FRENOVO

Legionella Urinary Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

Legionella Urinary Antigen Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Legionella Urinary Antigen Rapid Test is a lateral flow, qualitative immunoassay. It is intended for the qualitative detection of Legionella serogroup 1 antigen in urine samples. This test is intended as an aid in the diagnosis of Legionella infection (Legionnaires' Disease) caused by L. pneumophila serogroup 1 .

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Legionnaires' disease is a serious form of pneumonia that carries 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 is normally 2-10 days. Typically, the onset of illness occurs 3-6 days 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. It may also occur 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.

FRENOVO Legionella Urinary Antigen Rapid Test Kit is a single use rapid membrane immunoassay for the qualitative detection of L. pneumophila serogroup 1 soluble antigen in human urine. Specific antibodies to L. pneumophila serogroup 1 soluble antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A red line should always appear in the control line to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Droppers: 25 pieces droppers of 25 ul
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micropipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO Legionella Urinary Antigen Rapid Test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Legionella Urinary Antigen Rapid Test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The used test device should be discarded according to local regulations.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the kit past the expiration date (this date is printed on the kit box).
5. Adequate lighting is required to read the test results.

STORAGE INSTRUCTIONS

1. FRENOVO Legionella Urinary Antigen Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

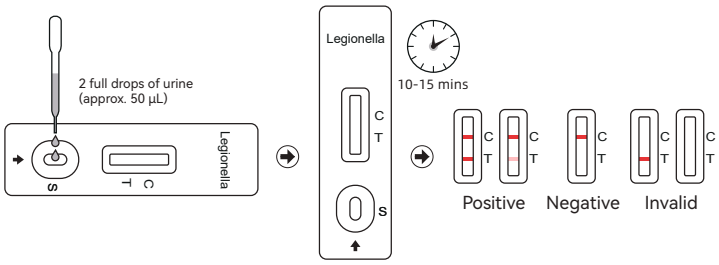
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, 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 PROCEDURE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of urine (approx. 50 µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating a negative result for L. pneumophila serogroup 1 antigen.

Positive result: if both the quality control line C and the detection line T appear, indicating a positive result for L. pneumophila serogroup 1 antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again.

LIMITATIONS

1. Legionella Urinary Antigen Rapid Test Kit has been validated using urine samples only. Other samples (e.g. plasma, serum or other body fluids) that may contain Legionella antigen have not been evaluated. The test cannot be used on environmental samples (e.g. potable water).
2. 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.
3. The diagnosis of Legionnaires' disease cannot be based on clinical or radiological evidence alone. There is no single satisfactory laboratory test for Legionnaires' disease. Therefore, culture results, serology and antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.
4. Excretion of Legionella 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 L. pneumophila test result can occur due to current or past infection and therefore is not definitive for infection without other supporting evidence.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Legionnaires' disease occurs in both epidemic and endemic forms, and sporadic cases are not easily differentiated from other respiratory infections by clinical symptoms. An estimated 25,000 to100,000 cases of Legionella infection occur in the US annually. The resulting mortality rate, ranging from 25% to 40%, can be decreased with rapid diagnosis and early appropriate antimicrobial therapy.

SENSITIVITY AND SPECIFICITY

The Legionella Urinary Antigen Rapid Test Kit was compared to a leading commercial immunoassay. Results were as follows:
Sensitivity: >99%
Specificity: >99%.

CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Legionella Urinary Antigen Rapid Test Kit. There is no cross reactivity with other pathogens occasionally present in urine: Streptococcus pneumonia.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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