Overview

Useful For
Rapid diagnosis of pneumococcal pneumonia

Method Name
Immunochromatographic Membrane Assay

NY State Available
Yes

Specimen

Specimen Type
Urine

Advisory Information
Pneumococcal pneumonia is best diagnosed by sputum culture. For more information, see SPUTS / Bacterial Culture, Aerobic, Respiratory with Antimicrobial Susceptibilities.

Specimen Required

Supplies: Urine Tubes, 10 mL (T068)

Container/Tube: Plastic, 10-mL urine tube

Specimen Volume: 2mL

Collection Instructions:

1. Collect a random urine specimen.
2. No preservative.
3. Excessively bloody or very turbid specimens containing protein, cells, or particulates will be cancelled as they can inhibit the function of the test.
4. Centrifuging to remove particulates is not approved.
5. Specimens with any dyes or unnatural color are not acceptable and will be cancelled.

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

Specimen Minimum Volume
0.25 mL

Reject Due To

<table>
<thead>
<tr>
<th></th>
<th>Reject</th>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Other</td>
<td>Turbid reject Dyes/unnaturally colored</td>
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Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
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Clinical and Interpretive

Clinical Information

*Streptococcus pneumoniae* is the most frequently encountered bacterial agent of community-acquired pneumonia (CAP). 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 provided for CAP without culture confirmation of *S pneumoniae*, antigen testing may be useful.

Reference Values

Negative

Interpretation

A positive result is indicative of pneumococcal pneumonia.

A negative result is a presumptive negative for pneumococcal pneumonia, suggesting no current or recent pneumococcal infection. Infection due to *Streptococcus pneumoniae* cannot be ruled out since the antigen present in the specimen may be below the detection limit of the test.

Cautions

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

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

*S 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.

The accuracy of this assay has not been proven in small children.

Clinical Reference

Performance

Method Description

The Binax NOW *Streptococcus pneumoniae* test is an immunochromatographic membrane assay used to detect pneumococcal soluble antigen in human urine and cerebrospinal fluid. Rabbit anti-*S 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-*S pneumoniae*-conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-*S pneumoniae*-conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-*S pneumoniae* 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 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 *S 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: Alere BinaxNOW *Streptococcus pneumoniae* Antigen Card, Alere Scarborough, Inc., Scarborough ME, 2018)

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, approved or is exempt 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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<thead>
<tr>
<th>Test ID</th>
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<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>SPNEU</td>
<td>Streptococcus pneumoniae Ag, U</td>
<td>77949-6</td>
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</table>

<table>
<thead>
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<tbody>
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<td>Streptococcus pneumoniae Ag, U</td>
<td>77949-6</td>
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