSF

Additional Testing Requirements
According to the College of American Pathologists (CAP, IMM.41830), cerebrospinal fluid (CSF) samples collected to make an initial diagnosis and submitted for detection of *Streptococcus pneumoniae* antigen testing should also be submitted for routine bacterial culture. Mayo Clinic Laboratories recommends that CSF bacterial cultures be performed at the **originating site**.

Specimen Required
Container/Tube: Sterile vial
Specimen Volume: 1 mL
Collection Instructions: Submit specimen collected in vial 2, if possible. If not possible, note which vial from which the aliquot was obtained.

Forms
If not ordering electronically, complete, print, and send [Infectious Disease Serology Test Request](https://) (T916) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK

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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
CSF	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Streptococcus pneumoniae is the most frequently encountered bacterial agent of community-acquired pneumonia, and can also be an agent of bacterial meningitis. Because of the significant morbidity and mortality associated with pneumococcal pneumonia, septicemia, and meningitis, it is important to have diagnostic test methods available that can provide a rapid diagnosis. In instances where empirical antibiotics are being considered prior to culture confirmation, antigen testing may be useful.

Reference Values

Negative
Reference values apply to all ages.

Interpretation

A positive result supports a diagnosis of pneumococcal meningitis.

A negative result suggests that pneumococcal antigen is absent in the cerebrospinal fluid (CSF). However, infection due to *Streptococcus pneumoniae* cannot be ruled out since the antigen present in the specimen may be below the lower limit of detection of the test.

If pneumococcal meningitis is suspected, bacterial culture and Gram stain analysis on CSF should be performed.

Cautions

A negative result does not exclude *Streptococcus pneumoniae* infection.

A diagnosis of *Streptococcus pneumoniae* infection must take into consideration all test results, culture results, and the clinical presentation of the patient.

Streptococcus pneumoniae vaccine may cause false-positive results, especially in patients who received the vaccine 5 or fewer days prior to specimen collection.

This assay has not been validated for use with body fluids other than urine or cerebrospinal fluid.

The performance of this assay has not been established for patients on antibiotic treatment for more than 24 hours.

Clinical Reference

1. Plouffe JF, Moore SK, Davis R, Facklam RR: Serotypes of Streptococcus pneumoniae blood culture isolates from adults in Franklin County, Ohio. J Clin Microbiol. 1994 Jun;32(6):1606-1607

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2. Johnston RB Jr: Pathogenesis of pneumonococcal pneumonia. Rev Infect Dis. 1991;13:509-517

3. Janoff EN, Musher DM: Streptococcus pneumoniae. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:2473-2491

Performance

Method Description

The BinaxNOW *Streptococcus pneumoniae* test is an immunochromatographic membrane assay used to detect pneumococcal-soluble antigen in cerebrospinal fluid. Rabbit anti-*Streptococcus pneumoniae* and anti-species antibodies are conjugated to visualizing particles that are dried onto an inert fibrous support. The resulting conjugate pad and the striped membrane are combined to construct the test strip.

To perform the test, a swab is dipped into the specimen, removed, and then inserted into the test device. Reagent A, a buffer solution, is added from a dropper bottle. The device is then closed, bringing the sample into contact with the test strip. Pneumococcal antigen present in the sample reacts to bind anti-*Streptococcus pneumoniae* conjugated antibody, forming the sample line. Immobilized control antibody captures anti-species conjugate forming the control line.

Test results are interpreted by the presence or absence of visually detectable pink-to-purple-colored lines. A positive test result, read in greater than or equal to 15 minutes depending on the concentration of antigen present in the sample, will include the detection of both a sample and control line. A negative test result, read in 15 minutes, will produce only a control line, indicating that *Streptococcus pneumoniae* antigen was not detected in the sample. Failure of the control line to appear, whether the sample line is present or not, indicates an invalid assay.(Package insert: BinaxNOW *Streptococcus pneumoniae* Test. Abbott; 01/15/2020)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 day

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes

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Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87899

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SPNC	Streptococcus pneumoniae Ag, CSF	20489-1

Result ID	Test Result Name	Result LOINC® Value
31667	Streptococcus pneumoniae Ag, CSF	20489-1

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