Legionella Pneumophila Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Legionella Pneumophila antigen in human urine specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Legionella Pneumophila Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

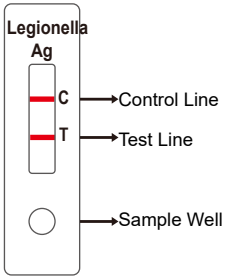
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The Legionella Pneumophila Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Legionella Pneumophila in human Urine. It is suitable for the auxiliary diagnosis of Legionella Pneumophila infection.

INTRODUCTION

Legionnaires' Diease, named after the outbreak in 1976 at the American Legion convention in Philadelphia, is caused by Legionella pneumophila and is characterized as an acute febrile respiratory illness ranging in severity from mild illness to fatal pneumonia. 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. Known risk factors include immunosuppression, cigarette smoking, alcohol consumption and concomitant pulmonary disease. The young and the elderly are particularly susceptible. Legionella pneumophila is responsible for 80%-90% of reported cases of Legionella infection with serpgroup 1 accounting for greater than 70% of all legionellosis. Current methods for the laboratory detection of pneumonia caused by Legionella pneumophila require a respiratory specimen (e.g. expectorated sputum, bronchial washing, transtracheal aspirate, lung biopsy) or paired sera (acute and convalescent) for an accurate diagnosis.



The BESTest Legionella allows for early diagnosis of Legionella pneumophila serogroup 1 infevtion 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

The Legionella Pneumophila Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant antigen conjugated with colloid gold (monoclonal mouse anti-Legionella Pneumophila antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing test band (T bands) and a control band (C band). The T band is pre-coated with monoclonal mouse anti-Legionella Pneumophila antibody for the detection of Legionella Pneumophila antigen, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Legionella Pneumophila virus if present in the specimen will bind to the monoclonal mouse anti- Legionella Pneumophila antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-Legionella Pneumophila antibody, forming a burgundy colored T band, indicating a Legionella Pneumophila antigen positive test result. Absence of test band (T) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Urine Cup	25 pcs	5 pcs	1 pcs
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

Mouse anti-Legionella Pneumophila antibody, Goat anti-rabbit IgG polyclonal antibody, Legionella Pneumophila antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

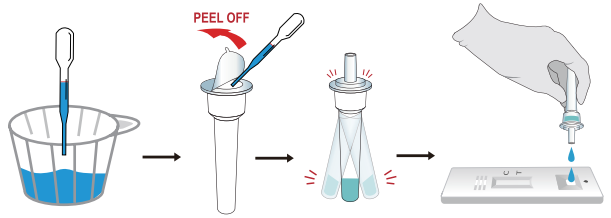
STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

Allow tests,urine samples, reagent and controls to reach room temperature(15-30°C) prior to testing.Do not open pounches untile the performance of the assay.

1.Using a separate urine cup for each sample.
2.Use transfer tube suck urine and add 3 drops to the sample diluent solution.
3.Homogenize the sample.
4.Remove Legionella card test from its sealed bag just before using it.
5.Dispense 3 drops from the treated sample diluent solution in the circular window marked with the letter S.
5.Read the results at 20 minutes.Do not read the test result later than 30min.



QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

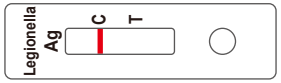
External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

a.New operator uses the kit, prior to performing testing of specimens.
b.A new lot of test kit is used.
c.A new shipment of kits is used.
d.The temperature used during storage of the kit fall outside of 2 -30℃ .
e.The temperature of the test area falls outside of 15℃ -30℃ .

INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C band is developed, the test indicates that no detectable Legionella antigen is present in the specimen. The result is non-reactive.



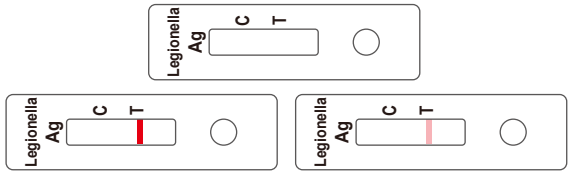
Positive Control:

If both C and T lines are developed, the test indicates the presence of Legionella antigen in the specimen. The result is positive.

INVALID:

If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.

Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).



The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

PERFORMANCE CHARACTERISTICS

1. Sensitivity, Specificity and Accuracy:

A total of 420 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Legionella Antigen Rapid Test	ELISA Test		
BESTest	Positive	Negative	Total
Positive	118	2	120
Negative	2	298	300
Total	120	300	420
Relative Sensitivity: 98.33%; Relative Sp ecificity:99.33%; Overall agreement: 99.05%.			

2. Cross-reactivity:

An evaluation was performed to determine the cross reactivity of BESTest Legionella, no cross reactivity against other pathogens occasionally present in urine:
Strptococcus pneumoniae:

3.Interfering Substances

This kit has no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.The Legionella Pneumophila Antigen Rapid Test Kit (Urine Specimen) is for in vitro diagnostic use only. This test should be used for the detection of Legionella Pneumophila antigens in human Urine specimens.
2.The Legionella Pneumophila Antigen Rapid Test Kit (Urine Specimen)will only indicate the presence to Legionella Pneumophila in the specimen and should not be used as the sole criteria for the diagnosis of Legionella Pneumophila infections.
3.If the symptom persists, while the result from Legionella Pneumophila Antigen Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few hours later.
4.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Legionella Pneumophila infection.
6.The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
7.Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
8.Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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