L.pneumophila Antigen Rapid Test

Cat. No.:DTS593
Pkg.Size:

Intended use

Anin vitro rapid immunochromatographic assay for the qualitative detection of Legionella pneumophila serogroup 1 antigen (L. pneumophilaserogroup 1 antigen) in urine specimens from patients with symptoms of pneumonia. It is intended to aid in the presumptive diagnosis of Legionella infection (Legionnaires' Disease) caused byL. pneumophilaserogroup 1 in conjunction with culture and other methods.

General Description

Legionnaires' disease is a serious form of pneumonia that carries with it a mortality rate in the order of 10-15% in otherwise healthy individuals. Symptoms include a flu-like illness, followed by a dry cough and frequently progress to pneumonia. Approximately 30% of people infected may also present with diarrhoea and vomiting and around 50% may show signs of mental confusion. The incubation period normally ranges from 2-10 days with 3-6 days the typical illness onset time after exposure. Legionnaires' disease may present as an outbreak of two or more cases following a limited temporal and spatial exposure to a single source, as a series of independent cases in an area in which it is highly endemic or as sporadic cases without any obvious temporal or geographical grouping. Outbreaks have occurred repeatedly in buildings such as hotels and hospitals.
The Legionella pneumophila Device allows for early diagnosis of Legionella pneumophila serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires' Disease.Legionella pneumophila serogroup 1 antigen has been detected in urine as early as three days after the onset of symptoms. The test is rapid, giving a result within 15 minutes, and utilizes a urine specimen which is convenient for collection, transport, and subsequent detection of early, as well as later, stages of disease.

Principle Of The Test

The Legionella pneumophila Device is an immunochromatographic membrane assay to detect Legionella pneumophila serogroup 1 soluble antigen in human urine. Anti-Legionella pneumophila serogroup 1 antibody, the test line, is adsorbed onto nitrocellulose membrane. Antibodies of the control line were adsorbed onto the same membrane as a second band. Anti-Legionella pneumophila serogroup 1 antibodies are conjugated to visualizing particles that are dried onto an inert absorbent support. During testing the sample is allowed to react with the conjugate which was pre-adsorbed on the strip test. The mixture then moves upward on the membrane bycapillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. L. pneumophilaserogroup 1 urinary antigen captured by immobilized anti- L. pneumophila serogroup 1 antibody reacts to bind conjugated antibody. The other immobilized antibodies also captures visualizing conjugate, forming the control line. A positive test result is read visually in 10-15 minutes or less depending on the concentration of antigen present in the urine specimen. A negative Legionella pneumophila Device result, read in 15 minutes, indicates that L. pneumophila serogroup 1 antigen was not detected in the urine sample. The test is interpreted by the presence or absence of visually detectable redish colored lines. A positive result will include the detection of both a test and a control line, while a negative assay will produce only the control line. Failure of the control line to appear, whether the test line is present or not, indicates an invalid assay.

Reagents And Materials Provided

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

Device
Instructions for use
Reagent A
Positive Control Swab: Inactivated L. pneumophilaswab + Reagent Control (+) vial + testing tube
Negative Control Swab:L. pneumophilanegative swab + Reagent Control (-) vial + testing tube
Testing tubes or vials 2mL

Materials Required But Not Supplied

Specimen collection container
Disposable gloves
Timer

Storage

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30°C/36-86°F). The test and reagents are stable until the expiration date printed on their packaging and external kit. Do not use the kit beyond its labelled expiration date.

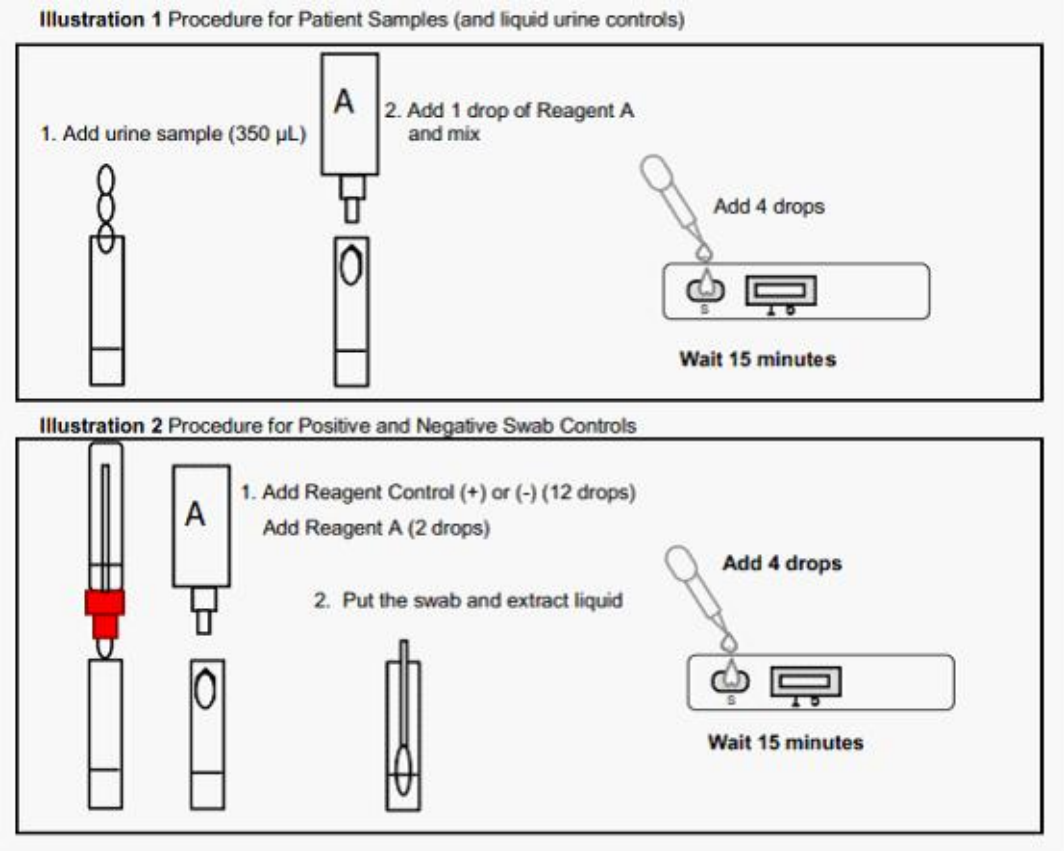
Specimen Collection And Preparation

Urine specimens should be collected in standard containers. The samples can be stored at room temperature (15-30°C/59-86°F) if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8°C for up to 14 days or at-10°C to-20°C for longer periods before testing. Boric acid may be used as a preservative.
When necessary, urine specimens should be shipped in leak-proof containers at 2-8°C or frozen. Allow all specimens to equilibrate to room temperature before testing.

Assay Procedure

Procedure for Patient Samples (and liquid urine controls).
Do not removedevice test from pack until test sample has reached room temperature. Bring patient urine and/or liquid urine control(s) to room temperature (15-30°C/59-86°F).
1. Use a separate testing tube or vial for each sample. Add 350 µL (7 drops) of urine sample or liquid urine control, add 50 µL (1 drop) of Reagent A into the testing tube or vial and mix.
2. Removethe test from its pack just before use. Use a separate test for each sample.
3. Place the test on a flat surface. Use separate pipette and device for each sample or control. Dispense exactly 4 drops or 100µL from the testing tube, into the circular window marked with an arrow. Start the timer. Read the result at 15 minutes.
Procedure for Positive and Negative Swab Controls.
Removedevice tests from the pack just before use. Run test as follows:
1. Hold Reagent Control (+) vial vertically. Add slowly twelve free falling drops of Reagent Control (+) into the testing tube. Add two free falling drops of Reagent A.
2. Immediately remove swab control from the pouch and put the swab into the testing tube with reagents, mix 1 minute and extract as much liquid possible from the swab, squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
3. Remove the device test from its sealed bag just before using.
4. Place the test on a flat surface. Use a separate pipette and device for each sample or control. Dispense exactly 4 drops or 100µL from the testing tube, into the circular window marked with and arrow. Start the timer. Read the result at 15 minutes.
Repeat the procedure for Negative Swab Control using the Reagent Control (-) instead the Reagent Control (+).

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com



Quality Control

Daily Quality Control:

The Legionella pneumophilaDevice contains built-in control features. The manufacturer's recommendation for daily quality control is to document these controls for each sample run.

Positive Procedural Control The reddish line at the Control line region can be considered an internal positive procedural control. If capillary flow has occurred, this line will always appear.

Negative Procedural Control The clearing of background color in the result window provides a negative background control. The background color in the window should be light pink to white within 10-15 minutes and should not interfere with the reading of the test result.

External Positive and Negative Controls:

Good Laboratory Practice recommends the use of positive and negative controls to assure functionality of reagents and proper performance of assay procedure. Positive and negative control swabs that will monitor the entire assay are provided in the kit. To use liquid urine controls, simplyprocess as you would a patient sample.

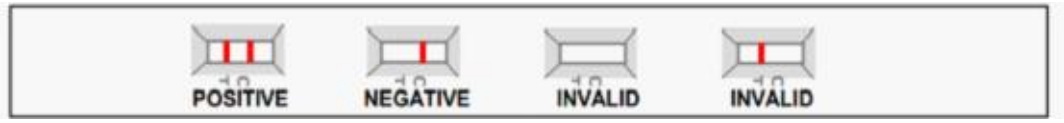
Positive and negative controls should be tested once for each new test kit opened and as otherwise required by your laboratory's standard quality control procedures.

Interpretation of Results

A POSITIVE sample or positive control swab will give two reddish lines across the central window, in the result line region (test line marked with the letter T in the illustration 3) and in the control line region (control line marked with the letter C in the illustration 3). This means that antigen was detected. Recommended report: Presumptive positive forL. pneumophilaserogroup 1

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

antigen in urine, suggesting current or past infection.
A NEGATIVE sample or negative control swab will give only one reddish band acrossthe control line region marked with the letter C (control line). The control line means that the detection part of the test was done correctly, but noL. pneumophila serogroup 1 antigen was detected. Recommended report: Presumptive negative forL. pneumophila serogroup 1 antigen in urine, suggesting no recent or current infection. Infection due toLegionellacannot be ruled out since other serogroups and species may cause disease, antigen may not be present in urine in early infection, and the level of antigen present in theurine may be below the detection limit of the test.
INVALID: if no lines are seen, or if just the test line is seen, the assay is invalid. Invalid tests should be repeated. If the problem persists, discontinue using the test kit and contact you local distributor.



Expected Values

The disease occurs in both epidemic and endemic forms and sporadic cases are not easily differentiated from other respiratory infections by clinical symptoms. An estimated 25000 to 100000 cases of Legionella infection occur in the United States annually. The resulting mortality rate, ranging from 25% to 40%, can be lowered if the disease is diagnosed rapidly and appropriate antimicrobial therapy is instituted early.

Sensitivity

The Legionella pneumophilaDevice was highly sensitive (>99%) compared with the results of the Binax NOW® Legionella Urinary Antigen Test.

Specificity

The Legionella pneumophilaDevice was highly specific (>99%) compared with the results of the Binax NOW® Legionella Urinary Antigen Test.

Precautions

Do not use components past its expiration date.
Do not mix components from different kit lots.
Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, andDevice tests should be handled as though they could transmit disease. Observe established precautions against microbial hazards.
The test should be discarded in a proper biohazard container after testing.

Limitations

1. Legionella pneumophila Devicehas been validated using urine samples only. Other samples (e.g. plasma, serum or other body fluids) that may containLegionellaantigen have not been evaluated. The test cannot be used on environmental samples (i.e. potable water).
2. This test will not detect infections caused by other L. pneumophila serogroups and by other Legionella species. A negative antigen result does not exclude infection with L. pneumophila serogroup 1. Culture is recommended for suspected pneumonia to detect causative agents other than L. pneumophila serogroup 1 and to recoverL. pneumophilaserogroup 1 when antigen is not

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

detected in urine.

3. The diagnosis of Legionnaires' disease cannot be based on clinical or radiological evidence alone. There is no single satisfactory laboratory test forLegionnaires's disease. Therefore, culture results, serology and antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.

4. Excretion ofLegionella antigen in urine may vary depending on the individual patient. Antigen excretion may begin as early as 3 days after onset of symptoms and persist for up to 1 year afterwards. A positive Legionella pneumophila device result can occur due to current or past infection and therefore is not definitive for infection without other supporting evidence.

5. Performance of the Legionella pneumophila Device on diuretic urine has not been evaluated. The Legionella pneumophila Device has been evaluated on hospitalized patients only. An outpatient population has not been tested.

REFERENCES

1. Roig, J., X. Aquiler, J. Ruiz, et. al. Comparative study of Legionella pneumophila and other nosocomial-acquired pneumoniaes. Chest. 1991;99:344-50.
2.Berdal, B.P., C.E. Farshy, and J.C. Feeley. Detection of Legionella pneumophila antigen in urine by enzyme-linked immunospecific assay. J. Clin. Microbiol. 1979;9:575-578.
3. White A., et al. Rapad diagnosis of Legionnaires' disease. Trans Am Clin. Climatol. Assoc.l 1982;93:50-62
4. Bibb, W.F., P.M. Arnow, L. Thacker, and R.M. McKinney. Detection of soluble Legionella pneumophila antigens in serum and urine specimens by enzyme-linked immunosorbent assay with monoclonal and polyclonal antibodies. J. Clin. Microbiol. 1984;20:478-482.
5. Tang, P.W., and S. Toma. Broad-spectrum enzyme-linked immunosorbent assay for detection of Legionella soluble antigens. J. Clin. Microbiol. 1986;24:556-558.
6. Kohler, R.B., W.C. Winn, Jr., and L.J. Wheat. Onset and duration of urinary antigen excretion in Legionnaires' disease.J. Clin. Microbiol. 1984;20:605-607.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com