MAYO CLINIC LABORATORIES

Test Definition: SPNEU

Streptococcus pneumoniae Antigen, Random, Urine

Overview

Useful For
Rapid diagnosis of pneumococcal pneumonia

Method Name
Immunochromatographic Membrane Assay

NY State Available
Yes

Specimen

Specimen Type
Urine

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

Specimen Required
Supplies: Urine Tubes, 10 mL (T068)
Container/Tube: Plastic, 10-mL urine tube
Specimen Volume: 2 mL
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 canceled, as they can inhibit the function of the test.
4. **Do not centrifuge to remove particulates**.
5. Specimens with any dyes or unnatural color are not acceptable and will be canceled.

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

Specimen Minimum Volume
0.25 mL

Reject Due To

Gross hemolysis	Reject
Turbid Dyes/unnaturally colored	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Ambient	24 hours	
	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

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

Reference Values

Negative

Interpretation

A positive result is indicative of pneumococcal pneumonia.

Negative:
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 sample 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 5 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 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

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;32(6):1606-1607
2. Johnston RB Jr. Pathogenesis of pneumococcal pneumonia. Rev Infect Dis. 1991;13 Suppl 6:S509-S517. doi:10.1093/clinids/13.supplement_6.s509
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 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 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 sample, 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 pneumonia*-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 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 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: BinaxNOW *Streptococcus pneumoniae* Antigen Card. Abbott Diagnostics; 01/2020)

PDF Report

No

Day(s) Performed

Sunday through Friday

Report Available

Same day/1 day

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & 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 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
SPNEU	Streptococcus pneumoniae Ag, U	77949-6

Result ID	Test Result Name	Result LOINC® Value
83150	Streptococcus pneumoniae Ag, U	77949-6