Overview

Useful For
Rapid diagnosis of pneumococcal meningitis

Note: 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.

Method Name
Immunochromatographic Membrane Assay

NY State Available
Yes

Specimen

Specimen Type
CSF

Specimen Required
Container/Tube: Sterile vial

Specimen Volume: 1 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th></th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td></td>
</tr>
<tr>
<td>Gross lipemia</td>
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</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>CSF</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
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Clinical and 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 have received the vaccine within 5 days of having the test performed.

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

The performance of this assay in patients who have received antibiotics for more than 24 hours has not been established.

Clinical Reference


Performance

Method Description

The Binax NOW*Streptococcus pneumoniae* test is an immunochromatographic membrane assay used to detect pneumococcal-soluble antigen in cerebrospinal fluid. Rabbit anti-*Streptococcus pneumoniae* and antispecies 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-\textit{Streptococcus pneumoniae} conjugated antibody, forming the sample line. Immobilized control antibody captures antispecies 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 \( > \text{or} = 15 \text{ minutes} \) 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 \textit{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: NOW\textit{Streptococcus pneumoniae} Test. Binax, Inc., Portland, ME, 1998)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday; 12 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
1 day

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and Codes

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 Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. 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

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>31667</td>
<td>Streptococcus pneumoniae Ag, CSF</td>
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