

LEGIONELLA PNEUMOPHILA

The PathFlow® *Legionella pneumophila* Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 in human urine specimen.



What is the Test?

- The PathFlow® *Legionella pneumophila* Rapid Test Cassette is a ready-to-use membrane test based on colloidal gold particles, allowing for the detection of *Legionella pneumophila* serogroup 1 from a urine sample.

What is the Disease?

- Legionellosis is a serious pneumonia caused by bacteria of the genus *Legionella*, assigned to the family Legionellaceae.
- This family includes 48 species and over 60 serogroups, approximately 20 species are implicated in human disease – predominantly by *Legionella pneumophila*.
- Legionnaires' disease is the major clinical manifestation of *Legionella* infection, although extra-pulmonary infection and non-pneumonic disease like Pontiac fever can occur.

Symptoms

- A cough can be the first sign of a lung infection, other common symptoms include: headaches, muscle aches, chest pain, and shortness of breath. Gastrointestinal symptoms are also common.
- The incubation period of Legionnaires' disease (perhaps the most serious clinical manifestation of *Legionella*) after being exposed to the bacteria is from two to ten days. Most patients who are admitted to the hospital develop high fever often higher than 39.5°C (103°F).

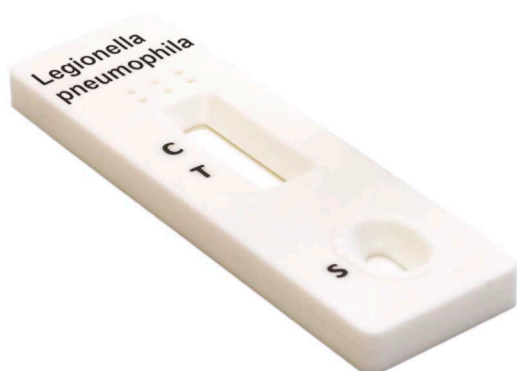
Mortality/Morbidity – Clinical Implications

- Legionnaires' disease (LD) is not contagious, the disease is transmitted by aerosol and there is no evidence for direct person-to-person transmission.
- *Legionella pneumophila* is responsible for approximately 90% of infections, and of these, over 80% are due to a single serogroup, serogroup 1.
- People at risk are those whose immune system is compromised, including transplant recipients, the elderly, smokers, or those showing chronic obstructive pulmonary disease or chronic renal disease.
- The mortality rate of Legionnaires' disease is reported to be 15-25%.

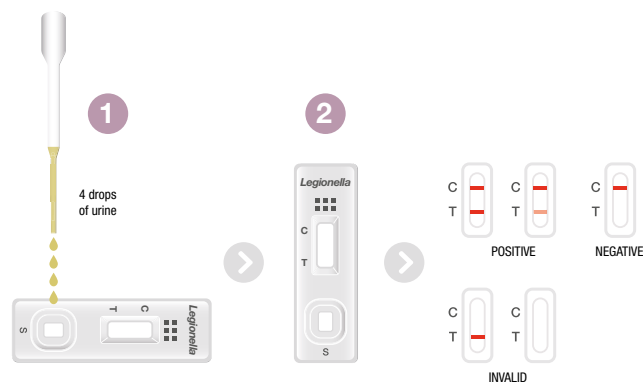
- Complete system, no additional reagents required.
- Simple and easy to use.
- Rapid result offered. Available after 15 minutes.
- In-built procedural control.
- Differential detection of *Legionella pneumophila* serotype 1 from other serotypes and *Legionella spp.*

Why use PathFlow®

- Diagnosis of legionellosis can be difficult because signs and symptoms are nonspecific and do not distinguish *L. pneumophila* infections from other common causes of pneumonia.
- *L. pneumophila* infections are considered fairly common, but they are probably underdiagnosed and under-reported.
- The underdiagnosis of legionellosis can in part be attributed to the need for rapid, specific and sensitive diagnostic testing methods.
- PathFlow® Legionella pneumophila allows for rapid and specific diagnosis of *Legionella pneumophila* serogroup 1, providing results from 15 minutes.



Procedure



Step 1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

Step 2. Swirl the urine sample gently to mix before testing.

Step 3. Add 4 drops of homoligised urine sample to the sample well.

Step 4. Wait for the colour line to appear. Read the results at 15 minutes, do not interpret the results after 20 minutes.

Performance vs. EIA

Sensitivity: 97.6%

Specificity: >99.9%

Accuracy: 99.1%

Ordering Information

Code: M593CE

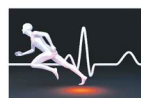
Description – PathFlow® Legionella pneumophila

Size: 25 Test Kits

Storage: 2°C-30°C

Distributed by:

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PathFlow® - Leading The
Way to a Better Diagnosis



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