MAYO CLINIC LABORATORIES

Test Definition: LAGU

Legionella Antigen, Random, Urine

Overview

Useful For
An adjunct to culture for the detection of past or current Legionnaires disease (*Legionella pneumophila* serogroup 1)

Method Name
Immunochromatographic Membrane Assay

NY State Available
Yes

Specimen

Specimen Type
Urine

Ordering Guidance
This assay has been verified using urine specimens only. For serum specimens, order SLEG / *Legionella pneumophila* (Legionnaires Disease), Antibody, Serum.

Other specimen types (eg, plasma or body fluids) that may contain *Legionella* antigen have not been verified for testing.

Specimen Required
Supplies: Urine Tubes, 10 mL (T068)
Container/Tube: Plastic, 10-mL urine tube
Specimen Volume: 0.5 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. 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 canceled.

Forms
If not ordering electronically, complete, print, and send 1 of the following with the specimen:
-Infectious Disease Serology Test Request (T916)
-Microbiology Test Request (T244)

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	Refrigerated (preferred)	7 days	
	Ambient	24 hours	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Legionnaires disease, named after the outbreak in 1976 at the American Legion convention in Philadelphia, is caused by *Legionella pneumophila* and is an acute febrile respiratory illness ranging in severity from mild illness to fatal pneumonia. Since that time, it has been recognized that the disease occurs in both epidemic and endemic forms, and that sporadic cases are not readily differentiated from other respiratory infections by clinical symptoms. It is estimated that about 25,000 to 100,000 *Legionella* infections occur annually. Known risk factors include immunosuppression, cigarette smoking, alcohol consumption, and concomitant pulmonary disease. The resulting mortality rate, which ranges up to 40% in untreated immunocompetent patients, can be lowered if the disease can be rapidly diagnosed and appropriate antimicrobial therapy instituted early. *L pneumophila* is estimated to be responsible for 80% to 85% of reported cases of *Legionella* infections with the majority of cases being caused by *L pneumophila* serogroup 1 alone.

A variety of laboratory techniques (culture, direct fluorescent antibody, DNA probes, immunoassay, antigen detection), using a variety of specimen types (respiratory specimens, serum, urine), have been used to help diagnose *Legionella* pneumonia. Respiratory specimens are preferred. Unfortunately, one of the presenting signs of Legionnaires disease is the relative lack of productive sputum. This necessitates the use of invasive procedures to obtain adequate specimens (eg, bronchial washing, transtracheal aspirate, lung biopsy) in many patients. Serology may also be used but is often retrospective in nature.

It was shown as early as 1979 that a specific soluble antigen was present in the urine of patients with Legionnaires disease.(1) The presence of *Legionella* antigen in urine makes this an ideal specimen for collection, transport, and subsequent detection in early, as well as later, stages of the disease. The antigen may be detectable in the urine as early as 3 days after onset of symptoms.

Reference Values

Negative

Interpretation

Positive:
Positive for *Legionella pneumophila* serogroup 1 antigen in urine, suggesting current or past infection. Culture is recommended to confirm infection.

Negative:
Negative for *L pneumophila* serogroup 1 antigen in urine, suggesting no recent or current infection. Infection with *Legionella* cannot be ruled out because:
-Other serogroups (other than serogroup 1, which is detected by this assay) and other *Legionella* species (other than *L pneumophila*) can cause disease
-Antigen may not be present in urine in early infection
-The level of antigen may be below the detection limit of the test

Legionella culture is recommended for cases of suspected *Legionella* pneumonia due to organisms other than *L pneumophila* serogroup 1.

Cautions

The diagnosis of Legionnaires disease cannot be based on clinical or radiological evidence alone. There is no single satisfactory laboratory test for Legionnaires disease. Culture results, serology, and antigen detection methods should all be used in conjunction with clinical findings for diagnosis.

The *Legionella pneumophila* serogroup 1 will not detect infections caused by other serogroups, *Legionella micdadei* or *Legionella longbeachae*. Culture is recommended for suspected pneumonia to detect causative agents other than *L pneumophila* serogroup 1 and to confirm infection.

Excretion of *Legionella* antigen in urine may vary among patients, depending on their underlying illness or treatment. Some individuals have been shown to excrete antigen for extended periods of time (up to 1 year after acute infection) and positivity may, therefore, indicate previous infection rather than current infection. Early treatment with appropriate antibiotics may decrease antigen excretion in some individuals, and the use of diuretics may affect the ability of the test to detect antigen. Consequently, patient history (eg, a history of a recent respiratory illness compatible with Legionnaires disease) must be considered when evaluating results.

Clinical Reference

1. Berdal BP, Farshy CE, Feeley JC. Detection of *Legionella pneumonophila* antigen in urine by enzyme-linked immunospecific assay. J Clin Microbiol. 1979;9(5):575-578
2. Fraser DW, Tsai TR, Orenstein W, et al. Legionnaires' disease: description of an epidemic of pneumonia. N Engl J Med. 1977;297(22):1189-1197
3. Stout JE, Yu VL. Legionellosis. N Engl J Med. 1997;337(10):682-687
4. Edelstein PH, Roy CR. Legionnaires disease and Pontiac fever. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:2807-2817

Performance

Method Description

The BINAXNOW Legionella Urinary Antigen Test is an immunochromatographic membrane assay to detect *Legionella*

pneumophila serogroup 1 soluble antigen in human urine. Rabbit anti-*L pneumophila* serogroup 1 antibody (the patient line) is adsorbed onto nitrocellulose membrane. Goat-anti-rabbit IgG (the control line) is adsorbed onto the same membrane as a second stripe. Rabbit anti-*L pneumophila* serogroup 1 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. This test strip and a well to hold the swab specimen are mounted on opposite sides of a hinged, book-shaped test device.

To perform the test, a swab is dipped into the urine specimen, removed, and then inserted into the test device. Reagent A is added from a dropper bottle. The device is then closed, bringing the specimen into contact with the test strip. *L pneumophila* serogroup 1 urinary antigen captured by immobilized anti-*L pneumophila* serogroup 1 antibody reacts to bind conjugated antibody. Immobilized goat-anti-rabbit IgG also captures visualizing conjugate, forming the control line. A positive test result is visually read in 15 minutes or less depending on the concentration of antigen present in the urine specimen. A negative result, read in 15 minutes, indicates that *L pneumophila* serogroup 1 antigen was not detected in the urine specimen.

The test is interpreted by the presence or absence of visually detectable pink-to-purple colored lines. A positive result will include the detection of both a patient and a control line, while a negative assay will produce only the control line. Failure of the control line to appear, whether the patient line is present or not, indicates an invalid assay.(Package insert: BinaxNOW *Legionella* Urinary Antigen Card. Abbott Diagnostics; IN852050 Rev.12, 01/2021)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 2 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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
LAGU	Legionella Ag, U	32781-7

Result ID	Test Result Name	Result LOINC® Value
81268	Legionella Ag, U	32781-7