

# Legionella

## RAPID TEST



*Rapid test for the qualitative detection of **Legionella pneumophila serogroup 1 antigen** (*L. pneumophila* serogroup 1 antigen) in urine specimens*



## 1. What is LEGIONELLA?

*Legionella* is a Gram negative bacterium, including species that cause legionellosis or Legionnaires' disease, most notably *L. pneumophila*.

*Legionella* live within amoebae in the natural environment. *Legionella* species are the causative agent of the human *Legionnaires' disease* and the lesser form, Pontiac fever. *Legionella* transmission is via aerosols — the inhalation of mist droplets containing the bacteria. Common sources include cooling towers, domestic hot-water systems, fountains, and similar disseminators that tap into a public water supply. Natural sources of *Legionella* include freshwater ponds and creeks. Person-to-person transmission of *Legionella* has not been demonstrated.

Once inside a host, incubation may take up to two weeks. Initial symptoms are flu-like, including fever, chills, and dry cough. Advanced stages of the disease cause problems with the gastrointestinal tract and the nervous system and lead to diarrhea and nausea. Other advanced symptoms of pneumonia may also present.

It tends to lead to harmful symptoms in those with a compromised immune system and the elderly. Consequently, it should be actively checked for in the water systems of hospitals and nursing homes. According to the journal "Infection Control and Hospital Epidemiology," Hospital-acquired *Legionella* pneumonia has a fatality rate of 28%, and the source is the water distribution system.

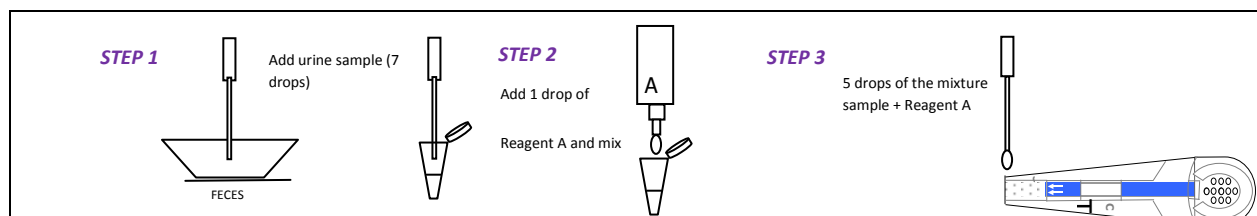
## 2. What is H&R Legionella test?

An *in vitro* rapid immunochromatographic assay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen (*L. pneumophila* serogroup 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 by *L. pneumophila* serogroup 1 in conjunction with culture and other methods.



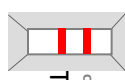
## 3. How is H&R Legionella test performed?

- Bring patient urine and/or liquid urine control(s) to room temperature (15-30°C/59-86°F).
- Use a separate testing tube or vial for each sample. Add seven (7) drops of urine sample or liquid urine control, add one (1) drop of Reagent A into the testing tube or vial and mix.
- Break off the tip of the vial and open the poche to take the H&R *Legionella* test device.
- Dispense five (5) drops into the specimen well (S). Start the timer. Read the result at 15 minutes after dispensing the sample.

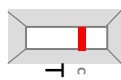


## 4. Interpretation of results

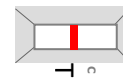
a. POSITIVE



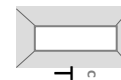
b. NEGATIVE



c. INVALID



d. INVALID



## 5. Performance Data

- Sensitivity is >99% compared to another commercial available rapid test.
- Specificity is >99% compared to another commercial available rapid test.